

**UNIVERSITY OF PÉCS**

**FACULTY OF LAW**



**DOCTORAL DISSERTATION**

**Liability of Medical Practitioners for Malpractices and Negligence in Rwanda  
—A Legal Perspective**

**Mahoro Jean Claude Geofrey**

**Supervised by**

**Prof. Dr. Kóhalmi László Levente and Dr. Tóth Dávid**

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## ABBREVIATIONS AND ACRONYMS

6Cs: Care, compassion, competence, communication, courage, and commitment  
ACTA: anti-corruption, transparency, and accountability  
ACTA: Anti-corruption, transparency, and accountability  
ADECOR: Rwanda Consumer's Rights Protection Organization  
ADR: Alternative Dispute Resolution  
ADRs: Adverse drug reactions  
AEFI: Adverse events following immunisation  
AEMT: Adverse effects of medical treatment  
AfCHPR: African Court on Human and Peoples' Rights  
BC: Before Christ  
BCE: Before Common Era  
BIH: BAHO International Hospital  
BMA: British Medical Association  
CARAES: Centre d'Appui et de Réhabilitation des Aveugles et des Epileptiques or Center for Support and Rehabilitation of the Blind and Epileptics  
CBHI: Community-based health insurance schemes  
CDP: Continuous Professional Development  
CHUB: University Teaching Hospital of Butare  
CHUK: University Teaching Hospital of Kigali  
CIVI: Commission d'indemnisation des victimes d'infraction  
CJEU: Court of Justice of the European Union  
CMPA: Canadian Medical Protective Association  
CPD: Continuous Professional Development  
CPT: Current Procedural Terminology  
C-section: Cesarean delivery  
DM: Defensive medicine  
DOH: Department of Health  
DPP Law: Data Protection and Privacy Law  
Dr.: Doctor  
ECHR: European Court of Human Rights  
EMR: Electronic Medical Record  
EMS: Emergency medical services  
ERDs: Ethical and Religious Directives  
FDA: Food and Drug Authority  
FFS: fee-for-service  
FGTI: Fonds de garantie des victimes  
GBV: Gender-based violence  
GDP: Gross Domestic Product  
GDPR: General Data Protection Regulation

GP: General Practitioner  
GPS: Global Positioning System  
HAIs: Hospital-acquired infections  
HAS: Haute Autorité de Santé  
HSSP IV: Fourth Sector Health Strategic Plan  
HSSP V: Health Sector Strategic Plan V  
ICESCR: International Covenant on Economic, Social and Cultural Rights  
ICU: Intensive Care Unit  
IHRs: International Health Regulations  
ILPD: Institute of Legal Practice and Development  
IM: Intramuscular  
IUD: Intrauterine device  
IV: Intravenous  
JCI: Joint Commission International  
JRLOS: Justice, Reconciliation, Law & Order Sector  
KFH: King Faisal Hospital  
KMC: Kibungo Medical Centre  
KPIs: key performance indicators  
LASA: Look-Alike, Sound-Alike  
LMICs: Low- and middle-income countries  
MAJ: Maison de l'Accès à la Justice  
MINIJUST: Ministry of Justice  
MININFRA: Ministry of Infrastructure  
MINISANTE: Ministry of Health of Rwanda  
MoH: Ministry of Health  
MPA: Canadian Medical Protective Association  
MPPD: Medical Procurement and Production Division  
NAT: Normal Accident Theory  
NCNM: National Council for Nurses and Midwives  
NHS: National Health Service  
NISR: National Institute of Statistics of Rwanda  
NST2: National Strategy for Transformation two  
OECD: Organisation for Economic Cooperation and Development  
OHCHR: Office of the High Commissioner for Human Rights  
OHSC: South Africa's Office of Health Standards Compliance  
OPOR: One Patient, One Record  
P4P: Pay-for-performance  
PAC: Parliament's Public Accounts Committee  
PbD: Privacy by design  
PBF: Pay-for-performance

PHI: Personal health information  
PREMs: patient-reported experience measures  
PREMs: Patient-reported experience measures  
PSIRF: Patient Safety Incident Response Framework  
PSIRF: Safety Incident Response Framework or PSIRF-style  
PTSD: Post-traumatic stress disorder  
RAAQH: Rwanda Agency for Accreditation and Quality Healthcare  
RAHPC: Rwanda Allied Health Professions Council  
RBC: Rwanda Biomedical Centre  
RF: Radiofrequency  
RHIE: Rwanda Health Information Exchange  
RICA: Rwanda Inspectorate, Competition and Consumer Protection Authority  
RLRC: Rwanda Law Reform Commission  
RMC: Referral Management Centres  
RMDC: Rwanda Medical and Dental Council  
RMNCAH: Rwanda reproductive, maternal, newborn, child, and adolescent health  
RMS: Rwanda Medical Supply  
RNEC: National Ethics Committee  
RPHC5: Population and Housing Census  
RSIs: Retained surgical instruments  
RURA: Rwanda Utility Regulatory Authority  
RVUs: Relative Value Units  
Rwanda FDA: Rwanda Food and Drugs Authority  
RWF: Rwandan franc  
SAP/ERP: Systems, Applications, and Products in Data Processing/Enterprise Resource Planning  
SARVI: Service d'aide au recouvrement des victimes d'infractions  
SDGs: Sustainable Development Goals  
SONARWA: Société Nouvelle d'Assurance du Rwanda  
SOPs: Standard Operating Procedures  
SSIs: Surgical site infections  
STIs: sexually transmitted infections  
THM: Traditional herbal medicine  
U.S.: United States of America  
UDHR: Universal Declaration of Human Rights  
UNICEF: United Nations Children's Fund  
VVF: Vesico-vaginal fistula  
WHO: World Health Organization  
WISN: Workload Indicators of Staffing Needs

## CHAPTER ONE

### GENERAL INTRODUCTION

Medical malpractice liability is an increasingly important topic for both legal and medical practitioners. Worldwide, these issues have attracted continuing attention from policymakers, scholars, healthcare providers, and media, forming part of larger discussions on patient safety, professional responsibility, and health system management.<sup>1</sup> In Rwanda, medical malpractice and negligence are gaining attention, but there is little research regarding these issues. The lack of case law and scholarly works highlights the need for a thorough investigation into the liability landscape of medical practitioners, particularly regarding malpractice and negligence.

This gap serves as the foundation for the present study, which investigates Rwanda's legal and regulatory framework governing medical liability. It examines relevant laws, policies, and institutional mechanisms designed to promote ethical compliance and protect patient rights within clinical practice. In this context, the primary goal of this introductory chapter is to outline the study's subject, rationale, context, and methodology. Organised into nine parts, this chapter begins with the research context and then addresses the research motivation, research questions, hypotheses, and significance of the study. It goes on to present the research aims and objectives, the specific methodology undertaken, and ethical considerations, and concludes with an overview of the dissertation structure.

#### **1.1. Research context**

It is essential to understand the context of the research for locating the study within the broader intellectual, institutional, and socio-political framework. The author links his study to Rwanda's national development plans, such as the National Strategy for Transformation (NST2) and Vision 2050, along with global initiatives like the Sustainable Development Goals (SDGs). This section demonstrates how the research relates to long-term reform, innovation, and inclusive growth. It helps readers grasp the foundation of the study. It clarifies the foundational influences behind the study, the conditions under which it was carried out, and the reasoning for choosing Rwanda as the case. It also offers a valuable framework for evaluating the study's impact on policy, practice, and academic discussions.

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<sup>1</sup> Gede Dian Astika Putera, I Wayan Parsa, and I Nyoman Prabu Buana Rumiarta, "Civil Liability of Medical Doctors in Cases of Medical Malpractice," *African Journal of Biomedical Research* 28, no. 1 (2025), <https://doi.org/10.53555/ajbr.v28i1s.7104>.

### 1.1.1. Introduction to Rwanda and its legal system

Rwanda is a small landlocked country in East-central Africa, south of the Equator. Its capital city, Kigali, serves as the country's principal political, economic, and cultural hub. Rwanda shares borders with Uganda in the north, Tanzania to the east, Burundi to the south, and the Democratic Republic of the Congo to the west. The country covers about 26,338 square kilometers, characterised by hilly and fertile land, earning it the nickname "Land of a Thousand Hills." Rwanda is one of the most densely populated countries in Africa, having a population density of 501 people per square kilometer.<sup>2,3</sup> As identified by the recent Population and Housing Census (RPHC5) completed by the National Institute of Statistics of Rwanda (NISR) in August 2022, the population was 13,2 million with a projected population growth rate of 6.8% in 2025,<sup>4</sup> and the majority of this population is youth.

Rwanda has been through transformative changes since the genocide against the Tutsi in 1994. Post-genocide governance has prioritized national unity and reconciliation by moving away from ethnic divisions. The country's rapid economic growth, coupled with institutional reforms, has positioned Rwanda as a regional leader in innovation, governance, and public health. The cornerstone of this transformation is the evolution of Rwanda's legal system, which has been instrumental in promoting social cohesion, institutional development, the rule of law, and gender equity<sup>5</sup>—evidenced by the fact that women occupy over 60% of parliamentary seats. These developments are underpinned by various strategic frameworks such as the National Strategy for Transformation (NST1 and NST2) and Rwanda Vision 2050,<sup>6</sup> which articulate the nation's ambition to attain high-income status through inclusive and sustainable development.

Rwanda's legal system is hybrid in nature, incorporating aspects of both civil law, inherited through its colonial links to Belgium, and common law resulting from the post-genocide legal reforms.<sup>7</sup> Traditionally, the system mainly relied on codified statutes and limited judicial precedent. Since the 2004 reforms to the legal system, there have been considerable improvements to the working capacity and professionalism of all judicial officers, resulting in improved quality and efficiency of the judiciary.<sup>8</sup> The laws are codified and officially published in the Official Gazette to be accessible to the public.

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<sup>2</sup> Ibid., p. 68.

<sup>3</sup> National Institute of Statistics of Rwanda (NISR), "The Fifth Population and Housing Census (RPHC5 2022), Thematic Report: Population Projections" (Kigali, Rwanda, 2023), p. 7.

<sup>4</sup> Ibid.

<sup>5</sup> Rwanda Women Alliance, "Priorities to Put Forward on Women and Girls Rights in the NST-2 Development Process" (Kigali, Rwanda, 2024), <https://haguruka.org.rw/wp-content/uploads/2024/06/Position-paper-NST2.pdf>.

<sup>6</sup> Republic of Rwanda, "Rwanda Vision 2050" (Kigali, 2015), p. 7,13.

<sup>7</sup> "Justice and Reconciliation in Rwanda: Gacaca Courts and Their Role," *History Rise*, December 2024, <https://historyrise.com/justice-and-reconciliation-in-rwanda-gacaca-courts-and-national-healing/>.

<sup>8</sup> Sam Rugege, "Some Aspects of Judicial Reform in Rwanda from 2004 to 2019," *Rwanda Law Journal* 1, no. 1 (2020): 1–37, <https://www.rwandalawjournal.ac.rw/frontend/article/8/>.

The Justice, Reconciliation, Law & Order Sector (JRLOS) was established as a coordination structure enabling institutions in the sector to work together towards common goals while maintaining their operational, legal, and constitutional autonomy.<sup>9</sup> Additionally, recent reforms, in which the Rwanda Law Reform Commission (RLRC) played a key role, have focused on harmonising domestic laws with international standards, improving access to justice, and enhancing the capacity of legal professionals.<sup>10</sup> From these initiatives, some common law elements have been introduced, especially in commercial and procedural law, enhancing judicial discretion and case law development.<sup>11</sup> Customary law remains relevant in rural communities, particularly for land and family disputes. However, it is secondary to statutory law, reflecting Rwanda's commitment to modernizing its legal framework and progressing towards a unified, rights-based system.

Rwanda's judiciary operates as an independent institution, structured into two principal categories: Ordinary Courts and Specialised Courts. The Ordinary Courts encompass the Supreme Court, Court of Appeal, High Court, Intermediate Courts, and Primary Courts, forming the backbone of the general judicial system. In contrast, the Specialised Courts include the Commercial Courts and Military Courts, which address specific legal domains requiring distinct procedural and substantive expertise.<sup>12</sup> Oversight of judicial discipline and administrative matters is vested in the High Council of the Judiciary, the supreme body responsible for maintaining integrity and efficiency within the judicial branch.<sup>13</sup>

In support of its growing legal system, Rwanda has made significant investments in legal education and scholarship. The increase in private higher education institutions offering law degrees is evidence of the commitment to education in the legal field. In addition to these private institutions, the University of Rwanda School of Law and the Institute of Legal Practice and Development (ILPD) play a crucial role in advancing legal research and providing professional legal training for legal practitioners, thereby strengthening the capacity of the legal profession.

The legal framework governing medical liability in Rwanda underscores the country's dedication to aligning domestic law with international standards, particularly in the areas of clinical research and patient safety. Rwanda's active participation in global health initiatives and clinical trials necessitates a legal infrastructure that fosters innovation while upholding ethical responsibility. Key legal instruments in this area include the Law on Medical Practice, the Regulation of Clinical

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<sup>9</sup> MINIJUST, "Justice, Reconciliation, Law & Order Sector (JRLOS)," accessed September 15, 2025, <https://www.minijust.gov.rw/justice-sector-coordination>.

<sup>10</sup> Rwanda Law Reform Commission, "ANNUAL ACTIVITY REPORT 2022 / 2023" (Kigali, Rwanda, 2023), <https://www.rlrc.gov.rw/index.php?eID=dumpFile&t=f&f=92448&token=2a42359d76a6b6480ab8cf594f83b88be815efd0>.

<sup>11</sup> Célestin Mutabazi, "PRECEDENT AS A BINDING SOURCE OF LAW UNDER RWANDAN LEGAL SYSTEM: Applicability of Stare Decisis under Rwandan Law," *Rwanda Law Journal*, no. 02 (2020): 1–18, <https://www.rwandalawjournal.ac.rw/frontend/article/16/>.

<sup>12</sup> Article 153 of the Constitution of the Republic of Rwanda, Official Gazette N° Special of 04/08/2023 (2023).

<sup>13</sup> *Ibid.*, art. 150.

Trials, the Consumer Protection Law, and the Penal Code. Besides, multiple institutions, notably the Rwanda Medical and Dental Council (RMDC), the National Ethics Committee (RNEC), the Judiciary, and the Ministry of Health (MINISANTE), contribute to the regulation and decision of medical liability. These institutions work towards assuming accountability, safeguarding patient rights, and promoting ethical standards in medical practice.

### 1.1.2. Evolution of Rwanda's healthcare system

Rwanda's healthcare system has undergone significant transformation, shaped by historical events and policy reforms. The evolution of patients' rights is inseparable from this progress, alongside legal frameworks that have adapted to reflect broader institutional reforms and societal advancements.

The historical development of Rwanda's healthcare system can be examined through two distinct periods: the pre-Genocide era and the post-Genocide era. Before the 1994 Genocide against the Tutsi, Rwanda faced significant healthcare challenges, characterised by a fragile system with limited access to medical services, particularly in rural areas.<sup>14</sup> Although Rwanda participated in the 1987 Bamako Initiative, a joint effort by the WHO and UNICEF to improve access to essential medicines across sub-Saharan Africa, the initiative did not bring about significant improvements in the country.<sup>15</sup> The healthcare system remained vulnerable, and critical programs aimed at strengthening primary healthcare were insufficiently implemented. These difficulties were exacerbated by systematic political discrimination and sectarianism, which hindered the development of healthcare infrastructure and the training of medical personnel.

The Genocide itself led to an extensive ruin of the healthcare system, claiming over a million lives and leaving countless individuals physically and psychologically traumatised. Medical professionals were among those affected—some were murdered, others fled the country, and some were convicted of genocidal crimes and imprisoned. Consequently, essential healthcare programs, including preventive services such as vaccinations and prenatal care, were severely disrupted, further deepening the crisis.<sup>16</sup>

After the Genocide, Rwanda pursued a core restructuring of its health system, implementing wide-reaching reforms to expand access,<sup>17</sup> enhance medical infrastructure, and assure equitable delivery of healthcare.<sup>18</sup> Besides, the country strategically reinforced priority initiatives, notably universal

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<sup>14</sup> Shriya Yarlagadda, "Growth from Genocide: The Story of Rwanda's Healthcare System," *Harvard International Review*, 2022, <https://hir.harvard.edu/growth-from-genocide-the-story-of-rwandas-healthcare-system/?form=MG0AV3>.

<sup>15</sup> Kasa Asila Pangu, "The Bamako Initiative," *World Health* 50, no. 5 (1997): 1–2, <https://doi.org/10.1093/tropej/39.2.66>.

<sup>16</sup> Shriya Yarlagadda, "Growth from Genocide: The Story of Rwanda's Healthcare System."

<sup>17</sup> Agnes Binagwaho and Richard Freeman, "Decolonization of the Legal Code: The End of Colonial Laws in Rwanda and a Model for Other Post-Colonial Societies," *Harvard International Law Journal Online* 62 (2021): 97–135.

<sup>18</sup> Partners In Health, "Research: Strong Health System Key to Growth in Post-Genocide Rwanda," Partners In Health, 2019, <https://www.pih.org/article/research-strong-health-system-key-growth-post-genocide-rwanda?form=MG0AV3>.

healthcare and public health programs, thereby establishing a framework for a more resilient, legally compliant, and inclusive healthcare system.

Despite this ambitious journey, challenges still exist, including a severe shortage of healthcare professionals, particularly in specialised fields, and a shortage of modern medical infrastructure. Besides, many laws inherited from the colonial era required reforms to align with decolonisation and national reconstruction,<sup>19</sup> calls for effective enforcement mechanisms to render the existing laws operational and achieve their intended purposes. Health literacy gaps in remote areas lead to delays in care-seeking and poor adherence to preventive measures.<sup>20</sup> Patients' rights, including informed consent and privacy, are not always fully upheld. Enforcement of rights and accountability for medical malpractice remains inconsistent due to resource limitations and a lack of awareness.

### 1.1.3. Rationale for Rwanda as a case study

Rwanda's dynamic and evolving legal landscape offers a unique context for examining medical liability within a post-conflict, reform-driven framework. Its hybrid legal tradition, combining civil law with increasing influences from common law principles, along with a system that adapts to legal changes, and a rapidly transforming healthcare sector, makes Rwanda a compelling case for academic study. With the country's ambitious healthcare reforms, greater involvement in clinical research, and a stronger focus on patient rights and ethical medical practices, the legal landscape plays a vital role in building a robust system of medical accountability.

In Rwanda, medical liability is maintained through a complex system of laws, regulations, and ethical standards that provide an essential framework for how legal scholarship can help shape policy, promote patient welfare, and encourage professional accountability in practice. For example, Rwanda has advanced in legal frameworks, but significant challenges remain in medical liability. These include outdated laws, a lack of robust enforcement, limited oversight, inadequate reporting structures, and insufficient legal education and training. A lack of awareness of medical rights further undermines accountability and patient protection, creating significant barriers to a fully functional legal framework. Subsequently, the intersection of law, medicine, and ethics offers an opportunity for academic study that can help build the nation, as well as advance international discussions about medical law and accountability.

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<sup>19</sup> Agnes Binagwaho, Richard Freeman, and Gabriela Sarriera, "The Persistence of Colonial Laws: Why Rwanda Is Ready to Remove Outdated Legal Barriers to Health, Human Rights, and Development," *Harvard International Law Journal* 59 (2018): 49–62, <https://journals.law.harvard.edu/ilj/2018/06/the-persistence-of-colonial-laws-why-rwanda-is-ready-to-remove-outdated-legal-barriers-to-health-human-rights-and-development/>.

<sup>20</sup> Corneille Killy Ntuhabose et al., "Patient Satisfaction with Ambulatory Care Services Delivery and Respect for Patient Rights: Findings from 2022 National Survey in Rwanda," *BMC Health Services Research* 25, no. 1 (December 1, 2025): 1–12, <https://doi.org/10.1186/s12913-025-12596-x>.

## 1.2. Research motivation

Patient safety remains one of the most pressing challenges in modern medical practice.<sup>21</sup> As former World Bank Group President Jim Yong Kim correctly stated, “Good health is the foundation of the country’s human capital, and no country can afford low-quality or unsafe healthcare.”<sup>22</sup> In alignment with this perspective, the World Health Organisation (WHO) recognises that unsafe healthcare significantly contributes to mortality and morbidity, particularly in low- and middle-income countries (LMICs), including Rwanda.<sup>23</sup> Given this reality, a 2017 joint study conducted by the WHO, the Organisation for Economic Co-operation and Development (OECD), and the World Bank highlights the urgent need for policymakers to implement measures aimed at enhancing healthcare quality and service delivery. Further supporting this imperative, the 2020 OECD report on the economics of patient safety emphasises the necessity for governments to adopt evidence-based decision-making when implementing safety policies, programs, and interventions. These strategic choices must be made within the constraints of scarce resources to ensure optimal value and return on investment across healthcare systems.<sup>24</sup>

To address the implementation gaps identified in the first Global Patient Safety Report 2024, the 7<sup>th</sup> Global Ministerial Summit on Patient Safety was held in Manila, Philippines, on April 3 and 4, 2025, with the theme “Weaving Strengths for the Future of Patient Safety Throughout the Healthcare Continuum.” This summit adopted the Mandaluyong Declaration, which supports patient safety as “a universal imperative by establishing patient safety as a foundational pillar of resilient, people-centred, and equitable health systems that deliver quality care and drive improved health outcomes.” In this summit, the WHO Director-General Dr. Tedros stated that “Patient safety must be a non-negotiable priority in all health systems, at all levels of care, in all communities, and at all income levels.”<sup>25</sup>

Unsafe healthcare not only poses a threat to patient safety<sup>26</sup> but also imposes a substantial economic burden on healthcare institutions, service providers, and communities worldwide.<sup>27</sup> Low- and middle-income countries (LMICs) are disproportionately affected by the adverse effects

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<sup>21</sup> Katharine A. Wallis, “No-Fault, No Difference: No-Fault Compensation for Medical Injury and Healthcare Ethics and Practice,” *British Journal of General Practice* 67, no. 654 (2017): 38–39, <https://doi.org/10.3399/bjgp17X688777>.

<sup>22</sup> World Health Organization, “Low Quality Healthcare Is Increasing the Burden of Illness and Health Costs Globally,” 2018, <https://www.who.int/news/item/05-07-2018-low-quality-healthcare-is-increasing-the-burden-of-illness-and-health-costs-globally>.

<sup>23</sup> WHO, “Patient Safety,” 2023, <https://www.who.int/news-room/fact-sheets/detail/patient-safety?form=MG0AV3>.

<sup>24</sup> Luke Slawomirski and Niek Klazinga, “The Economics of Patient Safety: From Analysis to Action” (OECD Publishing, 2020).

<sup>25</sup> WHO, “The 7th Global Ministerial Summit on Patient Safety 2025,” 2024, <https://www.who.int/news/item/04-04-2025-the-7th-global-ministerial-summit-on-patient-safety-2025>.

<sup>26</sup> “Medical Malpractice: An Ongoing Crisis,” *The Rwandan* (Kigali, November 2020), <https://www.therwandan.com/medical-malpractice-an-ongoing-crisis/>.

<sup>27</sup> Femi Oyebo, “Clinical Errors and Medical Negligence,” *Medical Principles and Practice* 22, no. 4 (2013): 326, <https://doi.org/10.1159/000346296>.

of medical treatment (AEMT).<sup>28</sup> Research indicates that the financial implications of unsafe healthcare are significant, with direct costs accounting for approximately 13% of global healthcare expenditure.<sup>29</sup> The estimated annual economic impact exceeds \$1 trillion, placing a considerable strain on even the most developed economies. Additionally, patient harm contributes to a 0.7% annual slowdown in global economic growth.<sup>30</sup>

Beyond the economic consequences, the human cost of medical malpractice is immense, representing a critical threat to patient safety,<sup>31</sup> exacerbating systemic healthcare challenges. The economic consequences pale in comparison to the human cost of medical malpractice. Studies have highlighted the overwhelming number of deaths attributable to medical malpractice. In the United States alone, research has estimated that adverse medical events result in more than 250,000 deaths annually,<sup>32</sup> placing medical error among the leading causes of mortality.<sup>33; 34</sup> Globally, unsafe healthcare is projected to contribute to approximately three million preventable deaths each year, with developing nations disproportionately affected, recording approximately four deaths per hundred individuals due to inadequate healthcare practices.<sup>35</sup> Reports published by the World Health Organisation (WHO), the Organisation for Economic Cooperation and Development (OECD), and the World Bank further underscore the severity of the issue, identifying patient harm as a significant contributor to the global burden of disease.<sup>36</sup>

Although no comprehensive study has yet examined the financial burden of medical malpractice and negligence cases in Rwanda, the issue has recently been highlighted by the Parliament's Public Accounts Committee (PAC) as a contributing factor to governmental fiscal strain.<sup>37</sup> Several healthcare institutions were found liable in court and subsequently ordered to provide substantial compensation to affected patients. In addition to the hospital expenses borne by victims' families for the treatment of iatrogenic injuries and the costs associated with legal proceedings, there exist further financial burdens that are difficult to quantify. These include the economic and social

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<sup>28</sup> Javaid Nauman et al., "Global Incidence and Mortality Trends Due to Adverse Effects of Medical Treatment, 1990–2017: A Systematic Analysis from the Global Burden of Diseases, Injuries and Risk Factors Study," *Cureus* 15–17, no. 3 (2020), <https://doi.org/10.7759/cureus.7265>.

<sup>29</sup> Luke Slawomirski and Niek Klazinga, "The Economics of Patient Safety: From Analysis to Action," OECD Health Working Papers No. 145 (Paris, 2022), <https://doi.org/https://doi.org/10.1787/761f2da8-en>.

<sup>30</sup> Slawomirski and Klazinga.

<sup>31</sup> "Medical Malpractice: An Ongoing Crisis."

<sup>32</sup> Michael Wiklund, "Wiklund's Perspective: Patient Deaths Due to Medical Error," February 2023, <https://www.emergobyul.com/news/wiklunds-perspective-patient-deaths-due-medical-error>.

<sup>33</sup> Benjamin A. Rodwin et al., "Rate of Preventable Mortality in Hospitalized Patients: A Systematic Review and Meta-Analysis," *Journal of General Internal Medicine* 35, no. 7 (2020): 2099–2100, <https://doi.org/10.1007/s11606-019-05592-5>.

<sup>34</sup> Steve Sternberg, "Medical Errors Are Third Leading Cause of Death in the U.S.," May 2016, <https://www.usnews.com/news/articles/2016-05-03/medical-errors-are-third-leading-cause-of-death-in-the-us>.

<sup>35</sup> Slawomirski and Klazinga, "The Economics of Patient Safety: From Analysis to Action."

<sup>36</sup> *ibid.* p. 34.

<sup>37</sup> Emmanuel Ntirenganya, "PAC Warns against Negligence in the Medical Sector," *The New Times*, September 2021, <https://www.newtimes.co.rw/article/189406/News/pac-warns-against-negligence-in-the-medical-sector>.

consequences of an adverse medical event resulting in death, prolonged physical or psychological impairment, and even the breakdown of familial structures.

The Government of Rwanda has undertaken significant efforts to strengthen its healthcare system through various initiatives.<sup>38</sup> However, despite these advancements, certain challenges persist. While the Constitution of the Republic of Rwanda guarantees the right to good health, alongside other national and international legal instruments that establish a foundation for judicial remedies,<sup>39</sup> medical malpractice claims have continued to rise.<sup>40</sup> Such claims manifest in diverse healthcare settings and vary in both form and severity. The actions and omissions of some medical practitioners within different health institutions<sup>41</sup> have resulted in iatrogenic injuries<sup>42</sup> and, in severe cases, premature patient deaths. Rwandan courts have adjudicated numerous medical malpractice cases over time, contributing to an increase in civil claims and growing public concern regarding healthcare accountability. Documented cases include improper medication or dosage administration,<sup>43</sup> neonatal injury or death during childbirth, maternal injury or fatality, unnecessary ablation or resection procedures, surgical errors, failure to consider patient history, breaches of patient confidentiality, unnecessary surgical interventions, retained surgical instruments, and instances of offensive language within medical interactions.

Several systemic factors have been identified as contributors to medical malpractice incidents in Rwanda, including inefficiencies in top-down healthcare planning, a shortage of qualified physicians, a shortage of up-to-date infrastructure, and regulatory gaps,<sup>44</sup> productivity-driven compensation models,<sup>45</sup> shortage and malfunction of essential medical reagents and equipment, and public unawareness of medical rights and accountability mechanisms.<sup>46</sup>

Some healthcare providers attribute instances of medical malpractice to systemic vulnerabilities within Rwanda's healthcare infrastructure, highlighting gaps that may compromise patient safety. A notable concern is the disproportionate growth of the medical sector in comparison to the

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<sup>38</sup> WHO, "Rwanda's Primary Health Care Strategy Improves Access to Essential and Life-Saving Health Services," 2022, <https://www.who.int/news-room/feature-stories/detail/rwanda-s-primary-health-care-strategy-improves-access-to-essential-and-life-saving-health-services>.

Rwanda has international obligations stemming from the Banjul Charter (Article 16), the UDHR, the ICCPR, the ICESCR, the CRC, and the SDGs (Goal 3), which have become a global commitment.

<sup>40</sup> Ivan R. Mugisha, "Rwanda Calls for Tougher Penalties as Medical Negligence Cases Rise," *The East African*, 2018, <https://www.theeastafrican.co.ke/tea/rwanda-today/news/rwanda-calls-for-tougher-penalties-as-medical-negligence-cases-rise-1384134>.

<sup>41</sup> Those organisations include Among others Rwanda Ministry of Health, Rwanda Biomedical Centre (RBC), and hospitals including La Croix du Sud Hospital, King Faisal Hospital, Rwanda Military Hospital, Byumba District Hospital, Baho International Hospital, to mention a few.

<sup>42</sup> A damage of tissue or organ resulting from a medical procedure, pharmacotherapy, or other medical act that has not adequately served its purpose.

<sup>43</sup> King Faisal Hospital v. Kamatenesi Jovia, RCA 00056/2016/HC/KIG - RCA 00057/2016/HC/KIG (2016).

<sup>44</sup> Nathan Cortez, "A Medical Malpractice Model for Developing Countries?," *Drexel Law Review* 4, no. 217 (2010): 220–24, [https://drexel.edu/~media/Files/law/law review/fall\\_2011/Cortez.ashx](https://drexel.edu/~media/Files/law/law%20review/fall_2011/Cortez.ashx).

<sup>45</sup> "Medical Malpractice: An Ongoing Crisis."

<sup>46</sup> Rosine Ishimwe, "Assessment of the Status of Medical Negligence and Malpractice in Musanze District, Rwanda" (University of Kigali, 2021).

availability of adequate professional training.<sup>47</sup> This discrepancy has placed medical practitioners in increasingly complex professional dilemmas, further exacerbated by inefficiencies in top-down healthcare planning. One illustrative example is the method hospitals use to estimate the number of patients to be treated daily. Instead of prioritising individual patient cases based on medical necessity, this numerical approach risks reducing care delivery to a quantitative metric, thereby undermining the quality of treatment that practitioners are ethically and professionally obligated to provide. Besides, tensions exist between medical practitioners' claims regarding their professional rights and their concurrent duty to uphold patient rights. While practitioners seek recognition of their own legal and ethical protections, they remain obligated to ensure high-quality care.

Beyond deficiencies in medical training, several systemic issues continue to hinder the effective delivery of healthcare services in Rwanda. One significant challenge is the difficulty in implementing adequate hospital infrastructure due to various constraints. The demand for medical personnel remains exceptionally high, especially in public hospitals, where shortages of qualified practitioners exacerbate existing healthcare inefficiencies.<sup>48</sup>

Additionally, healthcare facilities frequently experience shortages and malfunctions of essential medical reagents and equipment,<sup>49</sup> particularly in decentralised health centres.<sup>50</sup> These shortcomings are primarily attributed to bureaucratic inefficiencies and prolonged procurement processes for medical supplies,<sup>51</sup> which significantly disrupts the functioning of healthcare institutions.<sup>52</sup> Furthermore, inadequate remuneration for medical practitioners remains a persistent concern, contributing to dissatisfaction within the profession and further exacerbating workforce retention issues.<sup>53</sup>

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<sup>47</sup> Ishimwe, p. 18, 24-26.

<sup>48</sup> National Academies of Sciences, Engineering, and Medicine Evaluation of PEPFAR's Contribution (2012-2017) to Rwanda's Human Resources for Health Program (2020) (Washington, DC: National Academies Press (US), 2020), <https://doi.org/10.17226/25687>.

<sup>49</sup> Tshilombo Tshama Sylvain, "Challenges and Solutions of Shortage of Essential Drugs, Supplies and Equipment at the Emergency Department of CHUK: A Mixed Method Study" (University of Rwanda, 2021), [https://dr.ur.ac.rw/bitstream/handle/123456789/1649/Dr.Tshilombo Tshama Sylvain.pdf?sequence=1&isAllowed=y](https://dr.ur.ac.rw/bitstream/handle/123456789/1649/Dr.Tshilombo%20Tshama%20Sylvain.pdf?sequence=1&isAllowed=y).

<sup>50</sup> Dane Emmerling, Alexander Dahinten, and Robert A. Malkin, "Problems with Systems of Medical Equipment Provision: An Evaluation in Honduras, Rwanda and Cambodia Identifies Opportunities to Strengthen Healthcare Systems," *Health and Technology* 8, no. 1-2 (2018): 129-35, <https://doi.org/10.1007/s12553-017-0210-6>.

<sup>51</sup> Leandro Donisi et al., "Medical Technologies Procurement, Management and Maintenance in Developing Countries: The Case of Health Challenges in Africa," in *Influence of the Backpack on School Children's Gait: A Statistical and Machine Learning Approach*, vol. 80 (Springer Nature Switzerland, 2021), 793-801, <https://doi.org/https://doi.org/10.1007/978-3-030-64610-3>.

<sup>52</sup> Aderaw Yenet, Getinet Nibret, and Bantayehu Addis Tegegne, "Challenges to the Availability and Affordability of Essential Medicines in African Countries: A Scoping Review," *ClinicoEconomics and Outcomes Research* 15, no. June (2023): 443-58, <https://doi.org/10.2147/CEOR.S413546>.

<sup>53</sup> Adolphe Ndikubwimana et al., Strengthening Rwanda's Health Workforce Strategies to Improve Retention in the Health Sector Strengthening Rwanda's Health Workforce Strategies to Improve Retention in the Health Sector, African Health Observatory - Platform on Health Systems and Policies (AHOP) (Brazzaville: WHO Regional Office for Africa, 2024), p. 6-7, <https://ahop.aho.afro.who.int/2025/03/19/new-ahop-policy-brief-presents-strategies-to-address-health-worker-attrition-in-rwanda/?form=MG0AV3>.

The interplay between healthcare organisations and medical insurers significantly influences clinical decision-making, often at the expense of patient care.<sup>54</sup> Insurers frequently impose financial restrictions that limit physicians' autonomy, resulting in decisions driven by cost considerations rather than medical necessity. This dynamic heightens the risk of misdiagnosis, delayed treatment, and suboptimal care, thereby exposing healthcare providers and institutions to legal liability for malpractice.

Economic pressures further exacerbate these challenges, as medical clinics, constrained by financial sustainability concerns, may adopt selective service delivery models. In many cases, physicians and healthcare providers prioritise cases based on insurer coverage rather than clinical urgency, leading to inadequate care and potential medical negligence. This approach increases the likelihood of premature patient discharge or the avoidance of complex treatments, potentially compromising patient safety and escalating the risk of litigation.

In addition, deficiencies in legal and regulatory adherence have been observed,<sup>55</sup> particularly concerning outdated laws and policies that fail to align with the rapid evolution of medical technology and changing societal needs. These shortcomings undermine effective healthcare governance, limiting the capacity of legal frameworks to address emerging challenges in contemporary medical practice. Crucially, they contribute to increased medical malpractice risks and hinder effective liability enforcement, limiting patient protection and accountability.

Despite the above factors and justifications, compliance with legal frameworks, professional ethics, and established standards constitutes the cornerstone of all professions, particularly the medical field, which is often regarded as a model of integrity due to its fundamental role in preserving human life.<sup>56</sup> Within medical practice, healthcare professionals' decisions are

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<sup>54</sup> Stephen Hill et al., *Professional Responsibility: The Fundamental Issue in Education and Health Care Reform*, ed. Douglas E. Mitchell and Robert K. Ream, *Value in a Changing Built Environment*, 4th ed. (New York: Springer, 2017), <https://doi.org/10.1007/978-3-319-02603-9>.

<sup>55</sup> Ishimwe, "Assessment of the Status of Medical Negligence and Malpractice in Musanze District, Rwanda."

<sup>56</sup> M. S. Pandit and Shobha Pandit, "Medical Negligence: Coverage of the Profession, Duties, Ethics, Case Law, and Enlightened Defense - A Legal Perspective," *Indian Journal of Urology* 25, no. 3 (2009): 372–75, <https://doi.org/10.4103/0970-1591.56206>.

predominantly shaped by deontological ethics and institutional theory principles, which collectively exert a profound positive or negative influence on healthcare systems.<sup>57</sup> ;<sup>58</sup> ;<sup>59</sup> ;<sup>60</sup>

Importantly, the prevailing standards of care and best medical practices serve as critical benchmarks, ensuring quality and safety in patient treatment. While the professional custom rule is primarily governed by reasonableness and the requisite degree of skills and knowledge, these elements collectively function to safeguard the rights and well-being of patients and other healthcare users. Therefore, adherence to these principles is crucial in establishing an equitable, reliable, and ethically sound healthcare system.

Following the above background, any medical practice that undermines patients' dignity not only breaches fundamental moral obligations but is also widely condemned by society and is legally actionable. Medical practitioners whose actions or inactions violate medical ethical principles and health services consumer safety standards, as outlined in various laws and regulations, may be liable for medical malpractice or negligence in Rwanda. However, it has been a challenge for competent organs to document many cases due to a lack of information and proof. For this reason, only a few cases with evidence have been successful in the Rwandan courts, in which some medical providers were held accountable.

Medical practices that compromise patient dignity not only violate fundamental ethical principles but are also widely condemned and can be legally actionable. Healthcare practitioners whose actions or omissions breach medical ethics and patient safety standards, as defined by existing legal frameworks, may be held liable for medical malpractice or negligence. However, challenges in documenting and proving malpractice cases have limited successful litigation in Rwanda, with only a few cases resulting in legal accountability due to a lack of sufficient evidence.

Various mechanisms could be implemented to enhance accountability for medical malpractice and negligence. Comparative legal analyses indicate that jurisdictions adopt either fault-based or no-

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<sup>57</sup> Institutional theory explores how behaviour within organisations or systems is shaped by both formal norms (laws, regulations) and informal norms (traditions, cultural expectations). It focuses on how institutions contribute to stability, direct decision-making, and affect how people and organisations acquire legitimacy by conforming to social standards. Institutional theory describes how formal regulations, cultural norms, and standards influence the conduct of healthcare practitioners and organisations.

This approach might benefit the health care system by standardising procedures, fostering legitimacy and trust, facilitating change adaptability, and establishing accountability systems. It may, however, also have negative consequences, such as resistance to innovation (putting conformity above creativity), disparities or imbalances in healthcare access, and systemic failures brought on by ineffective institutional rule implementation that lead to medical malpractice and negligence and ultimately jeopardising patient safety. See Jason Beckfield et al., "An Institutional Theory of Welfare State Effects on the Distribution of Population Health," *Social Theory and Health* 13, no. 3–4 (2015): 228–41, <https://doi.org/10.1057/sth.2015.19>.

<sup>58</sup> Sara Javanparast et al., "How Institutional Forces, Ideas and Actors Shaped Population Health Planning in Australian Regional Primary Health Care Organisations," *BMC Public Health* 18, no. 1 (2018): 8–13, <https://doi.org/10.1186/s12889-018-5273-4>.

<sup>59</sup> Balon, "Bureaucracy, Institutional Theory and Institutionaocracy: Applications to the Hospital Industry."

<sup>60</sup> Hans Maarse, "The Institutional Model in Health Policy Analysis," in *Health Policy Analysis - An Introduction* (Maastricht University, The Netherlands: Maastricht University Press, 2023), 17–23, <https://doi.org/10.26481/mup.2303>.

fault liability systems in malpractice adjudication.<sup>61</sup> While Rwanda has yet to test the no-fault liability approach, medical liability in the country may be classified as administrative, professional, civil, or criminal, depending on the circumstances and severity of the malpractice. Both formal judicial proceedings and alternative compensation mechanisms offer potential remedial forums.

Moreover, healthcare institutions may bear liability for malpractice committed by their employees or agents, particularly in cases involving contractual breaches,<sup>62</sup> fiduciary misconduct, and violations of patient rights. Under tort law, medical negligence can also invoke tortious liability principles, ensuring that institutions uphold ethical and professional standards in care delivery. The purpose of medical liability in the Rwandan health care system is to reinforce professional accountability and deter harmful medical practices.<sup>63</sup>

In addition to the information gathered from scholarly writings, case laws, and media outlets nationwide, the researcher visited healthcare facilities on several occasions at various times and in different locations to seek medical treatment. Through unstructured observation, he could freely observe the type of care the patients were receiving. This involves the use of offensive language and negligence of various kinds that could result in patient adverse events. This made him think of what could be done to raise the standard of patient safety and healthcare in Rwanda.

A review of existing literature on medical liability in Rwanda highlights a significant gap in documented cases, underscoring the need for further research. This absence of systematic reporting informed the development of the present study, which seeks to analyse the complexities of liability for medical malpractice and negligence in Rwanda.

Although the study's conceptual foundation is based on observation, a key limitation is the absence of direct engagement with patients and medical practitioners, restricting firsthand documentation of their perspectives on malpractice and liability. However, consolidated data from the Rwanda Medical and Dental Council (RMDC), the Rwanda Food and Drug Authority (FDA), and the Ministry of Health, alongside case laws from the Judiciary, offer valuable insights. These sources serve as critical references for analysing liability frameworks and formulating structured reforms to enhance patient safety and strengthen professional accountability.

### **1.3. Research question**

The present research focuses on personal and institutional liability for medical malpractice and negligence, examining various approaches and theories. It examines the following primary question: "How does Rwanda implement its medical liability framework, and what can be done to

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<sup>61</sup> Kenneth Watson and Rob Kottenhagen, "Patients' Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe," *European Journal of Health Law* 25, no. 1 (December 11, 2017): 13–23, <https://doi.org/10.1163/15718093-12460348>.

<sup>62</sup> *St-Jean v. Mercier*, [2002] 1 S.C.R. 491, 2002 SCC 15.

<sup>63</sup> Edwin Durbin, "Torts – Nature of Tort Law and Liability," THOMAS REUTERS WESTLAW CANADA, accessed November 28, 2021, <https://www.westlawcanada.com/academic/ced/torts>.

strengthen healthcare accountability and patient safety?” This question has the following four sub-questions:

- (1) To what extent do medical malpractice and negligence cases occur in Rwanda, and what are their predominant forms and underlying contributing factors?
- (2) How do Rwanda’s legal and regulatory frameworks establish a liability regime for malpractice and negligence, and what challenges undermine its effectiveness?
- (3) What mechanisms can promote healthcare accountability and patient safety in Rwanda?

#### **1.4. Hypotheses**

- Medical liability is an essential factor in protecting the rights of patients, healthcare quality, and the confidence of the population in the health system.
- Rwanda’s medical malpractice liability system does not accurately reflect the extent of injuries suffered by healthcare service users in health facilities, thereby undermining its remedial role for the victims.

#### **1.4. Research significance**

Malpractice liability seeks to strike a balance between the interests of medical practitioners and those of patients by establishing accountability for their conduct.<sup>64</sup> Danzon argues that the liability of healthcare service providers can encourage the most effective treatment for patients.<sup>65</sup> Nonetheless, a clash is likely to arise between medical experts and compensation authorities if all medical injury remedial measures focus solely on economic compensation. Such compensation would prioritise the future quality of healthcare, in addition to the financial loss already suffered. All forms of liability ultimately aim to prevent medical malpractice by providing victims of medical injuries with a flexible remedy and successful compensation. As previously stated, one of the goals of medical liability is to create "deterrence," whereby medical practitioners must exercise caution in their professional endeavors to prevent medical errors that could subject them to liability.

In this context, the proposed research will shed light on medical liability, a public concern. It aims to contribute to the legal and policy frameworks by providing remedial approaches for victims of medical malpractice in Rwanda. The research is therefore envisaged to contribute to the development of sound healthcare that guarantees compliance with international health regulations (IHR) and meets minimal standards for health services. Ultimately, the research is expected to inform the government and its stakeholders in the healthcare sector to take action to prevent medical malpractice and negligence, and advance “patient safety” and “access to justice” as the two most important aspects of the right to good health.

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<sup>64</sup> Ronen Avraham and Max M. Schanzenbach, “Medical Malpractice,” in *The Oxford Handbook of Law and Economics: Volume 2: Private and Commercial Law*, ed. Francesco Parisi, vol. 2 (Oxford University Press, 2017), p. 122, <https://doi.org/10.1093/oxfordhb/9780199684205.013.006>.

<sup>65</sup> Danzon M. Patricia, “Liability For Medical Malpractice,” *Journal of Economic Perspectives* 5, no. 3 (1991): 52–53, 64–65.

## **1.5. Research aim**

Medical malpractice and negligence are frequently seen as threats to patient safety and as financial burdens on the country, healthcare organisations, and the community. However, there has not been substantial reporting on the liability of medical practitioners for such patient harm in Rwanda. From a legal perspective, the present research aims to investigate the liability of medical practitioners for malpractice and negligence in Rwanda. The research uses the existing data from various claims submitted to the Ministry of Health, the RMDC, and the Judiciary of Rwanda. Those sources of data were supplemented by interviews conducted with key informants.

## **1.6. Objectives**

### 1.6.1. General objective

The general objective of this study is to contribute to the improvement of Rwanda's healthcare system by strengthening patient safety and compensation regime towards medical malpractice claims.

### 1.6.2. Specific objectives

- Evaluate the degree of the medical malpractice situation in Rwanda;
- Identify the forms and factors that contribute to medical malpractice and negligence;
- Assess the existing modes of liability for medical practitioners;
- Evaluate the loopholes and challenges in the legal and policy frameworks that may lead to medical malpractice;
- Explore various theories and doctrines associated with medical liabilities;
- Suggest possible legal remedies for victims of medical malpractice and negligence;
- Define the mechanisms that could strengthen patient safety and promote medical malpractice compensation system in Rwanda;
- Provide appropriate recommendations on the prevention of medical malpractice and negligence and enhance the healthcare service users' rights and safety;

## **1.7. Dissertation structure**

This treatise is organised into nine chapters. The introductory part forms the first chapter. It details the research context, motivation, aim, significance, and research questions. Chapter two explores the conceptual and theoretical framework underpinning medical liability. This chapter explains various concepts essential for understanding the context of medical liability. It also lays the foundation for the entire work by establishing theories and paradigms supporting the research. Chapter three describes the research methodology, which comprises both doctrinal and non-doctrinal approaches. It also details all steps and processes of the study, from data collection to data analysis, while considering the ethical parameters. Chapter four provides an overview of medical malpractice and negligence cases in Rwanda, their predominant forms, and underlying contributing factors. Chapter five reviews the legal and regulatory frameworks for medical malpractice and negligence in Rwanda. This section discusses the fundamentals of medical ethics and standards of care, legal protections of patients' rights, duties and responsibilities of medical

practitioners, the institutional framework for ensuring patient safety, and existing legal and regulatory loopholes. Chapter six discusses the liability for medical malpractice and negligence in Rwanda. It begins with the history and rationale of medical liability and the ethical dilemmas related to healthcare accountability. It then presents the existing models of medical liability before discussing the application of tort liability in malpractice cases. The chapter further explores the available forms of liability in medical malpractice cases and the recoverable damages in comparison with other jurisdictions. Then, it dives into available remedial recourse and forums for healthcare users in Rwanda. It also examines the consequences of medical litigation before concluding. Chapter seven explores the informed consent in healthcare and related liability. It sheds light on the essence of informed consent, its forms, application, validity, as well as medical liability resulting from its violation. Finally, chapter eight presents a comprehensive framework to enhance accountability and patient safety in the Rwandan healthcare system, leading into the ninth chapter, which provides a general conclusion.

## **CHAPTER TWO**

### **CONCEPTUAL AND THEORETICAL FRAMEWORK**

This chapter presents the major concepts integral to this dissertation and discusses how they interconnect within the framework of the entire research design. It also explores the theoretical foundations on which substantive arguments in the study are established, highlighting the significance of contextualising these concepts, theories, models, and paradigms to enhance the understanding of the research context and the interpretation of the findings.

#### **2.1. Key concepts**

##### **2.1.1. Medical practitioner**

In the context of this study, the terms ‘medical practitioner,’ ‘health care practitioner,’ ‘medical expert,’ ‘healthcare professional,’ and “physician” are used interchangeably to refer to a medical doctor or dental surgeon licensed by the Rwanda Medical and Dental Council (RMDC). Such a doctor or surgeon may be practicing as a general practitioner (GP) or as a specialist in a particular field. Although the research focuses on medical practitioners, the researcher cannot exclude surgeons, nurses, midwives, ambulance teams, and other professionals involved in delivering healthcare services or medical interventions. This inclusion highlights the collaborative nature of critical practice, where interprofessional cooperation can influence outcomes and, in some cases, contribute to malpractice or negligence. Additionally, the term ‘healthcare provider’ encompasses physical healthcare facilities, whether public or private, including hospitals, ambulatory centers, acute care facilities, mental health and addiction treatment centers, rehabilitation centers, medical clinics, and medical offices.

### 2.1.2. Medical negligence

A medical professional owes a patient the duty of care. This duty involves providing ‘aid’ and ‘protection’. When an infringement of that duty injures the patient, the negligence is actionable.<sup>66</sup> In that context, medical negligence refers to an act or omission by a health care professional that derogates the standards of the medical profession, which can result in injury or death of a patient.<sup>67</sup> Medical negligence arises when damage occurs because of the inattention of a health professional or health care organisation. Although it is hard to define medical negligence because of a cost-benefit standard in the medical market, which unbalances the health care services provisions,<sup>68</sup> it entails all circumstances in which medical professionals fail to abide by the standards of care. In other words, when the health care provider’s action or omission does not meet the medical ethics and standards of care, it constitutes medical negligence. However, negligence in a medical context is not a simple term. It encompasses the non-application of ancient knowledge and skills and the non-observance of essential safety measures during medical procedures.<sup>69</sup>

Negligence can be either intentional or unintentional. It is intentional when the health professional engages in medical treatment or procedure, or decides not to do something, by familiarising himself with the associated potential consequences that are reasonably foreseeable.<sup>70</sup> In contrast, nonintentional negligence occurs when a health professional chooses to act or abstain from acting without reasonably predicting the outcomes. In this situation, there is no apparent risk of harm to the patient.

### 2.1.3. The proximate cause

The proximate cause, also called a “responsible cause” by some scholars,<sup>71</sup> is a cause that is more direct or necessary for an injury to occur. Despite the other causes leading to the occurrence of such an injury, the proximate cause is legally sufficient to establish liability against the wrongdoer.<sup>72</sup> In this regard, the foreseeability of the consequences of an action or inaction that resulted into harm is a test determinant of a proximate cause in tort law. Besides, another test determinant of the proximate cause is the substantial factor to the harm. Thus, if an action is a substantial factor in the harm, it is likely to be the proximate cause compared to the remote or intervening factors that will remain the actual causes.

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<sup>66</sup> John Devereux, “Medical Negligence,” in *Health Law: Frameworks and Context*, 1st ed. (Cambridge University Press, 2017), 139–41.

<sup>67</sup> Oludamilola Adebola Adejumo and Oluseyi Ademola Adejumo, “Legal Perspectives on Liability for Medical Negligence and Malpractices in Nigeria,” *Pan African Medical Journal* 35, no. 44 (2020): 5, <https://doi.org/10.11604/pamj.2020.35.44.16651>.

<sup>68</sup> Cost-benefit standard brings an imbalance between the wealthy people and the poor. Thus, people with financial capacity with have access to the best health care services comparing to the poor.

<sup>69</sup> Riis, “Medical Negligence”, p. 215-216.

<sup>70</sup> OpenStax, “Product and Strict Liability,” in *Business Law I Essentials* (Rice University, 2019), 71–72, <https://openstax.org/books/business-law-i-essentials/pages/6-2-product-and-strict-liability>.

<sup>71</sup> Joshua Knobe and Scott Shapiro, “Proximate Cause Explained: An Essay in Experimental Jurisprudence,” *The University of Chicago Law Review* 88, no. 1 (2021): 169, <https://lawreview.uchicago.edu/print-archive/proximate-cause-explained-essay-experimental-jurisprudence>.

<sup>72</sup> Knobe and Shapiro.

#### 2.1.4. The acceleration theory

The acceleration theory is a tort law principle founded on the idea that a pre-existing injury or condition that would have eventually happened on its own can be accelerated.<sup>73</sup> In this situation, even though the injury would have occurred independently of the defendant's acts, the defendant may still be held liable for the entire extent of the harm. Thus, speeding up the inevitable damage is the defendant's responsibility.

#### 2.1.5. Administrative negligence

Administrative negligence in healthcare refers to shortcomings in the organisational, managerial, or operational processes that play a crucial role in patient care.<sup>74</sup> These lapses are distinct from clinical errors and instead arise from failures within hospital systems or administrative protocols.<sup>75</sup> Examples include insufficient staffing, which can lead to care delays or errors, and breakdowns in communication, whether between staff or with patients, potentially causing incorrect treatments. Failure to uphold safety standards, such as proper sanitation or infection control, may lead to preventable health complications. Additionally, mishandling patient records—whether through loss, disorganisation, or incomplete updates—poses significant risks of incorrect treatment. Administrative inefficiencies, such as scheduling errors or poor resource allocation, can result in delays that adversely affect diagnoses or care delivery.<sup>76</sup>

The challenges arising from administrative negligence in healthcare emphasise the significant legal implications tied to failures in non-clinical management and organisational processes. From a legal perspective, these deficiencies may give rise to liability claims, as they can breach the standard of care expected from healthcare institutions.<sup>77</sup> Examples include insufficient staffing that delays or compromises patient care, mismanagement of medical records leading to errors in treatment, or the failure to uphold safety protocols such as infection control, which can result in preventable harm to patients.

Addressing cases of administrative negligence necessitates a thorough investigation of institutional policies, adherence to regulatory frameworks, and the establishment of causal relationships between administrative failures and resulting patient harm. A comprehensive understanding of the intersection between healthcare laws, administrative responsibilities, and professional standards is essential for evaluating liability and ensuring accountability. Effective administrative systems serve not only as ethical necessities but also as critical legal mechanisms, safeguarding institutions

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<sup>73</sup> Legal Information Institute, “Acceleration Theory,” Cornell Law School, 2024, [https://www.law.cornell.edu/wex/acceleration\\_theory#:~:text=The acceleration theory helps identify,by the Wex Definitions Team %5D](https://www.law.cornell.edu/wex/acceleration_theory#:~:text=The acceleration theory helps identify,by the Wex Definitions Team %5D).

<sup>74</sup> “When Hospital Protocol Fails: How Administrative Negligence Can Lead to Medical Malpractice Claims Blog,” Andres Berger Tran, accessed April 26, 2025, <https://www.andresbergertran.com/blog/when-hospital-protocol-fails-how-administrative-negligence-can-lead-to-medical-malpractice-claims-blog/?form=MG0AV3>.

<sup>75</sup> Adejumo and Adejumo, “Legal Perspectives on Liability for Medical Negligence and Malpractices in Nigeria.”

<sup>76</sup> “When Hospital Protocol Fails: How Administrative Negligence Can Lead to Medical Malpractice Claims Blog.”

<sup>77</sup> Adejumo and Adejumo, “Legal Perspectives on Liability for Medical Negligence and Malpractices in Nigeria.”

against claims of negligence and reinforcing their commitment to patient safety and operational integrity.

#### 2.1.6. Gross or overwhelming negligence

Medical negligence may become gross or overwhelming when a medical expert causes fatal harm to a patient to whom he otherwise owes a duty of care. This happens when the expert has fallen very short of reasonable standards of care, which raises the attention of the state, for it is against public morals. In that situation, a civil court is petitioned for gross negligence. Also, this is considered an offence of gross negligence or involuntary manslaughter in various jurisdictions, including Rwanda.

The 1994 *R v. Adamako* case is believed to be the foundation of gross negligence manslaughter against health care professionals. In this historic British case, an anaesthetist performed an eye operation while negligently failing to maintain the patient's safety because the oxygen tube was disconnected during the procedure, which resulted in the patient's death. The appellate court found the defendant guilty of gross negligence manslaughter after upholding the legal standards for gross negligence manslaughter. This landmark case is thought to have established the legal criteria for gross negligence, requiring the defendant to meet four standards for liability: a breach of the duty of care, reasonable foreseeability of an evident risk of death, a causal link between the defendant's actions or inactions and the patient's death, and the degree to which the defendant's misconduct constituted an offence.<sup>78</sup>

Typically, the severity of the harm inflicted determines the civil court's determination of punishment rather than the level of responsibility. Also, the degree or extremity of carelessness must be considered when determining whether it is gross negligence against mere negligence.<sup>79</sup> The following factors supporting the state of mind must be considered when determining whether the medical provider's actions or omissions constituted gross negligence:<sup>80</sup>

- Disloyalty to an evident patient injury;
- Foreseeability of risk paired with reconciliation with it;
- Acknowledgement of the risk associated with willful mind and the severity of negligence in the presumed risk prevention; and
- Inability to avoid a severe risk beyond “mere heedlessness” regarding the evident and vital concern.

Gross negligence shows the clumsiness of the health care professional in actions or inactions, combined with those factors listed above. Besides, the overwhelming risks undertaken must be

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<sup>78</sup> *R v Adomako* (1994).

<sup>79</sup> Michelle Robson, Jon Maskill, and Warren Brookbanks, “Doctors Are Aggrieved—Should They Be? Gross Negligence Manslaughter and the Culpable Doctor,” *Journal of Criminal Law* 84, no. 4 (2020): 314–20, <https://doi.org/10.1177/0022018320946498>.

<sup>80</sup> Robson, Maskill, and Brookbanks.

underscored as the basis of determining an offence of gross negligence manslaughter or involuntary manslaughter in various jurisdictions.

#### 2.1.7. Wanton misconduct and willful misconduct

“Wanton misconduct” refers to a deliberate doing of an act which one has a duty to avoid or the intentional failure to perform a duty, in reckless disregard of the consequences and under circumstances that a reasonable person would know, or should know, that such conduct would likely cause substantial harm to another.<sup>81</sup> This is slightly different from “willful misconduct,” which denotes the intentional commission of an act from which one has a duty to refrain or an intentional failure to perform an act which one has the duty to do with actual knowledge of risks that will be created, and/or intentional failure to prevent damage or actual intention to cause harm.<sup>82</sup>

The difference lies in the fact that in wanton misconduct, the medical professional disregards the consequence of acting or failing to act that a reasonable person would or should know, while in willful misconduct, a reasonable person performs a prohibited act or refrains from performing an obligation with the intent to cause harm that they are fully aware of the risk at the moment.

#### 2.1.8. Medical malpractice

Patrick Lingibé has defined medical malpractice as “any act, emanating from the caregiver, having caused abnormal damage to the foreseeable evolution of the patient's state of health.”<sup>83</sup> Assessing medical malpractice mainly relies on the custom of the medical profession, underpinned by ‘due care’. Medical malpractice is also known as ‘substandard health care’ or simply medical error, which can result from the negligence of a healthcare provider or physician. The report “*To Err Is Human*” describes an error as failing to carry out a planned activity as intended or using the incorrect strategy to accomplish a plan.<sup>84</sup> This concept distinguishes between execution errors and planned errors. Then, medical malpractice encompasses diagnostic error, inadequate patient treatment, and lack of aftercare or unsuitable health management.

Medical malpractice arises when medical procedure or treatment results in an adverse outcome compared to the anticipated outcome. Medical malpractice is, in most cases, associated with negligence. However, all medical events not meeting the mutual expectations from the agreement between a health professional and a patient are not founded on negligence and therefore do not constitute liability for the health professional.

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<sup>81</sup> “WPI 14.01 Willful Misconduct and Wanton Misconduct—Defined,” *Thomas Reuters*, April 2022, [https://govt.westlaw.com/wciji/Document/I2c83cab4e10d11dab058a118868d70a9?contextData=%28sc.Default%29&transitionType=Default#:~:text=%5BWanton misconduct is the intentional,known%2C or should know%2C that.](https://govt.westlaw.com/wciji/Document/I2c83cab4e10d11dab058a118868d70a9?contextData=%28sc.Default%29&transitionType=Default#:~:text=%5BWanton%20misconduct%20is%20the%20intentional,known%20or%20should%20know%20that.)

<sup>82</sup> “WPI 14.01 Willful Misconduct and Wanton Misconduct—Defined.”

<sup>83</sup> Patrick Lingibé, *The Medical Error Responsibility of the Health Professional*, 2018, <https://www.village-justice.com/articles/erreur-medicale,29911.html>.

<sup>84</sup> Linda T Kohn, Janet M Corrigan, and S Molla, eds., *To Err Is Human: Building a Safer Health System, Regulatory Toxicology and Pharmacology*, vol. 52 (Washington, D.C.: National Academy Press, 2000).

In a medical malpractice action, the establishment of mere negligence does not suffice. Instead, there should be an establishment of a breach of the standards of care and customary medical practice. Medical malpractice can only be assessed by experts from the same or a similar professional group as the one alleged to have caused the damage.<sup>85</sup> The claimed injury or death should be closely connected to the relationship between the medical professional and the patient, wherein the former's role was to relieve the unlikely health situation. However, failing to provide aftercare, particularly to a patient who underwent a surgical procedure, falls into medical malpractice. Unlikely health situations entailing body deformities, imperfections, and traumatic injuries to be treated through plastic or cosmetic surgery are also considered.

Although some scholars have differentiated medical negligence from medical malpractice,<sup>86</sup> they are associated. Thus, malpractice is related to negligent behaviour, although the latter does not always result in bad results. For example, a medical professional might skip some of the medical procedures, which is also against the duty of care, but luckily, such a break does not affect the patient. However, mere negligence might be considered malpractice in the medical profession since it violates the standards of care. As it is deemed unsound, it is hard to determine the occurrence of negligence without its consequences. Besides, there are specific medical treatments and operations whose patients experience harm due to their risky nature.<sup>87</sup> For example, a surgery that leaves a significant scar or a medication that presents a side effect to a patient. In those situations, it is hard to determine the health provider's fault despite the harm suffered by the patient.

Despite the tremendous role of health care providers in saving people's lives, their errors or negligence can contribute to severe morbidity and premature mortality of patients on the other hand. One of the severe morbidity problems they may cause is an iatrogenic injury.<sup>88</sup> This is a serious health problem leading to most hospital admissions.<sup>89</sup> Iatrogenic injury refers to tissue or organ damage as a result of a medical procedure, pharmacotherapy, or other medical act that has not served its purpose.<sup>90</sup> According to Cheng et al., it increases hospital stays, treatment costs, preoperative surgeries, and implant removal.<sup>91</sup> In this regard, iatrogenic injury is said to have occurred when the prior medical procedure has worsened the patient's condition, brought a new

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<sup>85</sup> Roger B Dworkin, "The Process Paradigm : Rethinking Medical Malpractice," *Wake Forest Law Review* 41 (2006): 509–10, <https://www.repository.law.indiana.edu/facpub/768>.

<sup>86</sup> LM Sykes, WG Evans, and HD Dullabh, "Negligence versus Malpractice: The 'Reasonable Man Rule,'" *South African Dental Journal* 72, no. 9 (2017): 430–32, <https://doi.org/10.17159/2519-0105/2017/v72no9a7>.

<sup>87</sup> OpenStax, "Product and Strict Liability."

<sup>88</sup> Gilbert Lau, "Iatrogenic Injury: A Forensic Perspective," in *Forensic Pathology Reviews*, ed. M. Tsokos, vol. 3 (Totowa: Humana Press Inc, 2005), 352.

<sup>89</sup> Luciano A. Sposato and Osvaldo Fustinoni, "Iatrogenic Neurology," in *Handbook of Clinical Neurology*, 1st ed., vol. 121 (Elsevier B.V., 2014), 1635, <https://doi.org/10.1016/B978-0-7020-4088-7.00107-3>.

<sup>90</sup> Biao Cheng et al., "Iatrogenic Wounds: A Common but Often Overlooked Problem," *Burns and Trauma* 7 (2019): 1–7, <https://doi.org/10.1186/s41038-019-0155-2>.

<sup>91</sup> Cheng et al.

medical problem, or taken the patient's life. In this research, iatrogenic injury is a technical term with the same meaning as medical malpractice.

In case of failure to abide by the duty of care or acting negligently, medical practitioners are subject to liability for the damage they have caused. This is what is considered a medical liability for malpractice or negligence. The malpractice itself is founded on negligence, since it is a breach of the professional duty of care that can be avoided by adherence to accepted norms. Negligence alone might suffice to establish malpractice in medical practice, but it never necessarily results in injury or liability except where a breach proximately causes harm or damages to the patient or health care user.

Although medical "negligence" and "malpractice" are often used, other terminologies may be encountered throughout this work. Different terms, including "medical error/fault," "medical misadventure," "medical negligence," "avoidable misadventure," "patient harm," "iatrogenic injury," and "avoidable/adverse event," are used interchangeably to describe medical malpractice in different settings and jurisdictions. However, an avoidable or adverse event is commonly used in no-fault systems, while the rest are familiar in tort liability systems.

#### 2.1.9. Duty of care

The duty of care has been defined as a legal obligation imposed on an organisation, requiring adherence to a reasonable standard of care while preventing any acts that could foreseeably harm others.<sup>92</sup> This implies a reasonable management of the foreseeable risks that may harm others by protecting their health, safety, security, and well-being. In the medical context, the duty of care requires a medical practitioner to exercise the diligence and skills a reasonable person would exercise in similar circumstances.<sup>93</sup>

A physician's duty of care includes a number of responsibilities, such as adhering to current rules and protocols, protecting patients from harm, and choosing treatments that are both effective and acceptable. According to Hannah Karim, duty of care in health and social care settings encompasses providing safe and compassionate care to healthcare service users, safeguarding vulnerable people, maintaining confidentiality, and providing a secure environment.<sup>94</sup> However, the duty of care premise changes along with society. Ima Farboud claims that it is essentially based on reasonableness, which considers the risks involved, the nature of the relationships involved, and other relevant conditions.<sup>95</sup>

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<sup>92</sup> Beatrix Renault, "What Is Duty of Care?," *internationalosos.com*, 2023, <https://www.internationalosos.com/insights/what-is-duty-of-care>.

<sup>93</sup> Sinikiwe Bbabbie Singini, "An Analysis on the Applicability of Medical Negligence and Its Relevance Under Zambian Health Laws," *Pharmacognosy Magazine* (Cavendish University Zambia, 2021).

<sup>94</sup> Hannah Karim, "Duty of Care in Health and Social Care," *lottie.org*, 2024, <https://lottie.org/care-guides/duty-of-care/>.

<sup>95</sup> Ima Farboud, "Understanding Duty of Care: Your Essential Guide to Responsibility and Safety," *Vatix.com*, accessed February 13, 2025, <https://www.vatix.com/blog/duty-of-care>.

Applying the necessary duty of care helps health professionals to maintain high standards of care and professionalism in healthcare settings. Thus, a medical practitioner has the duty of care towards the patient by following the accepted medical standards, applying relevant diagnostic procedures, and administering appropriate treatments or medications. Nevertheless, ethical components such as delivering essential information in a safe and conducive atmosphere, considering the patient's opinions, and offering physical and emotional support represent the physician's fulfilment of the duty of care. In health and social care, the duty of care is coined into the "6Cs", comprising care, compassion, competence, communication, courage, and commitment.<sup>96</sup>

It is worth noting that medical professionals have a duty of care to all patients they encounter in their professional settings, not just those they directly interact with.<sup>97</sup> Even if they were not assigned to that patient or department, a hospital physician or ostensible doctor passing by a hospital ward and hearing a patient asking for help at the moment, they are directly required to intervene within their capacity and report the matter if it is beyond their capacity. This will not be considered a good samaritan's act.<sup>98</sup> It highlights the broader scope of responsibility within healthcare, ensuring that patients receive appropriate care and support at every stage, whether in-person or remotely.

According to Ann Sommerville, the duty of care in healthcare is multifaceted, encompassing various professionals and roles. It begins with those who receive the patient upon entry into a healthcare institution and extends to individuals conducting triage. It also includes general practitioners or consultants responsible for diagnosing, recommending tests, and initiating treatment, as well as nurses and junior doctors involved in the patient's care. Additionally, referral management centres (RMC) play a crucial role, ensuring that appropriate actions are taken to address the patient's needs. Each of these parties is bound by the duty of care, ensuring that patients receive safe, effective, and timely healthcare services.<sup>99</sup> Even specialists such as radiologists or endoscopists, who are only involved with one aspect of the patients' examination, are bound by this duty.<sup>100</sup> In cases where a patient has been referred from another healthcare institution, this duty of care extends to the professionals involved in the patient's previous medical treatment, emphasising the continuity of care and shared responsibility across all levels of healthcare provision.

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<sup>96</sup> "What Is Duty of Care in Health and Social Care?," One Education, 2024, <https://www.oneeducation.org.uk/duty-of-care/#:~:text=This principle encompasses safeguarding%2C informed,abuse%2C and creating secure environments.>

<sup>97</sup> Ann Sommerville, *Everyday Medical Ethics and Law*, ed. Sophie Brannan et al., Everyday Medical Ethics and Law (London: Blackwell Publishing, 2013), p. 18-19.

<sup>98</sup> Daniele Bryden and Ian Storey, "Duty of Care and Medical Negligence," *Continuing Education in Anaesthesia, Critical Care and Pain* 11, no. 4 (2011): 125-27, <https://doi.org/10.1093/bjaceaccp/mkr016>.

<sup>99</sup> Ann Sommerville, *Everyday Med. Ethics Law*.

<sup>100</sup> Ann Sommerville, *Everyday Med. Ethics Law*, p. 21.

The duty of care in healthcare is not confined to instances of physical interaction between doctor and patient. It can begin even before the patient is physically seen, through alternative means of communication such as phone consultations, emails, or remote medical advice. This duty transcends the traditional boundaries of the doctor-patient relationship, encompassing all professionals and situations where medical guidance, advice, or actions are provided.

#### 2.1.10. Breach of a duty of care

The duty of care is necessary since it forms the foundation of numerous legal actions. Essentially, it mandates that in order to prevent harming patients, healthcare providers must adhere to a certain standard of care that is both effective and acceptable. When they breach this duty and their deeds or inaction cause injury to healthcare users, a negligence tort claim can ensue. Malfeasance, misfeasance, and nonfeasance constitute a breach of the duty of care. In this regard, all clinical practitioners and health care providers, even the healthcare organisations, are accountable for any malpractice or negligence.<sup>101</sup>

#### 2.1.11. Medical standard of care

Medical professional associations, speciality societies, and voluntary health organisations started rigorously developing medical standards of care in the 1980s.<sup>102</sup> The terminology “standard of care” is predominantly used in common law to mean “the level and type of care that a reasonably competent and skilled health care professional, with a similar background and in the same medical community, would have provided under the circumstances that led to the alleged malpractice.”<sup>103</sup> It is also known as the minimally competent care that a physician must provide to meet the quality of care.<sup>104</sup> Vera Lúcia considers the standard of care the medical *leges artis* (rules of behaviour) to which medical practitioners should adhere.<sup>105</sup> The *leges artis* results from the codes of ethics, medical councils’ professional guidelines, clinical guidelines and protocols, and best practices of the medical profession.<sup>106</sup> However, the standard of care is determined by various factors all associated with the common practice agreed by the community or team of medical professionals in a particular area of medical specialty. Such practice involves technical skills, knowledge, treatment and diagnostic regimen choice,<sup>107</sup> and attitude demonstrating every team member practising the profession.<sup>108</sup>

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<sup>101</sup> Saad Dahlawi et al., “Medical Negligence in Healthcare Organizations and Its Impact on Patient Safety and Public Health: A Bibliometric Study,” *F1000Research* 10 (2021): 3, <https://doi.org/10.12688/f1000research.37448.1>.

<sup>102</sup> Its Specialties, “The Origins and Promise of Medical: Standards of Developments over the Course of Its History,” *History of Medicine* 6, no. 12 (2004): 574–76, <https://doi.org/10.1001/virtualmentor.2004.6.12.mhst1-0412>.

<sup>103</sup> Nancy J. Niles, U . S . Health Care System, third edit (Jones & Bartlett Learning, 2018), p. 418.

<sup>104</sup> Federation of State Medical Boards, “Considerations for Identifying Standards of Care,” 2023, p. 2-4.

<sup>105</sup> Vera Lúcia Raposo, “Defensive Medicine and the Imposition of a More Demanding Standard,” *Journal of Legal Medicine* 39, no. 4 (2020): 404–5, <https://doi.org/10.1080/01947648.2019.1677273>.

<sup>106</sup> Raposo.

<sup>107</sup> Avraham and Schanzenbach, “Medical Malpractice.”

<sup>108</sup> Carolyn Sappideen, “Medical Teams and the Standard of Care in Negligence,” *Journal of Law and Medicine* 23, no. 03 (2015): 72–75, <https://pubmed.ncbi.nlm.nih.gov/26554200/>.

All licensed medical practitioners have an obligation to adhere to the established standards of care. To maintain these standards, the government has established quality assurance mechanisms, including regular audits, licensing and accreditation processes for medical practitioners and healthcare facilities, and continuous professional development (CDP) for healthcare workers. In this regard, the Rwanda Biomedical Centre (RBC) and professional councils are significant in monitoring health service delivery and ensuring compliance with established standards. Thus, establishing medical standards of care has not been easy. However, it, in conjunction with liability, has been found crucial to improving medical treatment.<sup>109</sup>

The standard of care is not custom-based.<sup>110</sup> In a medical malpractice lawsuit, the plaintiff has an obligation to establish the standard of care and show that the medical practitioner violated the standard. To determine the standard of care, the court should hear the expert witnesses and then decide whether the defendant's conduct meets the acceptable conduct by a responsible body of similar professionals.<sup>111</sup>;<sup>112</sup> Slightly different, the reasonable physician standard of care is another concept for assessing what appropriate conduct a medical practitioner would have manifested to avoid an adverse event. Customary professional practices do not determine this.<sup>113</sup> Under this standard of care, a physician should undergo a practice that is non-customary if it would be a reasonable decision. Thus, reasonable practice, which is not universally customary, could be used as a measuring tool for the standard of care. Hence, there is a slight difference between the two concepts. Indeed, in most cases, reasonable practice is common practice although it is not its measure.<sup>114</sup> The standards of care can vary based on medical circumstances. However, the most important things to consider are how the average doctor would deliver the same care, medical knowledge, and traditional medical practices, as well as assessing and comparing the skills of an average doctor in the field in question.<sup>115</sup>

The custom-based standard of care and the reasonable physician standard of care could be applied in Rwanda,<sup>116</sup> although the former was eschewed in some jurisdictions.<sup>117</sup> Sarah Simon considers the custom-based standard of care superior as it enables the medical profession to regulate itself,

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<sup>109</sup> Avraham and Schanzenbach, "Medical Malpractice."

<sup>110</sup> Raposo, "Defensive Medicine and the Imposition of a More Demanding Standard.," p. 407-8

<sup>111</sup> Sarah K. Simon, "Medical Malpractice: The Custom-Based Standard vs. the Reasonable Physician Standard," *University of Cincinnati Law Review*, 2021, <https://uclawreview.org/2021/04/06/medical-malpractice-the-custom-based-standard-vs-the-reasonable-physician-standard/>.

<sup>112</sup> Ben A Rich, "Medical Custom and Medical Ethics: Rethinking the Standard of Care," *Cambridge Quarterly of Healthcare Ethics* 14, no. 1 (2005): 27–28, <https://doi.org/https://doi.org/10.1017/S0963180105050048>.

<sup>113</sup> "Chapter 4.B.1: The Custom-Based Standard of Care," William S. Boyd School of Law, accessed December 27, 2024, <https://law.unlv.edu/book/health-law/10th-edition/chapter-4b1-custom-based-standard-care>.

<sup>114</sup> Peter Moffett and Gregory Moore, "The Standard of Care: Legal History and Definitions: The Bad and Good News," *Western Journal of Emergency Medicine* XII, no. 1 (2011): 109, [https://doi.org/https://doi.org/10.4103/sni.sni\\_373\\_18](https://doi.org/https://doi.org/10.4103/sni.sni_373_18).

<sup>115</sup> "What Is Standard of Care in Medical Malpractice?," Wilson Kehoe Winingham, 2024, <https://www.wkw.com/indianapolis-medical-malpractice-lawyers/faqs/what-is-the-standard-of-care-in-medical-malpractice/>.

<sup>116</sup> NYIRABATESI Laurence v. King Faisal Hospital, RCAA 00073/2018/CA [30] (2019).

<sup>117</sup> Avraham and Schanzenbach, "Medical Malpractice," p. 123

while judges are not well equipped or expected to keep up with the latest practices. In contrast, a reasonable physician's standard of care ignores the advancements in contemporary medicine and enables courts to overregulate the profession, which has much oversight.<sup>118</sup> The latter is considered vague as it is applied uniquely depending on the individual case as what is reasonable in one case might be unreasonable in another, which might bring an inconsistency in practice.

It should be noted that while customary practice may serve as a foundation for establishing the standard of care in the medical profession, its acceptance is not determined by the number of practitioners who adhere to it. Rather, it must be acceptable in light of the medical knowledge available at the time of the treatment, as following the tradition (the practice of others in the same kind of neglect) may be a failure and not be a valid ground for an excuse.<sup>119</sup>

The standard of care in the context of evidence-based testimony and medicine is not far from standard care, where a physician addresses clinical problems that are well-understood and have certain evidence-based medications. By citing Bohmer's concepts of standards versus custom care, Abed ascertains that "standard care involves the application of clear and well-understood interventions that include investigations and treatment through a sequential process." It then involves compliance with well-known and well-understood good practices.<sup>120</sup>

Although Nancy E. Epstein appeals that there are many standards of care depending on the subspecialty,<sup>121</sup> the present definitions are suitable for this study. The good or the best practices are not considered a measure of the standard of care. Depending on the patient's needs, the practice should use average or reasonable care to meet the standards of care.<sup>122</sup> This is because the legal standards are set at an acceptable minimum, although clinical standards aim for optimal care. Nonetheless, the current medical standard of care is dynamic and adaptable, taking into account many factors, including the physician's specialty, the available resources, and the advancements of the medical profession at the time.<sup>123</sup>

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<sup>118</sup> Simon, "Medical Malpractice: The Custom-Based Standard vs. the Reasonable Physician Standard."

<sup>119</sup> Rich, "Medical Custom and Medical Ethics: Rethinking the Standard of Care," p. 32-35.

<sup>120</sup> Riadh T. Abed, "Custom and Standard Care: Implications for the Future Role of Doctors in Mental Health,"

Psychiatrist 34, no. 12 (2010): 505–6, <https://doi.org/10.1192/pb.bp.110.031658>.

<sup>121</sup> Nancy E Epstein, "Legal and Evidenced-Based Definitions of Standard of Care: Implications for Code of Ethics of Professional Medical Societies," *Surgical Neurology International* 9 (2018): 255, <https://doi.org/10.4103/sni.sni>.

<sup>122</sup> Robert I. Simon, "Standard-of-Care Testimony: Best Practices or Reasonable Care?," *Journal of the American Academy of Psychiatry and the Law* 33, no. 1 (2005): 9–11.

<sup>123</sup> Mindy Nunez Duffourc, "Dissecting Tort Liability for AI-Driven Technologies in Surgery," 2024, <https://www.maastrichtuniversity.nl/blog/2024/11/dissecting-tort-liability-ai-driven-technologies-surgery>.

### 2.1.12. Principle of justice in healthcare

The principle of justice in healthcare requires equal treatment for all patients, regardless of their socioeconomic status, and simultaneously expects healthcare practitioners to uphold high ethical and professional standards.<sup>124</sup> The principle is a fundamental concern in the health system and encompasses distributive, procedural, and social justice. Preservation of distributive justice enables responsible resource utilisation within medical facilities and prevents substandard medical practice as a result of deficits.<sup>125</sup> Procedural justice ensures that medical experts adhere to standard procedures, thereby avoiding disparate practices and biased judgments. Social justice also guarantees healthcare equity by offering the proper medical care to vulnerable or protected groups. The concept of justice also guarantees equal treatment to the patient and practitioner in court proceedings and rejects unjust blame or undue punishment. Justice establishes standards that protect both patient safety and the practitioners' accountability, minimising the risk of malpractice through transparent policies, informed consent, and adherence to best practices. Besides, the principle of justice is critical in preventing medical malpractice and negligence by promoting fairness and ethical decision-making in healthcare. Lastly, the addition of justice in preventing medical malpractice and negligence builds trust, encourages ethical care, and reduces legal disparities.

### 2.1.13. The neighbour principle

The neighbour principle stems from the religious precept that “you must not injure your neighbour.”<sup>126</sup> Lord Atkin first introduced it in the *Donoghue v. Stephenson* case in 1932.<sup>127</sup> In essence, it requires everyone to exercise reasonable care to avoid acts or omissions that could be perceived as likely to harm a neighbour. In law, a neighbour is anybody who is so closely and immediately impacted by another person's actions that the latter should have reasonably noticed. The neighbour principle could not be separated from the duty of care. It is notably utilised to determine when there is a duty of care.<sup>128</sup>

## 2.2. Theories/paradigms

### 2.2.1. Deontological paradigm

The deontological paradigm of Immanuel Kant can significantly contribute to modern medicine. This theory underpins this study. It offers a compelling framework for addressing medical

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<sup>124</sup> Raanan Gillon, “Raising the Profile of Fairness and Justice in Medical Practice and Policy,” *Journal of Medical Ethics* 46, no. 12 (2020): 789–90, <https://doi.org/10.1136/medethics-2020-107039>.

<sup>125</sup> John Kennelly, “Medical Ethics: Four Principles, Two Decisions, Two Roles and No Reasons,” *Journal of Primary Health Care* 3, no. 2 (2011): 170–74, <https://doi.org/10.1071/hc11170>.

<sup>126</sup> Richard Castle, “Lord Atkin and the Neighbour Test: Origins of the Principles of Negligence in *Donoghue v Stevenson*,” *Ecclesiastical Law Journal* 7, no. 33 (2003): 210, <https://doi.org/10.1017/S0956618X00005214>.

<sup>127</sup> “The Neighbour Principle in Tort Law,” *LawTeacher.Net*, December 2023, <https://www.lawteacher.net/free-law-essays/tort-law/neighbour-principle.php>.

<sup>128</sup> Jonathan Law and Elizabeth A. Martin, *Neighbour Principle, A Dictionary of Law*, 7th ed. (Oxford University Press, 2014), <https://doi.org/10.1093/acref/9780199551248.001.0001>.

malpractice by emphasising the moral duties and principles that healthcare professionals must uphold, irrespective of outcomes.<sup>129</sup> This moral theory centers on the intrinsic value of human beings and the obligation to treat them as ends in themselves, not merely as means to an end.<sup>130</sup>

According to Kant, the concept of duty in medical ethics demands attention to the empirical specificities of healthcare. While physicians are often regarded as experts, Kant rejects the notion that this expertise justifies paternalistic attitudes. The inherent asymmetry in the doctor-patient relationship creates a power imbalance, which may lead to violations of the duty to respect the patient as an autonomous individual. By ensuring the respect of patient autonomy, which is a foundation for informed consent, medical practitioners can reduce the incidence of medical malpractice resulting from inadequate communication. The Kantian ethical theory emphasises the significance of adhering to the law and professional standards as the healthcare professionals' duty to protect patients' rights. This framework compels physicians to prioritise the protection and dignity of patients, recognising their moral duty as fundamental to ethical medical practice.<sup>131</sup>

This paradigm can contribute to the accountability of medical practitioners and thus the mitigation of medical malpractice and negligence. In this regard, deontology, in medical practice, focuses on the health care providers' duty to abide by moral principles, such as beneficence and non-maleficence, which compels them to prioritise patient welfare and adhere to professional standards, thereby minimising negligence and harm. Another key point raised by Immanuel Kant is the “intentionality in action,” whereby healthcare professionals are encouraged to act out of a sense of duty and moral obligation rather than external pressures or personal gain.<sup>132</sup> The intentionality behind their actions fosters ethical decision-making and accountability.

Besides, Kantian categorical imperative, which advocates acting according to principles that can be universally applied, provides a robust ethical foundation for medical practice, and this could be the foundation for many principles, such as honesty or truth-telling,<sup>133</sup> and apology in medical practice, contributing to the prevention of medical malpractice. In the context of medical error, a healthcare provider's failure to disclose a mistake during treatment—motivated by concerns over reputational harm—can have significant ethical and legal implications. Such concealment may exacerbate the patient's condition, potentially leading to allegations of malpractice. From the perspective of Kantian deontology, the healthcare provider is morally obligated to act with honesty and integrity, irrespective of personal or institutional repercussions.

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<sup>129</sup> Chase M. Donaldson, “Using Kantian Ethics in Medical Ethics Education,” *Medical Science Educator* 27, no. 4 (2017): 841–44, <https://doi.org/10.1007/s40670-017-0487-0>.

<sup>130</sup> Mark Bernstein and Barry Brown, “Doctors’ Duty to Disclose Error: A Deontological or Kantian Ethical Analysis,” *Canadian Journal of Neurological Sciences* 31, no. 2 (2004): 171–74, <https://doi.org/10.1017/S0317167100053816>.

<sup>131</sup> Friedrich Heubel and Nikola Biller-Andorno, “The Contribution of Kantian Moral Theory to Contemporary Medical Ethics: A Critical Analysis,” *Medicine, Health Care and Philosophy* 8, no. 1 (2005): 5,9-16, <https://doi.org/10.1007/s11019-005-0104-7>.

<sup>132</sup> Donaldson, “Using Kantian Ethics in Medical Ethics Education.”

<sup>133</sup> Bernstein and Brown, “Doctors’ Duty to Disclose Error: A Deontological or Kantian Ethical Analysis.”

The Kantian deontology underscores the critical role of cultivating an ethical culture within healthcare institutions. By embedding fundamental moral principles into organisational policies and professional development programs, healthcare systems can foster environments that actively deter malpractice while safeguarding the intrinsic dignity and safety of patients. This ethical framework further affirms the institutional responsibility to prioritise patient welfare as a central tenet of healthcare practice and governance.

Kantian deontology, therefore, offers a powerful framework for healthcare professionals in addressing ethical dilemmas specifically related to medical liability. By emphasising universal moral duties and accountability, this ethical perspective provides clear guidance in navigating issues such as balancing patient autonomy with medical recommendations and resolving conflicts of interest. Its principles underscore the necessity for healthcare providers to adhere to informed consent practices, disclose risks transparently, and maintain honesty in their interactions—key elements in mitigating medical liability claims. It also serves as a foundational tool for developing institutional policies that promote accountability and uphold ethical standards, ultimately enhancing the integrity of medical practice and patient care.

### 2.2.2. Professional liability theory

This research is also guided by professional liability theory, a legal framework that establishes the liability and accountability of professionals such as medical practitioners and legal professionals for their acts or omissions causing harm to patients, clients, or third parties.<sup>134</sup> In the medical liability sphere, the theory plays an important role in defining the responsibility of medical professionals in the event of malpractice and negligence.<sup>135</sup>

Professional liability entails both legal and ethical considerations requiring practitioners to meet required standards of care.<sup>136</sup> It possesses underlying principles of duty of care, breach of duty, and causation that all work together to enhance accountability in medical practice. Furthermore, the theory also informs regulatory and legislative frameworks, for instance, medical malpractice acts, institutional safeguards, and rules of governance.

Professional liability in Rwanda is backed by institutions, including the health professional councils, the Rwanda Food and Drugs Authority (Rwanda FDA), and the Ministry of Health (MoH). These institutions are instrumental in ensuring the balance between protecting patients and treating health professionals fairly, thereby ensuring a dynamic system of healthcare governance.

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<sup>134</sup> Leon Thomas, Law Review, and American Law Register, “Professional Negligence,” *The University of Pennsylvania Law Review* 121, no. 3 (1973): 654–65.

<sup>135</sup> “Liability and Professional Issues Source : Mental and Physical Disability Law Reporter , Vol . 29 , No . 6 ( November December Published by : American Bar Association Stable URL : [Http://Www.Jstor.Org/Stable/20786741](http://www.jstor.org/stable/20786741) to Mental and Physical Disability Law ” 29, no. 6 (2018): 835–39.

<sup>136</sup> Willis Rokes, “Professional Liability of Insurance Brokers and Agents,” *The Journal of Insurance Issues and Practices* 1, no. 4 (1977): 114–30, <https://www.jstor.org/stable/41943058>.

### 2.2.3. Human error theory

The third theory that guides this research is the “human error theory”. This theory, initially introduced by James Reason, has significantly transformed research in the areas of safety, risk management, and organisational behaviour in a wide range of settings, such as healthcare, air transport, and engineering.<sup>137</sup> The paradigm challenges traditional paradigms of individual blame and predicts the systemic factors that contribute to human error.<sup>138</sup> One of its most notable features is the classification of types of errors and the creation of models that assist organisations to reduce any negative consequences.

Under this theory, a ‘person’ approach to errors is systematically differentiated from a ‘system’ approach. The former attributes the causes of errors to personal deficiencies, such as forgetfulness, inattention, or recklessness, and typically appeals to punishment, including disciplinary action or retraining. Conversely, the system-focused perspective acknowledges the existence of errors but focuses the explanation on failures in organisational operations or harmful environmental factors. As a result, a sole focus on personal responsibility is likely to overpower latent systemic factors, thereby undermining the development of safer and more resistant institutional cultures.<sup>139</sup>

The human error theory divides errors into two main types: active and latent. Active errors occur at the point of operation and are frequently committed by front-line workers. These errors are immediate and easily noticeable, like when a nurse administers the wrong medication. Latent errors, in contrast, are hidden within the structure of the organisation, either in decision-making, structural defects, or management behaviour, and may lie dormant until they interplay with other factors to trigger adverse events. This distinction is crucial for developing effective safety interventions because it shifts the focus from personal fault to systemic resilience.

The most powerful contribution by the human error theory is the Swiss Cheese Model of accident causation.<sup>140</sup> This metaphor illustrates the concept that an organisation has many layers of defense, similar to slices of cheese, which are used as protection against error. The holes in every layer represent a failure or a weakness. As these holes intersect layer after layer, a path is formed through which an error may pass, ending in harm.<sup>141</sup> The model consequently highlights the key functions of redundancy, vigilance, and continuous improvement in the safety systems of organisations.

Applying the Swiss Cheese Model to the medical liability situation in Rwanda provides a robust analytical framework for understanding how systemic malfunctions in the healthcare industry can

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<sup>137</sup> “James Reason’s 12 Principles of Error Management,” *Aerossurance*, 2014, <https://aerossurance.com/safety-management/james-reasons-12-principles-error-management/>.

<sup>138</sup> Eva van Baarle et al., “Fostering a Just Culture in Healthcare Organizations: Experiences in Practice,” *BMC Health Services Research* 22, no. 1 (2022): 1–7, <https://doi.org/10.1186/s12913-022-08418-z>.

<sup>139</sup> James Reason, “Human Error: Models and Management,” *British Medical Journal* 320, no. 7237 (2000): 768–70, <https://doi.org/https://doi.org/10.1136/bmj.320.7237.768>.

<sup>140</sup> Michael S. Rosenwald, “Cheese to Explain Human Error, Dies at 86,” *The New Times*, March 13, 2025, <https://www.nytimes.com/2025/03/13/science/james-reason-dead.html#:~:text=By analyzing hundreds of accidents,has played such a role.”>

<sup>141</sup> Reason, “Human Error: Models and Management.”

result in patient injury and how liability can be assessed. This can be observed in three aspects: ‘defense layers,’ systemic ‘pitfalls,’ or ‘flaws,’ and the ‘harm path.’

Defense layers in Rwandan Hospitals might include clinical protocols, staff training, equipment checks, documentation standards, and oversight mechanisms. Each layer is designed to prevent medical errors—from misdiagnoses to surgical complications. However, there might be systemic ‘pitfalls’ or ‘flaws’ (leeway for error) that reflect challenges such as limited resources or outdated equipment, deficiency in training or supervision, inadequate patient record systems, overloaded healthcare workers, and weak enforcement of medical standards, to mention a few. These are factors contributing to medical malpractice or errors. In the same vein, the ‘harm path’ emerges when those weaknesses intersect. For example, an overloaded fatigued nurse administers the wrong dosage due to a Look-Alike, Sound-Alike (LASA) labelled medication and a lack of double-checking protocols—the error can reach the patient, resulting in injury or death. This is where medical liability becomes relevant. In Rwanda, the Swiss Cheese perspective can inform legal and ethical deliberations about whether liability lies with the practitioner, the institution, or the broader health system.

The human error theory has significant implications for cultivating a “just culture” within organisations. A just culture strikes a balance between accountability and learning, encouraging individuals to report errors without fear of punishment.<sup>142,143</sup> As organisational safety is underpinned by accurate and timely information, this openness is essential for identifying latent conditions, mitigating risks, and preventing future incidents. The theory emphasises that while some actions may be blameworthy, most errors are unintentional and should be treated as opportunities for systemic improvement rather than moral failure.<sup>144,145</sup> Suppose the “Human Error Theory” is adopted in Rwandan healthcare. In that case, there will be a shift in focus from blaming individual practitioners to systemic vulnerability, which enables organisations to build safer, more resilient environments through legal and regulatory reforms, improved training, reporting systems, organisational design, and Standard Operating Procedures (SOPs).<sup>146</sup> Besides, this promotion of a just culture within healthcare settings fosters shared accountability among healthcare professionals and enhances the transparent flow of information.<sup>147</sup>

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<sup>142</sup> Tom Geraghty, “Just Culture,” *Psych Safety*, May 23, 2025, <https://psychsafety.com/just-culture/>.

<sup>143</sup> Bianca Beentjes, “Human Error: Retributive Culture versus Just Culture,” *The Patient Safety Company (TPSC)*, 2025, <https://www.patientsafety.com/en/blog/human-error-retributive-culture-vs-just-culture>.

<sup>144</sup> John S. Murray et al., “Implementing Just Culture to Improve Patient Safety,” *Military Medicine* 188, no. 7–8 (2023): 1596–99, <https://doi.org/10.1093/milmed/usac115>.

<sup>145</sup> Bianca Beentjes, “Just Culture: Theory and Practice,” *The Patient Safety Company (TPSC)* (Online, June 2025), <https://www.patientsafety.com/en/blog/human-error-retributive-culture-vs-just-culture>.

<sup>146</sup> Ariel Braverman, “Integrating Human Factors in the Healthcare System: Embracing Aviation Methodologies and Artificial Intelligence (AI) to Enhance Provider Performance and Patient Safety,” *International Journal of Translational Medical Research and Public Health* 8, no. e016 (2024): 1–5, [https://doi.org/10.25259/ijtmrph\\_50\\_2024](https://doi.org/10.25259/ijtmrph_50_2024).

<sup>147</sup> van Baarle et al., “Fostering a Just Culture in Healthcare Organizations: Experiences in Practice.”

The workplace setting must be proactively planned and logically arranged to reduce the chances of and the effects of errors. Although human fallibility is an inevitable part of professional practice and cannot be eliminated, its impact can be significantly minimised by specific interventions that can alleviate the risks linked to it. Errors stemming from individual actions or systemic shortcomings can trigger incidents that, depending on the strength of safety mechanisms, may be detected, prevented, or mitigated.

Individual actions or systemic weaknesses can cause errors, and the likelihood of detecting, preventing, or responding to these errors depends on the strength of safety mechanisms. As Pascale Caro and Kenneth E. Wood emphasise, human error and organisational accident models contribute to a better understanding of the diverse nature of failures, the central role of latent conditions in undermining patient safety, and the role of error recovery strategies. These models also emphasise that systems or practices can quietly degrade, leading to serious accidents.<sup>148</sup> In the same vein, the focus should be placed on the process rather than the substance by maximising the institutional competencies for their productivity, as articulated by Dworkin.<sup>149</sup> Thus, if the system and the process are harmonised, it will be an ideal approach that would enable the system to establish sound patient-centered models, minimise errors, and ensure the safety of health services users.

In the context of the current national initiative to improve healthcare quality in Rwanda, implementing the human error theory into hospital management presents a promising opportunity to reduce preventable harms, support accountability, and foster a culture of safety and continuous improvement.

### 2.3. Conclusion

Practitioners' liability for medical malpractice is a critical aspect of healthcare governance. This chapter explores the conceptual and theoretical foundations underpinning the present research. This underscores the essential role of contextualisation in the study at hand. Various concepts and theories related to medical negligence and liability within the healthcare sector are discussed, including theories of deontology, professional liability, and human error. It is worth noting that understanding the factors contributing to clinical errors, the ethical responsibilities of healthcare professionals in ensuring patient safety and quality care, as well as the associated repercussions, are crucial. Additionally, the chapter helps to understand the research context and interpret findings by properly situating concepts, theories, models, and paradigms within that context. Thus, it enables the researcher to ensure consistent, more nuanced, and accurate comprehension of the subject matter.

Adapting to these theoretical approaches establishes a compelling environment for promoting patient safety and malpractice prevention as those approaches collectively require medical professionals to uphold moral duties and principles, regardless of the outcomes. They also help define their obligations in their daily clinical practice, taking into account legal and ethical

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<sup>148</sup> Pascale Carayon and Kenneth E. Wood, "Patient Safety: The Role of Human Factors and Systems Engineering," *Studies in Health Technology and Informatics* 153 (2010): 23–46, <https://doi.org/10.3233/978-1-60750-533-4-23>.

<sup>149</sup> Dworkin, "The Process Paradigm : Rethinking Medical Malpractice."

considerations. Besides, this chapter highlights the importance of transitioning from individual blame to systemic accountability in fostering a “just culture.” Therefore, medical liability is a complex area which necessitates the adoption of those theories that substantiate compliance with accepted medical standards to ensure the safety of healthcare service users and accountability within the Rwandan healthcare system. Thus, understanding this chapter is essential for contextual understanding of the meaningful insights and interpretations derived from research findings.

## **CHAPTER THREE**

### **RESEARCH METHODOLOGY**

#### **3.1. Introduction**

A combination of non-doctrinal and doctrinal approaches to legal research has been used in this dissertation to critically analyse the legal regimes governing patient safety and healthcare accountability in Rwanda. Doctrinal research focuses on analysing relevant laws, policies, regulations, and legal principles through a systematic review of legal texts, statutes, case law, and policy documents to establish the legal basis and identify gaps or uncertainties. This approach helps to understand the formal legal structure and how it aligns with international standards or best practices. To supplement this, a non-doctrinal approach has been employed to evaluate the actual working and effectiveness of those laws in practical settings, considering socio-legal contexts and stakeholders' perspectives.

Furthermore, to address the study's complexity, a mixed-method design that combines quantitative and qualitative data provides a comprehensive picture of medical malpractice incidents and medical practitioners' liability for negligence and malpractice in Rwanda. This method allows for the measurement of the extent of the problem while investigating legal, systematic, and contextual determinants influencing medical malpractice and alternatives for liability for physicians. Such a nuanced analysis is crucial for identifying shortcomings in Rwandan legal and regulatory

frameworks, enabling the development of sound strategies to improve patient safety, accountability, and public trust in the healthcare system.

This section entails the entire design of the prospective research entailing the methods and techniques employed throughout both the data collection and analysis stages. Various research steps and methods have been considered, including data collection, data analysis, and data interpretation.

### **3.2. Study description**

The study focuses on the liability of medical practitioners rather than the technicalities of adverse events, which may involve both practitioners and patients. It did not use human objects or specimens and is not concerned with personal patients' information. Thus, the required information could be obtained without disclosing any patient's personal information.

The necessary information on the medical malpractice phenomenon is primarily composed of statistics showing the number of received cases, the number of solved cases, their frequency, and the significant areas of concern, as well as the contributing factors. Additionally, information on the actions taken by relevant institutions (administrative or judicial) were required as part of the actual remedial approaches. The issue of whether they are satisfactory or not is beyond the scope of this research. Other information regarding existing legal and regulatory frameworks related to the prevention of medical malpractice and negligence, as well as the compliance of medical practice, is also crucial to this study.

To obtain the necessary data, the research employed a mixed-methods approach (qualitative and quantitative) using various techniques to construct a well-founded discussion and a reliable conclusion. Additionally, analytical legal research was necessary for analysing case laws on medical malpractice and information related to medical malpractice complaints from the Ministry of Health of Rwanda (MINISANTE).

As the sources of information were diverse, spanning the legal and medical spectrums, triangulation was another useful research technique. Triangulation is another research technique that utilizes multiple sources of information and methodologies to enhance the validity and reliability of findings. In this regard, both data triangulation and methodological triangulation were employed. Data triangulation involves various methods of collecting information, including interviews, observations, laws, and document analysis, to gain a thorough understanding of the facts around adverse events and related liability. This process enables the researcher to validate his findings and minimise the possibility of bias that may arise when relying on a single method. In addition, the study aims to collect both qualitative and quantitative data, utilizing different techniques of one of these methods (qualitative). Methodological triangulation is important to answer research questions and achieve the research objectives.

The interview guide helped the researcher collect both qualitative and quantitative information. In this light, both open-ended and closed-ended questions were formulated to effectively and efficiently obtain both qualitative and quantitative information.

### **3.3. Data collection**

As the major information is expected to be retrieved from the existing claims data stored by MINISANTE, RMDC, and case laws from the Judiciary of Rwanda, data collection was conducted only by the principal investigator and the research assistant. Where necessary, the number of research assistants may be increased. Data collection teams were constituted of a facilitator, a notetaker, and a recorder, where necessary, to ensure that the data is well captured. Interviews might be conducted in English or Kinyarwanda. However, data were transcribed and translated into English for reporting purposes. The researcher and research assistant would meet after every interview to reflect on and document emerging common themes, as well as the challenges faced. The purpose of these meetings was to inform and shape further questions, and to organise data while data collection is ongoing.

In addition, various techniques, including desk review, in-depth interviews, and key-informant interviews, were utilised to support the existing data. These interviews were conducted with specific institutions and individuals deemed relevant or experts in the research area, which justifies the relatively minimal but crucial number. Thus, the Ministry of Health (MINISANTE), the Rwanda Medical and Dental Council (RMDC), the Judiciary of Rwanda, and other experts whose backgrounds are considered helpful might be involved on a purposive basis.

### **3.4. Collection techniques and management of data**

Considering the nature of the research, the study on the liability of medical practitioners for malpractice and negligence in Rwanda involved methodological triangulation. The general methodological approach involved designing research tools to gather experiential data, addressing specific objectives and research questions.

Experiential data was explicitly collected through a comprehensive and in-depth desk review, as well as qualitative and quantitative information from the Ministry of Health of Rwanda (MINISANTE), and key informants from various councils that gather medical practitioners and the judiciary throughout the research process. In-depth interviews with specific actors brought empirical data to inform the strategic orientations during the study.

### **3.5. Desk review**

The desk review includes an analysis of already existing literature on the liability of medical malpractice and negligence. Although a focus was placed on domestic literature, literature from other jurisdictions was explored to shape a comprehensive understanding of the situation regarding medical malpractice and negligence, as well as the modes of liability of medical practitioners. Such an exploration can also help the researcher find further information that could be useful in discussing the matter and, together with other facts, in setting recommendations.

In that regard, the emphasis was put on the understanding of the phenomenon of medical malpractice, the existing laws and regulations, policies, and available case laws.

### **3.6. In-depth interviews**

Semi-structured interviews were conducted with targeted groups, individuals, or institutions to collect information on the current nature of medical malpractice and the liability of the involved medical practitioners in Rwanda. The Ministry of Health (MINISANTE), Rwanda Medical and Dental Council (RMDC), The Judiciary of Rwanda, and experts in this field were consulted to ensure that a clear picture of the current situation is captured at the national level.

#### **3.6.1. Key informant interviews (KIIs)**

A key informant interview, another technique of qualitative in-depth interviewing, was employed to investigate the state of affairs regarding medical malpractice, negligence, and liability of medical practitioners further.<sup>150</sup> The purpose of key informant interviews is to collect detailed, rich, and strategic information from individuals of diverse backgrounds, including, inter alia, leaders of specific institutions and professionals who have firsthand knowledge about the subject matter of the research.

By conducting this research, face-to-face interviews were utilised to help the researcher obtain the necessary information. However, where deemed impossible, video conferences and telephone Interviews were employed. In this regard, a selection of key informants was made, and their knowledge and understanding contributed to this research process.

It was expected that the existing quantitative information from the highlighted institutions would play a significant role in this research. Thus, the interviews were used at the institutional level to obtain qualitative information from relevant experts and, on an individual basis, from other experts who may not necessarily belong to those institutions. In this regard, university lecturers and judges whose professions enable them to deal with issues related to the present research topic were consulted.

### **3.7. Sampling technique**

As the research was expected to employ a methodology of triangulation (mixed approach), a selection of samples was required. Purposive or selective sampling was applied as a non-probability sampling technique. Under the purposive sampling technique, the researcher relies on his own judgment when choosing participants in the study.

Quota sampling is another sampling technique that was employed. This technique is a non-probabilistic sampling method in which participants are selected based on predetermined characteristics, ensuring the total sample has the same distribution of characteristics as the broader

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<sup>150</sup> UCLA, “Using Key Informants,” in *Key Informants* (Los Angeles: UCLA Center for Health Policy Research, 2016), 1.

population.<sup>151</sup> The predetermined characteristics of the research participants involve having been involved in any medical malpractice case in their work, either by receiving, settling, and/or advocating on such case issues in an administrative or judicial setting or an individual capacity. However, gathering firsthand data from participants through interviews has served as a supplement as the research is based on the existing data from medical malpractice and negligence received by the respective institutions in different periods for at least five (5) years.

In combination with purposive sampling, this technique is expected to be time-effective and yield manageable information.<sup>152</sup> In this light, key informants from highlighted institutions and concerned individuals were consulted to provide important information that could not be obtained from other sources.<sup>153</sup>

### 3.8. Study population

The Judiciary of Rwanda, MINISANTE, and RMDC constitute the primary focus of this research, as they are expected to be the significant sources of information. However, following the predetermined characteristics of the research participants discussed above, the following participants were targeted as key informants from each selected institution, as illustrated in the table below. It should be noted that this sampling is not representative; however, it has no negative effect on the research, as explained above.

*Table 1. Key informants and their institutions*

Number	Participant	Institution	Needed number and description
1	Judges	Judiciary of Rwanda	<ul style="list-style-type: none"> <li>- 8 judges from four intermediate courts (IC Gasabo, IC Nyarugenge, IC Gicumbi, IC Rubavu.)</li> <li>- 2 judges of the High Court</li> </ul>
2	Specialists	MINISANTE	<ul style="list-style-type: none"> <li>- 4 relevant officers (a lawyer, an officer who deals with malpractice cases, another one in planning, and a pharmacist)</li> </ul>
3	Specialists	RMDC	<ul style="list-style-type: none"> <li>- 2 senior officers in the management of the council (chairperson and registrar)</li> </ul>

<sup>151</sup> Hamed Taherdoost, “Sampling Methods in Research Methodology; How to Choose a Sampling Technique for Research,” *SSRN Electronic Journal*, no. September (2018): 18–23, <https://doi.org/10.2139/ssrn.3205035>.

<sup>152</sup> OpenLearn, “Objective and Subjective Research Perspectives,” accessed December 29, 2021, <https://www.open.edu/openlearn/money-management/understanding-different-research-perspectives/content-section-1>.

<sup>153</sup> Hamed Hameed Taherdoost, “Sampling Methods in Research Methodology; How to Choose a Sampling Technique for Research,” *International Journal of Academic Research in Management (IJARM)* 5, no. September (2016): 18–23, <https://doi.org/10.2139/ssrn.3205035>.

4	Specialist	NCNM	- A specialist who deals with legal affairs involving medical malpractice issues
6	Analyst	Rwanda FDA	- A senior officer who deals with legal and ethical compliance affairs

### 3.9. Data analysis

The gathered information was combined and analysed systematically to establish a more comprehensive understanding of the situation of medical malpractice and the liability of medical practitioners in Rwanda. Sources of information were mentioned, and any issues that might arise were documented.

Data analysis began at the interview level to ensure that fresh information was well captured and documented. Primary data analysis was conducted after all interviews were completed and the notes were transcribed and/or translated. While Microsoft Excel was used to analyse quantitative data for smoothing the work, thematic and content analysis methods were employed for the analysis of qualitative data. Patterns and concepts were derived from the analysis of all interviews conducted to compile coherent and consistent descriptions and themes.<sup>154</sup> The identified patterns, concepts, and themes were investigated further.

### 3.10. Ethical considerations

Participation in this research was voluntary. The participants in this study did not receive any direct benefits from their involvement. Nonetheless, the researcher expects that all the information gathered will contribute to advancements in patient safety, healthcare provision, and the overall Rwandan healthcare system. Additionally, participants were free to withdraw from the study at any time without being required to provide a reason. In addition, they were also free to opt not to respond to any questions they felt uncomfortable with without providing any explanation. There are no penalties or repercussions associated with withdrawing from the study or not participating at all.

#### 3.10.1. Data storage and management

##### 3.10.1.1. Confidentiality

The participant’s responses were captured in the form of notes and compiled into a single file, stored electronically in a secure environment accessible only to the research team. Besides, the stored information should be used for research purposes.

The information provided by the participants was kept secure and confidential in accordance with the Data Protection and Privacy Law (DPP Law) and the revised Data Protection Regulation of the University of Pécs, which complies with the General Data Protection Regulation (GDPR),

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<sup>154</sup> Alyona Medelyan, “Coding Qualitative Data: How to Code Qualitative Research,” *Thematic*, 2021, 1–16, <https://getthematic.com/insights/coding-qualitative-data/>.

a European data protection law. Thus, information that could identify the participant will not be disclosed unless the following conditions, as provided by the law, are met:

- If the participant consents to the present researcher's release of any specific recorded information,
- If the participant authorises the researcher to share any research records with third parties,
- If the researcher has a legal obligation to report anything you share with the appropriate authorities for violations of the Rwandan law.

Additionally, the research team did not request any personally identifiable information from participants, and they could not be identified by the information they provided. Therefore, the researchers have not identified them as participants in this study or any subsequent reports, nor will they associate their names with any of their responses.

#### *3.10.1.2. Informed consent*

As previously stated, participation in the research remains voluntary. Without the participant's permission, no interview was conducted. The interview could be audio-recorded with the participant's consent. This could enable the interviewer to record everything that was said, as they may not be able to transcribe or recall everything that was said after the interview. However, this approach was not used as it was found to invoke discomfort.

#### *3.10.1.3. Risks/discomforts*

The study could involve certain risks. Some of the subjects covered might make the participant uncomfortable or seem too sensitive if they are related to their experience or violence. In this situation, the interviewer would ask the participant if there was any question that made them uncomfortable before moving on. Additionally, it was expected that the participant would be allowed to end the interview at any moment. Furthermore, the latter might not agree with the final interpretations of the data from the interview; however, the researcher assures that every effort was made to represent the viewpoints of all research participants fairly.

## CHAPTER FOUR

### LANDSCAPE OF MEDICAL MALPRACTICE IN RWANDA: FORMS AND CONTRIBUTING FACTORS

*Worldwide, millions of patients suffer or get injured and die annually due to the provision of unsafe care and treatment. Hospital infections, inadequate diagnosis, delays in treatment, adverse drug events, and omissions of surgical procedures make up the most common root causes of medical errors or adverse events that may be avoided.*<sup>155</sup>

The above excerpt from Kapaki and Souliotis provides a comprehensive synthesis of the most prevalent forms of medical malpractice, along with their corresponding impacts on patient outcomes. This chapter begins by providing a global overview of medical malpractice incidents and a comprehensive examination of medical malpractice cases in Rwanda. Additionally, it discusses forms of medical malpractice that have been documented, reflecting both clinical and systemic vulnerabilities within the healthcare system. These cases include medication error; neonatal injury or death during childbirth; maternal injury or fatality; unnecessary ablation or resection procedures; surgical errors; incorrect count and retained surgical instruments (RSIs); and the lapse in standard medical protocol; defective drug supply; failure to consider patient history; breaches of patient confidentiality; and offensive or dehumanising language within the therapeutic relationship. These forms lead to medical legal claims, as Larisse asserts.<sup>156</sup> With selected case law summaries, this section illustrates their legal and ethical implications. It also delves into factors contributing to medical malpractice incidents. Although they are not classified throughout the discussion, these factors may be systemic, organizational, or human.

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<sup>155</sup> Vasiliki Kapaki and Kyriakos Souliotis, “Patient Safety and Medical Errors: Building Safer Healthcare Systems for Better Care,” in *Impact of Medical Errors and Malpractice on Health Economics, Quality, and Patient Safety*, 2017, 61–90, <https://doi.org/10.4018/978-1-5225-2337-6.ch003>.

<sup>156</sup> Larisse Prinsen, “The Leading Causes of Medicolegal Claims and Possible Solutions,” *South African Medical Journal = Suid-Afrikaanse Tydskrif Vir Geneeskunde* 113, no. 4 (2023): 1140.

#### 4.1. Overview of medical malpractice on a global scale

Despite global health regulatory regimes aiming to improve health systems across various jurisdictions, balancing clinical risk management with patient safety remains a complex challenge in health service delivery.<sup>157</sup> This issue can be observed from the volume of claims against medical professionals and their social and economic effects. Patient harm or an adverse event in medical treatment and procedures remains a threat to the healthcare system. These instances of medical malpractice that can be avoided or minimised undermine the efficiency and worth of health care. They are the reasons behind numerous sequelae, early mortality, and increased healthcare costs.<sup>158</sup>

Due to the unsafe health care system, medical malpractice incidents can manifest in many forms and sizes. They appear in all medical departments with different effects. The unsafe health care has been the primary source of patient harm, although it has received less attention. According to the 2020 OECD report on the economics of patient safety, in the developed world, unsafe health care claims the lives of 4 out of every 100 patients. More than 1 in 10 patients incur injury due to safety lapses in their treatment.<sup>159</sup> This substandard healthcare is exacerbating the cost of health services globally. Medical malpractices occur in all countries, with exceptionally high intensity in low—and middle-income economies where the situation worsens.<sup>160</sup> In those countries, 10% of hospitalised patients acquire infection before their discharge compared to 7% in the rest of the globe. For example, according to Forbes' medical malpractice statistics, medical malpractice has become a public health challenge in the United States.<sup>161</sup> It is estimated that medical errors are responsible for about 251,000 deaths per year, making it the third leading cause of death nationwide.<sup>162</sup> The statistics indicate that errors happen regularly, with about one-third of care providers having been sued for malpractice, and preventable errors happen in 3% to 15% of interventions. The frequency, severity, and mortality of medical malpractice create a significant public health impact on the quality of healthcare and patient safety in the United States.<sup>163</sup>

The forms of medical malpractice range from misdiagnosis, delayed diagnosis, failure of treatment or transfer, surgical and anaesthesia errors, childbirth injury, and application of defective medical devices to the lack of aftercare. The magnitude of medical malpractice cases has been minimised. Only claims that are reported can be documented. Yet, it is hard to trace and find all the patient's

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<sup>157</sup> Marco Bonetti et al., "An Analysis of the Number of Medical Malpractice Claims and Their Amounts," *PLoS ONE* 11, no. 4 (2016): 1–2, <https://doi.org/10.1371/journal.pone.0153362>.

<sup>158</sup> Luke Slawomirski, Ane Auraen, and Nicolaas S. Klazinga, "The Economics of Patient Safety - Strengthening a Value-Based Approach to Reducing Patient Harm at National Level," *OECD Health Working Papers No 96*, no. 96 (2018): 11–49, [https://www.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-patient-safety\\_5a9858cd-en](https://www.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-patient-safety_5a9858cd-en).

<sup>159</sup> WHO, OECD, *Delivering Quality Health Services: A Global Imperative for Universal Health Coverage*.

<sup>160</sup> WHO, OECD.

<sup>161</sup> Christy Bieber and Adam Ramirez, "Medical Malpractice Statistics of 2025," *Forbes*, January 2025, [https://www.forbes.com/advisor/legal/personal-injury/medical-malpractice-statistics/#sources\\_section](https://www.forbes.com/advisor/legal/personal-injury/medical-malpractice-statistics/#sources_section).

<sup>162</sup> Bieber and Ramirez.

<sup>163</sup> Bieber and Ramirez.

harm. Although it is an overlooked problem,<sup>164</sup> iatrogenesis or sequelae cases are enormous. It is estimated that 15% of hospital activity and expenditure is incurred on direct sequelae due to medical negligence and malpractice.<sup>165</sup> This interprets the health systems' waste of opportunity cost.

The 1991 research by Harvard Medical Practice found that 3-4 per cent of medical admissions had avoidable adverse events, while 1.7 per cent resulted in death.<sup>166</sup> Negligence was reported to contribute significantly to the most severe adverse events. The release of the "To Err Is Human" report helped raise public awareness by calling for action to minimise medical errors and improve patient safety.<sup>167</sup> Yet, several studies highlighting the concern of medical mishaps came afterwards. Several nations launched national agendas to avoid patient harm, and the International Alliance for Patient Safety was founded in 2004 to make it a worldwide effort.

Darius and Seth attempted to estimate the financial consequences of medical malpractice liabilities in the United States.<sup>168</sup> However, monetising the impact of medical negligence and malpractice remain difficult. Still, unsafe health care has a significant indirect effect on nations' socio-economic growth through slowing productivity. The OECD report on the economics of patient safety estimates its social cost between US\$1 and US\$2 trillion annually. According to the report, reducing patient injury would boost annual global economic growth by 0.7%, or more than US\$29 trillion.<sup>169</sup>

Furthermore, health care providers may curtail some health service delivery due to the liability costs associated with medical malpractice. For instance, surveys conducted in 2003 and 2004 in Pennsylvania and Florida showed that 12% of specialised doctors restricted or eliminated high-risk patients, while 3% of other doctors reported being inclined to follow suit.<sup>170</sup> Because of a concern for liability expenses, high-risk instances are avoided, such as high-risk pregnancies and back surgery, which cause high-risk people to become victims.

By citing the "To Err Is Human" report, the book "Patient Safety and Quality" discusses several factors that can lead to medical malpractice if compromised, including medical staff

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<sup>164</sup> Cheng et al., "Iatrogenic Wounds: A Common but Often Overlooked Problem."

<sup>165</sup> Slawomirski, Auraen, and Klazinga, "The Economics of Patient Safety - Strengthening a Value-Based Approach to Reducing Patient Harm at National Level."

<sup>166</sup> Troyen A. Brennan et al., "Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I," *New England Journal of Medicine* 324, no. 6 (1991): 370-76, <https://doi.org/10.1056/nejm199102073240604>.

<sup>167</sup> Vivienne McLoughlin et al., "Selecting Indicators for Patient Safety at the Health System Level in OECD Countries," *International Journal for Quality in Health Care* 18, no. Suppl. 1 (2006): 15-16, <https://doi.org/10.1093/intqhc/mzl030>.

<sup>168</sup> Darius N. Lakdawalla and Seth A. Seabury, "The Welfare Effects of Medical Malpractice Liability," *International Review of Law and Economics* 32, no. 4 (2012): 356-69, <https://doi.org/10.1016/j.irle.2012.07.003>.

<sup>169</sup> Luke Slawomirski and Niek Klazinga, "The Economics of Patient Safety: From Analysis to Action."

<sup>170</sup> Frank A. Sloan and Lindsey M. Chepke, *Medical Malpractice* (Cambridge: The MIT Press, 2008).

communication, medical error reporting, and disclosure,<sup>171</sup> leadership and medication management, and medical safety systems.<sup>172</sup> Other factors include an improper and delayed referral to secondary care, a medical personnel's lack of knowledge and abilities, and a flawed medical process. All these elements contribute to three main issues: misdiagnosis, ineffective treatments, and the absence of aftercare.

According to various studies, the culture of blame and punishment hinders healthcare professionals from reporting their clinical errors.<sup>173</sup> Patients are the ones who typically report medical malpractice, which is frequently underreported and unreported because of ignorance.<sup>174</sup> Significantly, it has been discovered that revealing medical malpractice benefits patients, healthcare providers, medical organisations, and the healthcare system since it reduces patient claims and promotes patient satisfaction.

Medical malpractice poses a threat to people's lives. This development hindrance is far-reaching as it affects patients, their communities, and the country. Indeed, it undermines countries' economic growth by engaging extra health care services that would otherwise be provided to different patients and health care costs. Besides, it establishes the health care system's untrustworthiness to the public.

#### 4.2. Medical malpractice in Rwanda

Despite the Government of Rwanda's efforts to advance the health system, some challenges remain. The Auditor General has highlighted gaps in medical services on several occasions.<sup>175</sup> Medical malpractice and negligence cases have been documented in Rwandan courts several times, following the actions or inactions of some healthcare providers' personnel, which have resulted in iatrogenic injuries<sup>176</sup> and the premature deaths of many patients in Rwanda.

It has also been one of the sensitive topics in the media across the country. In 2021, this issue was highlighted by the Rwandan Parliament's Public Accounts Committee (PAC) for allegedly impoverishing the government.

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<sup>171</sup> Razan Mansour et al., "Disclosure of Medical Errors: Physicians' Knowledge, Attitudes and Practices (KAP) in an Oncology Center," *BMC Medical Ethics* 21, no. 1 (2020): 2–6, <https://doi.org/10.1186/s12910-020-00513-2>.

<sup>172</sup> Ronda G Hughes, ed., *Patient Safety and Quality: An Evidence-Based Handbook for Nurses* (Rockville (MD), 2008).

<sup>173</sup> Jessica Berthold, "Disclosing Medical Errors the Right Way," *ACP Internist*, June 2014, <https://acpinternist.org/archives/2014/06/errors.htm>.

<sup>174</sup> Zhila Najafpour et al., "Nurses' Decisions in Error Reporting and Disclosing Based on Error Scenarios: A Mixed-Method Study," *Health Scope* 10, no. 3 (2021): 6–7, <https://doi.org/10.5812/jhealthscope.114868>.

<sup>175</sup> "Annual Audit Report for the Year Ended 30 June 2022" (Kigali, Rwanda, 2023), p. 53-57, [https://www.oag.gov.rw/fileadmin/REPORTS/Annual\\_Audit\\_Report\\_2022.pdf](https://www.oag.gov.rw/fileadmin/REPORTS/Annual_Audit_Report_2022.pdf).

<sup>176</sup> A damage of tissue or organ resulting from a medical procedure, pharmacotherapy, or other medical act that has not adequately served its purpose.

The findings show that the field of Obstetrics/Gynecology leads the complaint volumes in both RMDC and NCNM. Although no publication exists for the number of medical malpractice cases by specialty jurisdictions like Hungary and France, the Canadian Medical Protective Association (CMPA) data indicate that obstetrics has been a leading source of medical-legal complaints and lawsuits between 2015 and 2024, compared to other specialties.<sup>177</sup> Additionally, maternity care (mostly obstetrics) accounts for a larger share of medical malpractice claims, at 13 percent in the United Kingdom.<sup>178</sup> Furthermore, 59 percent of medico-legal cases in South Africa from 2009 to 2019 were obstetric in nature.<sup>179</sup>

While competent organs could not document many cases due to a lack of information and evidence, a few instances with sufficient evidence have been successful in the Rwandan courts and have held convicted medical providers liable.<sup>180</sup> Consequently, courts have held the Ministry of Health (MINISANTE) and different health providers accountable for medical malpractice and negligence. Among others, we can mention King Faisal Hospital, University Teaching Hospital of Kigali (CHUK), University Teaching Hospital of Butare (CHUB), Rwanda Military Hospital, Byumba District Hospital, Muhima Hospital, Kibagaba Hospital, and La Croix du Sud Hospital.

Various healthcare providers justify their unresponsiveness due to the Rwandan healthcare system's vulnerability, presenting some gaps that can contribute to the existing issues of negligence and malpractice. One of the argued causes is that the training for medical professionals is not in proportion to this rapidly growing sector, where the complexity of the medical sector's settings has left doctors in an unprecedented dilemma. Another point is that there is a shortage of top-down planning in the healthcare system, where hospitals estimate the number of patients that should be treated daily, leading to treatment in terms of a number rather than an individual patient's case. This affects the quality of care that a caregiver owes a patient. In addition, medical professionals claim that their own rights are not respected, despite also having a duty to respect the patient's rights.

Behind the medical training, some issues may potentially affect healthcare services in Rwanda. For example, hospital structures could not be implemented due to various factors. There is a high demand for medical personnel, particularly in public hospitals. Medical practitioners are still few. For example, in 2018, Rwanda had 1,648 medical doctors, resulting in a doctor-to-population ratio of one doctor per 7,465 people.<sup>181</sup> In 2019, there were 1,492 medical doctors, or one doctor per 8,294, and 0,134 doctors per 1,000 population.<sup>182</sup> Although these figures were estimated to reach

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<sup>177</sup> "Medico-Legal Risk: What Obstetricians Need to Know," *Canadian Medical Protective Association* (Ottawa, June 2025), <https://www.cmpa-acpm.ca/en/research-policy/know-your-risk/what-obstetricians-need-to-know>.

<sup>178</sup> Javed Ahmed, "NHS Payouts for Medical Negligence Claims Hit New Annual High of £2.8," *Independent*, July 2024, <https://www.independent.co.uk/news/health/nhs-negligence-maternity-care-legal-costs-b2587544.html>.

<sup>179</sup> B Taylor and S Cleary, "A Retrospective , Observational Study of Medicolegal Cases against Obstetricians and Gynaecologists in South Africa ' s Private Sector," *South African Medical Journal* 111, no. 7 (2021): 661–67.

<sup>180</sup> *Nyirabatesi Laurence v. King Faisal Hospital*, RCAA 00073/2018/CA (2019).

<sup>181</sup> Ministry of Health of Rwanda, "Health Labour Market Analysis Report" (Kigali, Rwanda, 2019), p. 15.

<sup>182</sup> *Ibid.*, p. ii.

one doctor per 7,000 population in 2024, they are still below the health standards set by the Fourth Sector Health Strategic Plan (HSSP IV).<sup>183</sup> Nurses work many hours due to backlogs, which can also contribute to medical malpractice. This is generally combined with the shortage of medical reagents and other equipment in various health centers in Rwanda. These issues are associated with medical bureaucracy and the prolonged procurement process for medical equipment, which bothers medical personnel. The shortage of salaries for medical practitioners is also on the list.

Besides, there is a fight between healthcare organisations and medical insurers. Doctors' deeds go with the will of the insurers and pharmacists. On various occasions, doctors require approval from insurers to prescribe medicine to patients. Such approval undermines the doctors' role. In other words, a doctor will transfer a patient to the second care not because it is an appropriate option, but by considering the power of money to ensure that the insurer will cover the bill for the medical services undergone. Thus, medical clinics will choose to do less by accepting selected cases to reduce the risk of closing their doors.

However, despite the health system's vulnerability and other medical concerns, health providers whose actions or inaction violate medical ethical principles and health services consumer safety standards can be liable for medical malpractice or negligence in Rwanda.

#### 4.2.1. Do medical malpractices keep accelerating?

The statistical data of medical malpractice complaints collected in both RMDC and NCNM do not indicate an increase in malpractice case volume in Rwanda. However, other sources of information, such as interviews, case law, and online repositories, also underscore that this increase has been notable over the last decade. Such a rise has been associated with an increase in public awareness of medical malpractices and patients' rights.<sup>184</sup>

Medical malpractice is a growing problem worldwide.<sup>185</sup> Mary-Elizabeth Tumelty indicates that there has been an increase in the volume of medical litigation following the birth injury case of *Dunne v National Maternity Hospital* (1989), which established standards of care in medical negligence claims.<sup>186</sup> This has been attributed to factors such as increased awareness of patients'

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<sup>183</sup> National Academies of Sciences, Engineering, and Medicine *Evaluation of PEPFAR's Contribution (2012-2017) to Rwanda's Human Resources for Health Program (2020)* (Washington, DC: National Academies Press (US), 2020), <https://doi.org/10.17226/25687>.

<sup>184</sup> Ivan R. Mugisha, "Rwanda Calls for Tougher Penalties as Medical Negligence Cases Rise," *Rwanda Today*, April 2018, <https://rwandatoday.africa/rwanda/news/rwanda-calls-for-tougher-penalties-as-medical-negligence-cases-rise-2464822>.

<sup>185</sup> Bianca Hanganu et al., "Reasons for and Facilitating Factors of Medical Malpractice Complaints. What Can Be Done to Prevent Them?," *Medicina (Lithuania)* 56, no. 6 (2020): 1–16, <https://doi.org/10.3390/medicina56060259>.

<sup>186</sup> Mary-elizabeth Tumelty, "Exploring the Emotional Burdens and Impact of Medical Negligence Litigation on the Plaintiff and Medical Practitioner: Insights from Ireland," *Legal Studies* 41, no. 4 (2021): 633–56, <https://doi.org/10.1017/lst.2021.20>.

rights, a strong emphasis on preventing the recurrence of medical malpractice incidents, and a decline in public admiration for medical practitioners.<sup>187</sup>

Although there is no empirical research on the rise of medical malpractice incidents or lawsuits in Rwanda, it is not spared. The literature underscores this increase and the need for urgent action in Rwanda.<sup>188</sup> For example, between 2014 and 2016, reported cases of medical malpractice and negligence rose sharply from 12 to 34 annually.<sup>189</sup> This has some merit, as the current cost-benefit standards in the health sector can create an imbalance and expose the industry to negligence and malpractice. Besides, being linked to the morality of medical professionals may heighten the problem. However, the following reasoning can also be factual in the current situation.

The decline of religious beliefs and the evolution of society that brought liberties and rights have opened the eyes of society so that people can dare to hold healthcare providers accountable when they are not satisfied with their services.<sup>190</sup> Previously, anything ‘medical’ was considered trustworthy and respected, ultimately, unattackable. However, health care intervention slowly lost its original public trust due to its growing monetisation character. This demands that the medical sector balance the two rival things, profit maximisation, as any other business, and keeping medical ethics for public trust.

Moreover, the rapid growth of science and technology has led to a remarkable change in health service delivery, which demands further competencies and skills.<sup>191</sup> The advancement of science and technology has made the medical profession a sophisticated field that contributes to the healing of numerous previously incurable diseases. Still, it has also exposed it to many errors. In this light, it is not recommended that medical professionals adopt procedures that involve fewer risks and a higher chance of failure. Instead, they are compelled to adopt practices that involve higher risks, but honestly, they believe they increase the chances of patients’ recovery. In doing so, the health professional’s lack of updated knowledge and skills or any slight mistake results in patient harm. Thus, continuous medical training is inevitable to safeguard patient safety.

Nonetheless, the misunderstanding between the public and the healthcare system is another concern leading to confrontations. It has always been hard to bridge people’s expectations and the reality of what healthcare can deliver. Neither the public nor medical professionals are willing to understand each other. As the public contributes to health care, they also value money, similar to

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<sup>187</sup> Tumelty.

<sup>188</sup> Shreya Sahoo, “Medical Negligence and Liability under the Consumer Protection Act,” *Ipleaders*, January 2019, <https://blog.ipleaders.in/medical-negligence-liability-consumer-protection-act/>.

<sup>189</sup> Mugisha, “Rwanda Calls for Tougher Penalties as Medical Negligence Cases Rise,” 2018.

<sup>190</sup> Kim Price, “The Art of Medicine: Towards a History of Medical Negligence,” *Lancet* 375, no. 9710 (2010): 192–93, [https://doi.org/10.1016/S0140-6736\(10\)60081-5](https://doi.org/10.1016/S0140-6736(10)60081-5).

<sup>191</sup> Mohsen Hojat and Mahdi Karimyar Jahromi, “Assessment The Quality of Continuing Medical Education From Viewpoint of Personnel of Jahrom University of Medical Sciences 2016,” *International Journal of Pharmaceutical and Phytopharmacological Research* 7, no. 3 (2017): 13–14.

people's daily purchases.<sup>192</sup> These higher expectations could be irrational, leading to blame on the health professionals if they have been compromised.

### 4.3. Forms of medical malpractice in Rwanda

The findings further show that forms of malpractice include diagnostic errors, wrong-site surgeries, and documentation failures, as well as maternal, neonatal injuries, and death in obstetrics and pediatrics, respectively, emerging as high-risk areas. In addition, the assessed case laws have also revealed additional forms such as medication errors, lapse of attention, and defective drug supply.

Frequent forms of malpractice include diagnostic errors, medication errors, wrong-site surgeries, maternal and neonatal injuries and deaths, postoperative care and monitoring, documentation lapses, and breaches of informed consent.

*There was a case at CHUK in which the hospital was sued for carrying out surgery on the wrong kidney. The case was settled out of court. ... The [nurse] did not remove the tourniquet that was tied to a child patient's arm while tracing veins for blood (specimen) collection. So, the young patient and her parents thought it was part of the treatment and left it overnight. The following morning, the child's hand had been paralyzed due to a lack of blood and was amputated.<sup>193</sup>*

As exemplified above, cases include hand amputation following tourniquet oversight that took place at MUNINI Hospital and wrong kidney surgery at CHUK. Additionally, other illustrative case examples entail anaesthesia-induced coma that leads to end-of-life disputes and misdiagnoses that necessitate corrective treatment abroad. These and other cases have been attributed to inappropriate treatment plans and deficiencies in communication skills.

Before exploring each form of medical malpractice, the following discussion presents quantitative findings from data collected from RMDC and NCMN. The charts reflect data in tables. Tables and charts are organised into three categories: data by specialty, data by status, and data by frequency.

From data analysis, obstetrics and pediatrics emerge as high-risk areas, as shown in both Figure 1 and Figure 2, presenting RMDC and NCMN complaints by specialty. Internal medicine follows in RMDC, although it does not present any concern in the scope of nurses' and midwives' practice, as shown in Figure 2. Surgery is another area that needs attention under both councils, as they

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<sup>192</sup> Povl Riis, "Medical Negligence," *World Health Forum*, 1996. p. 217.

<sup>193</sup> Spenser Busingo (Rwanda FDA Legal Analyst), Kigali FDA headquarters, interview on medical malpractice in Rwanda with the author, April 28, 2025, transcript., n.d.

present relatively high malpractice incidents following internal medicine in RMDC and pediatrics in NCNM.

*Table 2. RMDC cases by specialty (2016–2022)*

Specialty	Count	Share (%)
Obstetrics/Gynecology	60	59.4
Internal medicine	12	11.9
Surgery	11	10.9
Pediatrics	8	7.9
Anesthesiology	4	4.0
Ethical	4	4.0
Ear, Nose, & Throat	1	1.0
Ophthalmology	1	1.0

*Table 3. NCNM complaints by specialty and year (2021–2024)*

Specialty	2021	2022	2023	2024	Total
Obstetrics/Gynecology	12	11	13	5	41
Surgery	0	1	0	2	3
Internal medicine	0	0	0	0	0
Pediatrics	2	0	2	4	8
Anesthesiology	0	0	0	0	0
Other areas	2	2	1	2	7
TOTAL	16	14	16	13	59

According to the data provided, 27 malpractice complaints from RMC have been pending for over two years as of March 2022. The cited cause of that delay includes investigation disruptions due to COVID-19. Besides, 4 cases were pending over the year 2025 due to investigation disruption resulting from a shortage of human resources (investigation team).

*Table 4. Distribution of RMDC complaints by status*

Status	Count	Percent (%)
Closed cases	63	62.4
Pending cases	21	20.8
Pending in PCC	11	10.9
Ongoing investigation	6	5.9

The analysis of data from both RMDC and NCNM on the number of received medical malpractice complaints from March 2016 to March 2022 reveals that RMDC received approximately 17.5 cases per year, and NCNM received approximately 18 cases per year.

The following discussion dives into various forms of medical malpractice in Rwanda and presents each category through relevant case summaries that are relevant to the form under discussion. These summaries are mainly drawn from specific judgements rendered by Rwandan courts and were selected to exemplify the malpractice forms under this discussion.

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#### 4.3.1. Medication error

According to WHO, medication error refers to failures in the treatment process, which reduces the probability of timely and effective treatment outcomes, thereby increasing the risk of patient harm resulting from the medicines and prescription contravening the generally accepted practice.<sup>194</sup> The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) defines it as “any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer”.<sup>195</sup> Medication errors constitute one of the most common forms of medical malpractice and are associated with a variety of adverse consequences, including physical injury, psychological distress, and economic burden for the affected patient or family.

A medication error occurs when a patient or health care seeker receives incorrect medication, inappropriate dosage, or an unsuitable administration route. The literature reveals that medication errors can also involve nurses providing medications without a physician’s order, improper documentation, and improper administration technique, wrong time, or wrong dosage.<sup>196</sup> A medication error could also result from drug administration without considering the known interactions or patient-specific allergies, resulting in harm.<sup>197</sup>

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<sup>194</sup> Abdul Mondul and Mei Kong, *Medication Error: Technical Series on Safer Primary Care, Patient Safety: A Case-Based Innovative Playbook for Safer Care: Second Edititon* (World Health Organization, 2023), [https://doi.org/10.1007/978-3-031-35933-0\\_11](https://doi.org/10.1007/978-3-031-35933-0_11).

<sup>195</sup> Pritama Paul, Nikhil Era, and Uttam K Paul, “Need for Implementation of Safe Medication Practice to Avoid Medication Errors – A Journey through Case Series,” *Journal of Family Medicine and Primary Care* 6, no. 2 (2017): 1464–67, [https://doi.org/10.4103/jfmpe.jfmpe\\_2016\\_22](https://doi.org/10.4103/jfmpe.jfmpe_2016_22).

<sup>196</sup> Aimable Nkurunziza et al., “Factors Contributing to Medication Administration Errors and Barriers to Self-Reporting among Nurses: A Review of Literature,” *Rwanda Journal of Medicine and Health Sciences* 2, no. 3 (2019): 295–301, <https://doi.org/10.4314/rjmhs.v2i3.14>.

<sup>197</sup> Rayhan A. Tariq et al., *Medication Dispensing Errors and Prevention, StatPearls* (Treasure Island (FL): StatPearls Publishing LLC, 2025), <https://www.ncbi.nlm.nih.gov/books/NBK519065/>.

Medication errors are categorised into three types: improper dosage, incorrect prescription, or improper administration.<sup>198</sup> Improper dosage refers to administering a medication in unauthorized doses, either too much or too little, which can affect the medication’s effectiveness and safety for the patient. Improper prescription can also include recommending unintended medication or the wrong medication, which can lead to patient harm and potential treatment failure. Improper drug administration encompasses a range of errors, including administering medication prematurely or belatedly, administering the drug to the wrong patient, or using the wrong route of administration, such as intravenous (IV) delivery instead of intramuscular (IM) routes. One example is dispensing instruction errors, in which a pharmacist incorrectly labels a medication as an IV medication even though the prescription clearly states IM administration. Once this is dispensed, the nursing staff may administer the medication incorrectly and potentially endanger the patient’s safety. This error may come from a physician’s erroneous prescription. Nonetheless, as the final checkpoint in the medication process, pharmacists have a professional and ethical responsibility to complete the necessary checks thorough verification and detect such discrepancies before dispensing. The obligation of physicians and pharmacists to care is also extended to clarify prescriptions that are vague or represent potential risks. This may include instances where the prescribed route is contrary to what would usually be expected or not indicated. The failure to recommend or clarify in these situations may constitute professional negligence or medical malpractice.

Additionally, misreading handwritten prescriptions, communication breakdowns between healthcare providers, and similar drug names known as look-alike sound-alike drugs (LASA) could lead to medication errors. Various factors, such as inadequate training, fatigue, distraction, interruptions during medication administration, poor communication, and LASA, could lead to medication errors.

Unlike other forms of medical malpractice, medication errors can occur at various stages of the medication management process, including transcription, dispensing, administration, monitoring, and documentation.<sup>199</sup> Thus, responsibility may extend beyond the prescribing physician to include the pharmacist who dispenses the improper dosage or the nurses who administer the incorrect dose to the patient,<sup>200</sup> even the systemic error that fails to implement adequate safety protocols.

In Rwanda, despite concerted efforts by the Government—particularly through the Rwanda Food and Drugs Authority (Rwanda FDA)—to mitigate medication errors via initiatives such as the national pharmacovigilance system, professional training programs and structured reporting mechanisms for adverse drug reactions (ADRs), and adverse events following immunisation

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<sup>198</sup> “Pharmaceutical Errors & Legal Implications,” Justia, accessed August 22, 2025, <https://www.justia.com/injury/medical-malpractice/common-types-of-medical-malpractice/medication-errors/>.

<sup>199</sup> Nasr Alrabadi et al., “Medication Errors: A Focus on Nursing Practice,” *Journal of Pharmaceutical Health Services Research* 12, no. 1 (2021): 78–86, <https://doi.org/10.1093/jphsr/rmaa025>.

<sup>200</sup> “Pharmaceutical Errors & Legal Implications.”

(AEFI), studies indicate that medication errors are common particularly in the highly pressured areas including neonatal and pediatric units.<sup>201</sup>

The case of *Kamatenesi Jovia v. King Faisal Hospital* exemplifies a critical instance of medication error within the Rwandan healthcare system and illustrates how the judiciary addressed the issue to ensure justice for the affected patient.

#### *4.3.1.1. Kamatenesi Jovia v. King Faisal Hospital*

Ms. Kamatenesi Jovia, an expectant woman, sought medical care at King Faisal Hospital (KFH) in Kigali. During the course of her treatment, she was allegedly administered an excessive dose of Cytotec, resulting in a ruptured uterus, the loss of her fetus, and permanent physical injuries, including the removal of one fallopian tube and one ovary. In response to these events, Ms. Kamatenesi initiated legal proceedings seeking compensation for the harm suffered.

The Intermediate Court of Gasabo found King Faisal Hospital liable for negligence and ordered SONARWA, the Hospital's insurer, to pay RWF 50 million in damages.<sup>202</sup> Against this decision, both KFH and SONARWA appealed to the High Court, which upheld the lower Court's ruling on April 21, 2017. In their appeal, the Hospital argued that liability should lie with the attending physician or that the incident constituted an unforeseeable accident. Still, the Court found KFH negligent for administering a third dose of Cytotec, which caused the uterine rupture as corroborated by the established medical teams' reports of May 20, 2015, and October 25, 2015. The High Court ruled in favour of Ms. Kamatenesi by ordering SONARWA to pay RWF 20 million as per the insurance contract limit, and KFH to pay the remaining sum of RWF 30 million. KFH was also ordered to pay RWF 600,000 to Ms. Kamatenesi Jovia for being forced into prolonged litigation. Dr. Muganda John was also awarded RWF 1,200,000 for being wrongly involved in the litigation.<sup>203</sup>

Following a further appeal by KFH, the Supreme Court issued a ruling on February 16, 2018, ordering King Faisal Hospital to pay additional compensation to both Ms. Kamatenesi and Dr. Muganda on the basis that the appeal lacked merit, as KFH had exhausted all available remedies.

Subsequently, Ms. Kamatenesi sought enforcement of the Supreme Court's judgment. In response, KFH claimed it was unable to fulfil the payment because its assets had been transferred to Oshen Health Care Rwanda and debts to the Government of Rwanda. However, the Supreme Court ruled that KFH remains legally responsible for the judgment and should execute it within one month, and that Oshen Health Care was not part of the case. In this ruling, the Court awarded Ms. Kamatenesi RWF 800,000 for legal costs and follow-up.<sup>204</sup>

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<sup>201</sup> Noella Nyirambarushimana, "Identifying Medication Errors in the Neonatal Intensive Care" (University of Rwanda, 2022), [https://dr.ur.ac.rw/bitstream/handle/123456789/1901/Nyirambarushimana Noella.pdf?sequence=1](https://dr.ur.ac.rw/bitstream/handle/123456789/1901/Nyirambarushimana%20Noella.pdf?sequence=1).

<sup>202</sup> "Kamatenesi Jovia v. King Faisal Hospital, RC 0107/15/TGI/GSBO," 2015.

<sup>203</sup> *King Faisal Hospital v. Kamatenesi Jovia*, RCA 00056/2016/HC/KIG - RCA 00057/2016/HC/KIG (2017).

<sup>204</sup> *Kamatenesi Jovia v. King Faisal Hospital*, RC00003/2018/SC (2018).

#### ***4.3.1.2. Prosecutor v. Dr. MUGEMANSHURO Alfred and Another***

On May 3, 2024, the Intermediate Court of Nyarugenge presided over the appellate-level criminal case against two medical doctors, Dr. Ntahonkirye Gasapard and Dr. Mugemanshuro Alfred; this case emanated from a previous criminal case ruled on December 9, 2022, by the Primary Court of Kicukiro.<sup>205</sup> During the December 2022 ruling, two medical doctors from BAHO International Hospital (BIH) -- Dr. Mugemanshuro Alfred and Dr. Ntahonkirye Alfred -- were charged with involuntary manslaughter in connection with Article 111 of the Law No. 8/2018 of August 30, 2018, that determines offenses and penalties in general. This case arose as a result of the death of its 54-year-old female patient, Kamanzi Ngwinondebe Chantal, who was admitted to BAHO International Hospital (BIH) on November 9, 2021, for the removal of an intrauterine device (IUD) from her body after the hospital's management issued an apology in response to public complaints about poor facility/customer care.

The autopsy report concerning the patient's death indicated a cause of death resulting from hypoxia after laryngospasm, due to anaesthesia. Although the physicians had proceeded normally, upon consultation, to attempt the removal, they chose hysteroscopy as an alternate method of removal based on the circumstances surrounding not only the surgery, but also additional issues involving oxygen shortages during the procedure and not having any of the medications that should have been available (e.g., adrenaline). However, despite testimonies concerning these issues, the appellate Court did not thoroughly investigate what caused the hypoxia or whether the clinical protocols were adequately followed. In the end, the Court ruled in favour of the accused by reaffirming the previous judgment made by the Primary Court of Kicukiro.<sup>206</sup> Despite the request for compensation related to Chantal's death, the plaintiffs could not receive any compensation, as this could only be based on the conviction of the accused. This is due to the fact that Rwanda uses a fault system to gain compensation for harm.

#### ***4.3.1.3. Juvenal Habyarimana v. Kibagabaga Hospital***

In 2017, Mr. Juvenal Habyarimana's wife was admitted to Kibagabaga Hospital to deliver a child. During the cesarean section, it was medically mismanaged when Ms. Elise Mukarukundo of the hospital staff inappropriately administered a fatal medication to the patient. Due to that error, the patient experienced a severe and irreversible brain injury that resulted in a coma of roughly one and a half years. After the incident, Mr. Habyarimana brought a civil action against Kibagabaga Hospital. The case was first filed at the Primary Court of Kibagabaga, where it did not go the way of the plaintiff, which led to an appeal in the Intermediate Court of Gasabo. The court's decision in July 2019 overturned the prior decision and positively ruled on the case brought by Mr. Habyarimana. At this point, the case was implicated as a criminal matter. Ms. Mukarukundo was found guilty of involuntary manslaughter based on the findings of the Rwanda Medical and Dental Council (RMDC) investigation report. The RMDC concluded the brain damage was caused by the alleged metabolic error, which caused a lack of oxygenation during the medical procedure. In its

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<sup>205</sup> Prosecutor v. Dr. MUGEMANSHURO Alfred and Another, RPA 00023/2023/TGI/NYGE (2024).

<sup>206</sup> Prosecutor v. Dr. MUGEMANSHURO Alfred and Another, RPA 00023/2023/TGI/NYGE.

final judgment, the court ordered Ms. Mukarukundo to pay damages of RWF 500,000. Subsequently, Gasabo District, which oversees the administration of Kibagabaga Hospital, was held liable for institutional negligence and ordered to pay RWF 20 million in compensation. The ruling emphasised the district's failure to exercise due diligence, which contributed significantly to the fatal outcome.<sup>207</sup>

The discussed cases of Kamatenesi Jovia's suffered injuries at King Faisal Hospital, death of Kamanzi Ngwinondebe Chantal at BAHO International Hospital, and the death of the spouse of Juvenal Habyarimana at Kibagabaga hospital underscore the potential harm and irreversible consequences associated with medication errors in clinical practice. These errors resulted in significant harm to the patient, including loss of life, illustrating how serious these errors impact healthcare delivery.

In addition, each case resulted in litigation and financial compensation, while also inflicting reputational damage on the respective healthcare institutions. For instance, the case involving Ms. Ngwinondebe prompted the temporary closure of BAHO International Hospital during the investigation phase, reflecting the broader institutional impact of clinical negligence.

#### 4.3.2. Neonatal injury or death during childbirth

Neonatal injury and death during childbirth remain a pressing global issue in maternal and child health, with profound implications for families and healthcare systems. While complications such as birth asphyxia, trauma, infections,<sup>208</sup> and congenital anomalies can happen naturally,<sup>209</sup> many cases are preventable and often result from clinical errors, delayed interventions, and inadequate care—key indicators of medical malpractice and professional negligence. Research shows that timely access to skilled birth attendants and emergency obstetric care could prevent many of these deaths.<sup>210</sup> In 2022, an estimated 2.3 million newborns died globally, with nearly half of under-five deaths occurring in the neonatal period.<sup>211</sup> Sub-Saharan Africa faces particularly high rates, averaging 27 deaths per 1,000 live births.<sup>212</sup> In Rwanda, birth asphyxia and delivery-related injuries are the most common causes of neonatal mortality.<sup>213</sup> These outcomes reflect systemic gaps in clinical standards, accountability, and CPD, which must be addressed to reduce preventable harm and avoid legal and ethical consequences.

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<sup>207</sup> Francis Byaruhanga, "Kibagabaga Hospital Fined Rwf 20m over Negligence," *Rwanda Today*, August 2019, <https://rwandatoday.africa/rwanda/news/kibagabaga-hospital-fined-rwf-20m-over-negligence-2471660>.

<sup>208</sup> Robert L. Goldenberg, Jennifer F. Culhane, and Derek C. Johnson, "Maternal Infection and Adverse Fetal and Neonatal Outcomes," *Clinics in Perinatology* 32, no. 3 (2005): 523–59, <https://doi.org/10.1016/j.clp.2005.04.006>.

<sup>209</sup> Renato Oliveira de Lima, "Studies Unveiling the Tragedy : Causes and Prevention of Newborn Deaths," *Journal of Neonatal Studies* 6, no. 5 (2023): 140–41, [https://doi.org/10.37532/jns.2023.6\(5\).140-141](https://doi.org/10.37532/jns.2023.6(5).140-141).

<sup>210</sup> Joy E. Lawn et al., "3.6 Million Neonatal Deaths-What Is Progressing and What Is Not?," *Seminars in Perinatology* 34, no. 6 (2010): 375, <https://doi.org/10.1053/j.semperi.2010.09.011>.

<sup>211</sup> WHO, "Newborn Mortality," March 2024, <https://www.who.int/news-room/fact-sheets/detail/newborn-mortality>.

<sup>212</sup> WHO.

<sup>213</sup> Arlette Nzeyimana and Amanuel Kidane Andegirogish, "Prevalence and Factors Associated with Neonatal Mortality at Masaka District Hospital , Rwanda : A Cross-Sectional Study," *Rwanda Public Health Bulletin* 5, no. 3 (2024): 44–54.

Failing to provide adequate neonatal care constitutes medical negligence and can lead to lawsuits against healthcare providers. The following cases show how Rwandan courts have handled such incidents and the role of judicial remedies in addressing medical liability.

#### *4.3.2.1. Mbareba vs. King Faisal Hospital Rwanda Ltd*

This is a wrongful birth case where Mbareba Geoffrey filed on behalf of his child, Muhinda Mbareba Allan, who was born with a disability caused by medical negligence by King Faisal Hospital's medical staff. In this case, MBABAZI Anet, the mother of Muhinda Mbareba Allan, visited the hospital on January 8, 2015, for prenatal diagnostics and counseling under Dr. Manzi, who recommended she return after four days on January 12, 2015, for a C-section. However, before that date, she experienced signs that labor was imminent and returned directly to the hospital on January 10, 2015, at 09:20 A.M. Although she completed all preliminary requirements, including payments, and notified the medical staff that she was not in natural labor, they ignored this and told her to wait for natural labor. They realised that this plan was no longer feasible around 15:00, prompting them to call Dr. Muganda Rwibasira John, an obstetrician and gynecologist at King Faisal Hospital, who arrived at 16:45. From that point, Anet was directed to the operating room, from which she emerged around 07:00 the next day (January 11, 2015), and was informed that the baby had been taken to the intensive care unit due to fetal distress. Since then, the child's condition has been traumatic. According to the medical report, the baby suffers from uncontrolled epilepsy, bilateral lesions in grey and white matter (a form of brain damage), lack of proper brain growth (encephalomalacia), thin bones due to lack of sunlight (clinical features of rickets), and signs of upper airway obstruction. This disability requires lifelong care.

The RMDC report from February 14, 2016, with reference No. 030/RMD/2016, indicated that the hospital's negligence caused the child's condition. The Ministry of Health (MINISANTE) then advised the hospital to cooperate with the child's family to resolve the matter outside of Court to protect the hospital's reputation and prevent loss. However, the hospital did not follow this advice, citing a lack of cooperation from SONARWA General Insurance Company Ltd., as stated in their letter dated March 20, 2018, responding to MINISANTE.

Following these incidents, Mbareba Allan's parents filed a lawsuit against King Faisal Hospital Rwanda Ltd. in the Intermediate Court of Gasabo, claiming that negligence resulted in the birth of a child with a preventable disability. The Court ruled in favour of the child, awarding 125 million Rwandan francs in compensation, of which 20 million was to be paid by SONARWA General Insurance Company Ltd. The hospital was also responsible for the Court's and the attorney's fees.

King Faisal Hospital filed an appeal with the High Court contesting the judgment issued by the Intermediate Court of Gasabo. In its ruling of June 18, 2024, the High Court amended the original decision by reducing the awarded compensation amount from RWF 125 million to RWF 70 million. In addition, the Court allocated RWF 3,770,000 for recovery costs as well as advocate and

court fees.<sup>214</sup> Despite the amendment of the decision, SONARWA General Insurance Company Ltd remained obligated to pay RWF 20 million, which is the insured amount that should be covered under its insurance policy.

#### 4.3.2.2. *NSABIMANA Etienne et. al. v. MINISANTE*

On July 11, 2015, Mr. Nsabimana Etienne accompanied his spouse, Mrs. Akayezu Gisele, to Masaka Hospital for childbirth. Mrs. Akayezu, a gravida 2 mother—indicating her second pregnancy—had previously undergone a cesarean section. Despite her repeated requests for medical attention, she remained unattended throughout the day.

On the following day, a physician informed her that the fetus no longer exhibited cardiac activity. Nevertheless, no medical intervention was provided. On July 13, 2015, the attending physician issued an apology to Mr. Nsabimana, confirming the infant’s death and acknowledging a critical error during labour. The mishandling of the delivery resulted in severe cranial trauma, with the infant’s brain protruding from the skull. This traumatic event led to significant psychological distress and severe depression in the mother.

Upon request by the MINISANTE, on February 20, 2017, the RMDC concluded that the incident was the result of professional negligence by Dr. Ndikumwenayo Guide and Mr. Nimpaye Donald. Following an extended period without resolution, and having lost confidence in MINISANTE’s assurances to address the matter, Mr. Nsabimana and Mrs. Akayezu filed a petition with the Nyarugenge Intermediate Court on February 18, 2022, seeking legal redress and compensation. Although a letter dated November 3, 2015, had indicated that their case had been referred to RMDC and NCNM, no agreement had been reached between the claimants and MINISANTE by February 22, 2027.

After the judicial process, Nyarugenge Intermediate Court ruled in favour of the claimants, awarding them RWF 10 million in moral damages, RWF 600,000 to cover burial expenses, and an additional RWF 620,000 for court fees and other recoverable costs. The compensation awarded by the Nyarugenge Intermediate Court was granted following the appreciation of the Court and in alignment with the precedent. Specifically, the Court referenced the precedent set in *Kabayijuka v. The Government of Rwanda*, wherein the Supreme Court of Rwanda, on December 19, 2014, held that in cases where claimants are unable to provide precise evidence of the financial expenditures incurred due to the harm suffered, yet it is evident that such harm necessitated remedial expenses, compensation should be awarded “*ex aequo et bono*”—that is, in equity and good conscience—with an amount deemed appropriate by the Court.<sup>215</sup>

#### 4.3.3. Maternal injury or fatality

Maternal injury or death is a major global public health issue with serious consequences. Maternal injury refers to physical or psychological harm a woman experiences during pregnancy, labour, or

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<sup>214</sup> King Faisal Hospital Ltd Rwanda v. Mbareba Geoffrey et. al., RCA 00094/2023/HC/KIG- CMB RCA 00108/2023/HC/KIG (2024).

<sup>215</sup> Kabayijuka v. The Government of Rwanda, RADA 0054/12/CS (2014).

the postpartum period, resulting from obstetric complications arising from labour, delivery, inadequate care, pre-existing conditions of the expectant mother, or medical interventions. While maternal psychological injuries include postpartum depression or anxiety, birth trauma/PTSD, maternal physical injuries encompass perineal tears, uterine or cervical injuries, pelvic floor damage, obstetric fistula, haemorrhage, postpartum infections, and nerve injuries.

Besides, maternal death is also another health threat to mothers. WHO defines maternal death as “the death of a woman during pregnancy or within six weeks of its termination due to complications directly or indirectly related to pregnancy.” In 2023 alone, over 260,000 women died from preventable causes associated with pregnancy and childbirth.<sup>216</sup> About 70% of these deaths occurred in Sub-Saharan Africa, where Rwanda is located.<sup>217</sup> Thus, both maternal injuries and deaths constitute a significant concern in clinical practice and public health due to their effects on maternal morbidity and mortality.

Despite the Government’s efforts in setting a convenient environment for expectant mothers, preventing the causes of maternal injuries or deaths, Rwanda still faces constraints that enable the prevalence of the problem. For example, the maternal mortality ratio was estimated at 229 deaths per 100,000 live births. These figures remain a health concern, while most of those deaths are linked to preventable causes such as lack of timely access to skilled obstetric care, insufficient emergency response systems, and gaps in clinical practice.

The leading causes of maternal injuries and deaths in Rwanda include postpartum hemorrhage (PPH),<sup>218,219</sup> often linked to uterine atony, tears, or post-cesarean complications, and sepsis,<sup>220</sup> resulting from infections post-delivery or post-cesarean. In addition, obstetric fistula is another prevalent maternal injury in Rwanda resulting from prolonged labour, leading to incontinence and social stigma.<sup>221</sup> Hypertensive disorder resulting from undiagnosed or untreated conditions is another cause.<sup>222</sup> Additionally, pelvic floor damage, uterine or cervical injuries,<sup>223</sup> In complicated deliveries or interventions like C-sections, they also contribute to maternal injuries.<sup>224</sup>

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<sup>216</sup> WHO, “Maternal Mortality,” April 2025, <https://www.who.int/news-room/fact-sheets/detail/maternal-mortality>.

<sup>217</sup> WHO.

<sup>218</sup> Eugene Ngoga, “Maternal Health in Rwanda,” *International Federation of Gynecology and Obstetrics*, December 2019, <https://www.who.int/news/maternal-health-rwanda>.

<sup>219</sup> Felix Sayinzoga et al., “Maternal Death Audit in Rwanda 2009-2013: A Nationwide Facility-Based Retrospective Cohort Study,” *BMJ Open* 6, no. 1 (2016): 3, <https://doi.org/10.1136/bmjopen-2015-009734>.

<sup>220</sup> Stephen Rulisa et al., “Causes of Maternal Mortality in Rwanda, 2017-2019,” *Obstetrics and Gynecology* 138, no. 4 (October 1, 2021): 552–56, <https://doi.org/10.1097/AOG.0000000000004534>.

<sup>221</sup> UNFPA, “Maternal Health,” accessed August 20, 2025, <https://rwanda.unfpa.org/en/topics/maternal-health-22>.

<sup>222</sup> Rulisa et al., “Causes of Maternal Mortality in Rwanda, 2017-2019.”

<sup>223</sup> Sayinzoga et al., “Maternal Death Audit in Rwanda 2009-2013: A Nationwide Facility-Based Retrospective Cohort Study.”

<sup>224</sup> Sayinzoga et al., p.3.

Psychological injuries such as postpartum depression, trauma, and birth trauma have also been reported in Rwanda.<sup>225,226</sup>

High parity or lack of skilled birth attendants,<sup>227,228</sup> and substandard care,<sup>229</sup> have been the main factors contributing to those injuries and deaths. To tackle this challenge, the WHO ascertains that timely interventions of skilled birth attendants in well-equipped settings could prevent most maternal injuries and deaths.<sup>230</sup> However, proper prenatal care can play a significant role in preventing maternal injuries or deaths. The following snippet explains the matter.

*Missing supplies, lack of staff, poor patient-provider interaction and suboptimal treatment, as described in the women's narratives, were identified as main barriers to an optimal care encounter. Repeated care-seeking occurred because women had either been misdiagnosed, received incomplete care, discharged too early, or received inappropriate treatment altogether. These were identified among women both in the early and late stages of pregnancy, and appeared to have contributed to some of the near-miss events. [...] Most women with a near-miss in late pregnancy had attended one antenatal check-up, but only a few had attended more than once. Several reported that healthcare providers had not been engaged in dealing with their symptoms or health concerns. Retrospectively, they believed their problems could have been avoided had the providers paid more attention and informed them of potential complications. This was especially apparent among women with hypertensive disorder. Their early signs were missed in consultations, misdiagnosed or not taken seriously, even though women had repeatedly sought advice at the health center. One woman explained: "When I went to the health center for the antenatal check-up, they always told me I had no problem. They said I should not work so hard and gave me pain killers whenever I complained of pain".<sup>231</sup>*

Maternal injury cases that have been recorded, such as uterine rupture, vaginal tears, and excessive bleeding, resulted from a lack of skilled birth attendants and substandard care, which are classified as medical negligence. The aforementioned case of *Kamatenesi Jovia v. King Faisal Hospital*

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<sup>225</sup> Aimable Nkurunziza et al., "Integrating Trauma - and Violence - Informed Care in Perinatal Services to Support Adolescent Mothers in Low and Middle - Income Countries: A Call to Action," *Discover Public Health*, 2024, <https://doi.org/10.1186/s12982-024-00313-8>.

<sup>226</sup> Jessica Påfs et al., "Beyond the Numbers of Maternal Near-Miss in Rwanda - a Qualitative Study on Women's Perspectives on Access and Experiences of Care in Early and Late Stage of Pregnancy," *BMC Pregnancy and Childbirth* 16, no. 1 (2016): 6, <https://doi.org/10.1186/s12884-016-1051-4>.

<sup>227</sup> Påfs et al., p. 8.

<sup>228</sup> UNFPA, "UNFPA ESARO | A Transformative Journey to Reach Zero Preventable Maternal Deaths in Rwanda," February 2024, <https://esaro.unfpa.org/en/news/transformative-journey-reach-zero-preventable-maternal-deaths-rwanda>.

<sup>229</sup> Sayinzoga et al., "Maternal Death Audit in Rwanda 2009-2013: A Nationwide Facility-Based Retrospective Cohort Study."

<sup>230</sup> "Maternal Health," accessed August 19, 2025, [https://www.who.int/health-topics/maternal-health#tab=tab\\_1](https://www.who.int/health-topics/maternal-health#tab=tab_1).

<sup>231</sup> Påfs et al., p. 6.

exemplifies maternal injury. In this incident, Ms. Kamatenesi suffered a ruptured uterus, the loss of her fetus, and permanent physical injuries, including the removal of one fallopian tube and one ovary during her labour. Besides, the following case summaries of *Nyirabatesi Laurence v. King Faisal Hospital and NIYONSENGA Pierre Celestin v. MNISANTE* underscore the importance of timely and specialised medical intervention in high-risk obstetric cases and how the Rwandan Courts can hold healthcare institutions responsible not only for the actions of their staff but also for systemic failures in assigning qualified personnel and ensuring proper care protocols.

#### ***4.3.3.1. Nyirabatesi Laurence v. King Faisal Hospital***

In November 2003, Nyirabatesi Laurence was admitted to King Faisal Hospital (KFH) for maternity care. Despite her previously documented history of cesarean deliveries, she was not operated on right away upon arrival. Instead, she was put into prolonged labour and then operated on late at night by one of the general practitioners (GPs) at the hospital, Dr. Ndagije Félix—believed to be the only doctor available despite the previous specialist monitoring her pregnancy.

Ms. Nyirabatesi Laurence subsequently sued King Faisal Hospital (KFH) for medical negligence during her childbirth in November 2003. She claimed that the delay in performing a C-section and being operated on by a GP instead of a specialist led to serious complications, including the formation of a vesico-vaginal fistula (VVF) (which, in layman’s terms, means that Ms. Nyirabatesi had uncontrollable urinary leakage). In addition, she had permanent reproductive damage and social dispossession, including the breakdown of her marriage and marital relationship.

The gaps in the standard of medical care led to further legal action from Ms. Nyirabatesi in the Gasabo Intermediate Court, with the court finding KFH liable for negligence. The court was served expert medical opinion confirming that the surgical error and blood loss, which led to the VVF, took place during the delayed cesarean section. Ms. Nyirabatesi was awarded RWF 20 million in damages and RWF 800,000 for her recovery costs on March 8, 2012.<sup>232</sup>

On November 1, 2013, the High Court heard the Hospital’s appeal and subsequently dismissed the case on jurisdictional grounds. In its holding, the Court stated that the case should have been submitted to the administrative chamber because the Hospital was a public hospital as defined by the Rwanda Biomedical Centre (RBC).<sup>233</sup>

Ms. Nyirabatesi filed an appeal with the Supreme Court against the High Court ruling. During the period of judicial reforms, the case was moved to the Court of Appeal, which made the final determination of the appeal on July 19, 2019.<sup>234</sup> The court found KFH had not exercised due diligence in delaying the C-section, despite Nyirabatesi’s previous surgical deliveries and known high-risk condition. The Court found surgery was performed by a general practitioner who was not accredited and was not Nyirabatesi’s qualified specialist, who was monitoring the pregnancy, which was a breach of professional standards. Expert evidence corroborated that the bladder injury

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<sup>232</sup> *Nyirabatesi Laurence v. King Faisal Hospital*, RC 0290/09/TGI/GSBO (2012).

<sup>233</sup> *Nyirabatesi Laurence v. King Faisal Hospital*, RCA 0187/12/HC/KIG (2013).

<sup>234</sup> *Nyirabatesi Laurence v. King Faisal Hospital*, RCAA 00073/2018/CA.

(which caused the fistula) was probably the result of surgical error and lack of experience. The Court found KFH to be vicariously and corporately liable for the conduct of its staff and for failing to provide appropriate medical personnel and timely medical intervention. The Court found in favour of Ms. Nyirabatesi Laurence and overturned the High Court's finding, reinstating the hospital's liability. The Court awarded RWF 28 million of compensation to Nyirabatesi for physical pain, emotional suffering, and permanent injury. In addition to the court fees arising from the appeal, which KFH was directed to pay directly to Nyirabatesi, the Court awarded Nyirabatesi RWF 2 million for costs and attorneys' fees.

#### *4.3.3.2. Ms. NIYIMUBONA Nadia's incident at Muhima Hospital*

On September 21, 2016, Ms. NIYIMUBONA Nadia, an expectant mother for her first pregnancy, was referred to Muhima Hospital because of High blood pressure and a big baby (Fetal macrosomia). Medical intervention to prevent the risk to the mother and baby should have been undertaken when the medical staff showed signs of fetal distress (e.g., abnormal heart rate) after observing for one day. After the medical staff delayed surgery for three days, the baby was lost. In addition to the loss of the baby, the hospital's medical staff damaged the uterus in performing this process, which resulted in a hysterectomy, or the surgical removal of the woman's womb.

On September 5, 2017, after her indicated sufferings, NIYIMUBONA Nadia requested compensation from the Ministry of Health (MINISANTE). The Ministry of Health (MINISANTE), based on the RMDC's report Ref:161/RMDC/2017, dated August 16, 2017 engaged in negotiations to reach an amicable termination and acknowledged the legal issues raised from the infraction of doctors and medical staff of the institution, who should have sanctioned optimal medical services respectively, which led to the loss of the child and to the inability to have any children. The report specifically outlined that Ms. NIYIMUBONA Nadia would have received attention in a timely and prompt manner, and undertaken a timely caesarean section as well. The initial meeting of the committee in charge of out-of-court settlement determined that Ms. Niyimubona was entitled to reasonable compensation. However, her requested amounts were considered excessive and difficult to justify. A subsequent committee meeting was scheduled to negotiate the appropriate compensation amount.

MINISANTE challenged the total amount claimed for "moral prejudice" and "biological/physiological prejudice." For "moral prejudice," including suffering from mistreatment and suffering for the loss of the first child, MINISANTE contended that there were no intentional elements to the incidents, meaning that there was no active intent by the physicians to harm or mistreat the patient. Nevertheless, on January 25, 2018, recognising that practising medicine comes with risks, MINISANTE made a compensatory payment of RWF 5 million for the loss of the child resulting from negligence. As to "biological/physiological prejudice," which covered the inability to have any children due to the hysterectomy, MINISANTE argued that the hysterectomy was a saving lives, albeit chance that she had a permanent inability to have children, there is no limit to happiness as it is not tied to children, and made a counter-offer of RWF 5

million citing other cases whereby the physician had no consent to a medical procedure, and the claimants were compensated for organ removal.

As to “economic prejudice,” MINISANTE argued that Ms. NIYIMUBONA Nadia was not rendered permanently disabled as to prevent her from working or not being able to earn a living less than prior to negligence. As such, MINISANTE rejected the claim for economic loss. In the end, MINISANTE contended that Ms. NIYIMUBONA Nadia should receive a total amount of RWF 10 million.

#### ***4.3.3.3. NIYONSENGA Pierre Celestin v. MNISANTE***

On October 16, 2015, Ms. NIKUZE Aloysia UMULISA was referred to Rwinkwavu Hospital for child labor. She had a C-section; however, during the operation, she bled heavily and suffered from hypovolemic shock secondary to uterine atony or inadequate closure of the uterine wall since the operation was done in torchlight due to the absence of fuel in the generator, as the power was cut. On top of that, the blood bank of the hospital was out of blood, hence the transfer of the patient to CHUK was done at a very late time, which made her die on the way. In the report by RMDC dated October 14, 2016, it was indicated that this death was preventable.

Following this incident, the spouse of the late Ms. NIKUZE Aloysia UMULISA, Mr. NIYONSENGA Pierre Celestin, approached the Ministry of Health, as Rwinkwavu Hospital is a public health facility without legal personality, seeking compensation. Subsequently, the Minister of Health at the time requested the Ministry of Justice (MINIJUST) to open the transaction process instead of court proceedings due to the serious grounds of medical liability conviction. This was done in accordance with the Prime Minister’s instructions No. 005/03 of 16/12/2015 governing the organization and functioning of the committee in charge of out-of-court settlement. In November 2016, the committee, made up of the Permanent Secretary of MINIJUST, the Permanent Secretary of the Ministry of Infrastructure (MININFRA), the Permanent Secretary of MINECOFIN, the Permanent Secretary of the Ministry of Internal Security, and a State Attorney appointed by the MINIJUST, granted RWF 35 million for economic prejudice. This amount was calculated based on the remaining years in the workforce before retirement of the deceased Aloysia, which would be 35 years by multiplying by 12 (the 12 months of one year), presuming that RWF 75,000 was the minimum monthly income of every person engaged in the workforce, as decided by the Supreme Court of Rwanda in its precedents.

In addition to these damages, professional and administrative sanctions were imposed on employees suspected of professional malpractice and negligence following the RMDC and NCNM joint investigation.

#### ***4.3.4. Surgical error***

Surgery is one of the most essential procedures for saving lives and one of the most error-prone areas in healthcare, despite its requirement for highly trained healthcare professionals and robust

infrastructure. The surgery error could result from human factors or systemic deficiencies.<sup>235</sup> Yet, the literature indicates that preventable human performance deficiencies contribute to approximately half of all incidents that occur.<sup>236</sup>

Surgical error, also known as perioperative error, is defined as unintended or preventable harm that occurs during the perioperative period but is not recognised as an inherent risk or an acceptable risk of the procedure. It should be emphasised that surgical error is not to be confused with surgical risks or other common risks of adverse outcomes contemplated in the informed consent process. Surgical errors occur in the perioperative phase and commonly arise from breakdowns in teamwork, communication failures, incomplete preparations, or failures within the healthcare system. The most common types of surgical error are wrong-site surgery, wrong-procedure or wrong-patient surgery, retained surgical instruments (RSIs), anesthesia errors, and complications arising post-operatively. These are all considered medical malpractice as they represent deviations from the standard of care that lead to preventable harm to patients. According to CNN Health, one in three surgical patients have complications after surgery. Many of those surgical complications stem from medical error.<sup>237</sup>

Surgical error constitutes an important global public health problem as it leads to avoidable morbidity, mortality, and economic burden on health systems. There are approximately 310 million major surgeries performed worldwide each year, of which the rates of complication are concerning: 1-4% result in patient death, 15% result in serious postoperative morbidity, and 5-15% result in readmission within 30 days.<sup>238</sup> Of the surgeries performed globally, only 6% are performed in countries considered to be low- and middle-income (LMICs), where errors related to surgical complications have an increased risk due to limited resources.

In Rwanda, despite the Government's strides in expanding surgical access after the 1994 genocide, some challenges persist, including a low number of specialists (particularly in surgery, anesthesiology, and obstetrics)<sup>239</sup> and resource constraints contributing to surgical errors. For example, research shows that between 2009 and 2010, more than 82.5% of major surgeries were performed in district hospitals, with non-specialist physicians carrying out 90% of C-sections and

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<sup>235</sup> Marie Josée Mukagendaneza et al., "Incidence, Root Causes, and Outcomes of Surgical Site Infections in a Tertiary Care Hospital in Rwanda: A Prospective Observational Cohort Study," *Patient Safety in Surgery* 13, no. 1 (2019): 4–11, <https://doi.org/10.1186/s13037-019-0190-8>.

<sup>236</sup> Dipali Pathak, "Study Identifies Human Errors Associated with Surgical Errors," *Baylor College of Medicine* (Houston, July 2019), <https://www.bcm.edu/news/human-errors-adverse-surgical-events>.

<sup>237</sup> Brenda Goodman, "More than 1 in 3 Surgical Patients Has Complications, Study Finds, and Many Are the Result of Medical Errors," *CNN Health*, November 2024, <https://edition.cnn.com/2024/11/15/health/surgical-complications-medical-errors>.

<sup>238</sup> Geoffrey P. Dobson, "Trauma of Major Surgery: A Global Problem That Is Not Going Away," *International Journal of Surgery* 81 (2020): 47–52, <https://doi.org/doi.org/10.1016/j.ijssu.2020.07.017>.

<sup>239</sup> Barnabas Tobi Alayande et al., "A Review of Global Surgery in Rwanda: Global Solutions from Rural Locations.," *Africa Health* 46, no. 2 (2024): 26–31, <https://search.ebscohost.com/login.aspx?direct=true&db=a9h&AN=178018633&site=ehost-live>.

80% of abdominal surgeries.<sup>240</sup> This is one of the factors contributing to preventable errors, such as hospital-acquired infections (HAIs), including surgical site infections (SSIs), that can occur following an invasive procedure. The research found that 10.9% of SSI incidents accounted for an estimated 76.8% of all HAIs in the surgical department in the CHUK.<sup>241</sup> Some of the identified causes include the surgeon's lack of skills and experience, longer surgery durations, prolonged hospital stays, blood transfusions, and emergency surgeries.<sup>242</sup>

Furthermore, the available data suggest that obstetrics/gynecology is the most prevalent medical error in Rwanda, followed by surgical errors. The literature and analysed Rwandan case laws show that and even many surgical errors are associated with maternal or neonatal errors occurring in the obstetric field, e.g., in C-section procedures. The following case, between *NDIZEYE Alphonse v. Kibungo Medical Centre (KMC)*, exemplifies the phenomenon of surgical error and how Rwandan Courts approach it. Besides, the discussion entails other examples of other types of surgical error.

The present case is about a medical malpractice claim, in which a child, dubbed I.A. for confidentiality, suffered permanent injury when Kibungo Medical Centre (KMC) staff committed an error during a circumcision procedure. As a result of their error, part of the child's genital organ was severed. The child's parent, NDIZEYE Alphonse, took legal action seeking monetary compensation with judicial remedies.

NDIZEYE Alphonse initially filed a lawsuit against KMC in the Intermediate Court of Ngoma, claiming damages of RWF 45 million. On July 31, 2018, the Court found KMC partly liable for the negligence of its employees, causing the child's injury. NDIZEYE, on behalf of his child, was awarded RWF 35 million as damages, RWF 500,000 for legal representation, and RWF 50,000 for court guarantee fees.<sup>243</sup> Prime Insurance Company Plc was also included in the proceedings initiated as the insurance company obtained by KMC.

KMC appealed the decision in the High Court, Chamber of Rwamagana, claiming that no clear legal basis for the damages awarded existed to NDIZEYE Alphonse, nor were the prior payments for the child's treatment considered with respect to the appeal. On July 30, 2019, the High Court ruling admitted the appeal in part by substituting the damages awarded to NDIZEYE with RWF 8,246,000. The legal and court guarantee fee was maintained. The Court also declared that the RWF 2,993,000 paid for the treatment of child I.A and the RWF 30,000 for an expert should not be deducted from the allocated compensation.<sup>244</sup>

Mr. NDIZEYE Alphonse, then appealed against the ruling to the Court of Appeal, submitting that the High Court had not applied the law correctly and had mischaracterised the injury as an accident rather than gross negligence. Essentially, the Court of Appeal determined that compensation should take KMC's admission of liability into account, which had to be assessed through the

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<sup>240</sup> Mukagendaneza et al., "Incidence, Root Causes, and Outcomes of Surgical Site Infections in a Tertiary Care Hospital in Rwanda: A Prospective Observational Cohort Study."

<sup>241</sup> Mukagendaneza et al.

<sup>242</sup> Mukagendaneza et al.

<sup>243</sup> *Ndizeye Alphonse v. Kibungo Medical Center*, RC 00222/2017/TGI/NGOMA (2018).

<sup>244</sup> *Kibungo Medical Center v. NDIZEYE Alphonse*, RCA00065/2018/HC/RWG (2019).

exercise of judicial discretion (*ex aequo et bono*), having regard to the gravity of the injury and lifetime effect.

The Court of Appeal set aside the decision of the High Court and awarded the RWF 35 million in damages, noting that Prime Insurance had to pay RWF 2 million—Prime Insurance was involved as it had an insurance agreement No. KMCN° 413/00021583- SG with KMC dated June 24, 2016. Additionally, the Court ruled that prior payments and fees of the experts were no longer to be deducted.<sup>245</sup> KMC was also ordered to pay NDIZEYE Alphonse, on behalf of his child I.A, RWF 800,000 and RWF 300,000 for costs of litigation, and to repay the fees for the court guarantee. Ultimately, the Court of Appeal reiterated that this case considered the significance of judicial discretion in cases of medical malpractice, as no state law guidance was available.

#### *4.3.4.1. Unnecessary ablation or resection procedures*

Ablation can be defined as the destruction or removal of abnormal tissue using heat, cold, lasers, radiofrequency (RF), and is most often completed with minimally invasive techniques and no large incisions. Ablation procedures are routinely utilised by oncologists, radiologists, and cardiologists when treating cancers or tumours of the breast, liver,<sup>246</sup> thyroid, lung, and other areas of the body.<sup>247</sup> Resection, on the other hand, is typically defined as the surgical removal or excision of part of an organ or tissue, such as in a liver resection for tumours. Resection is most often used to treat diseases or damage that cannot be treated medically or with less invasive methods.<sup>248</sup>

An ablation or resection is called “unnecessary” when it is done inappropriately without valid medical justification, e.g., no evidence of benefit; it is inaccurate based on information such as misdiagnosis; or because it is conducted for other less valid reasons, e.g., profit, or financial factors, to name a few. In other words, it is overtreatment, where the risks outweigh any perceived benefit, and potentially violates other ethical principles, including “do no harm,” for which there may be health problems stemming from a lack of justification.<sup>249</sup> Such overtreatment may be considered medical malpractice in several states, including Rwanda, if an injury occurs, including different health-related factors such as complications, prolonged recovery, or deterioration of health over time, if someone receives unnecessary treatment.<sup>250</sup> The summary below contains an

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<sup>245</sup> NDIZEYE Alphonse v. Kibungo Medical Center, RCAA 00008/2020/CA (2021).

<sup>246</sup> Kurinchi Gurusamy et al., “Liver Resection Surgery versus Thermal Ablation for Colorectal LiVer MetAstases (LAVA): Study Protocol for a Randomised Controlled Trial,” *Trials* 19, no. 1 (2018): 1–13, <https://doi.org/10.1186/s13063-018-2499-5>.

<sup>247</sup> “Ablation Therapy - Mayo Clinic,” accessed August 20, 2025, <https://www.mayoclinic.org/tests-procedures/ablation-therapy/about/pac-20385072>.

<sup>248</sup> “Overview of Colon Resection,” accessed August 20, 2025, <https://www.uptodate.com/contents/overview-of-colon-resection>.

<sup>249</sup> Craig Skerpac, “All Facility Medical Providers Must Have Malpractice Insurance,” *WORLD*, August 2023, <https://www.worldinsurance.com/blog/all-facility-medical-providers-must-have-malpractice-insurance>.

<sup>250</sup> Wendy Zw W Teo, Lawrence H. Brenner, and B. Sonny Bal, “Medicolegal Sidebar: Unnecessary Medical Care and Physician Liability,” *Clinical Orthopaedics and Related Research* 476, no. 12 (2018): 2322, <https://doi.org/10.1097/CORR.000000000000551>.

example of a case of *Mugabekazi Assumpta v. King Faisal Hospital Rwanda Ltd et. al.*, depicting such a health risk and a legal remedy from the Rwandan Court.

#### 4.3.4.2. *Postoperative care negligence*

Postoperative peritonitis is a serious and potentially life-threatening complication that occurs after abdominal surgery, involving inflammation and infection of the peritoneum—the thin membrane lining the abdominal cavity and covering the abdominal organs.<sup>251,252</sup> According to the recent multicenter prospective observational study of patients who underwent surgery between July 18-31, 2020, 54 (4%) of 1458 patients who undergone surgery in 47 different hospitals in the country, experienced postoperative complications.<sup>253</sup>

The discussed case of Ms. NIYIMUBONA Nadia could also exemplify the post-operative care negligence; during the cesarean section, there was an injury to the uterus, and after suturing, it developed postoperative peritonitis (infection), which resulted in hysterectomy. This is indicative of poor postoperative monitoring and infection control, which speaks to postoperative care negligence.

#### 4.3.4.3. *Anaesthesia error*

Anaesthesia malpractice is a situation when an anesthesiologist or other medical professional administering anaesthesia falls short of the accepted standard of care for anesthesiology and, as a result, harms the patient. This deficient care may take the form of: improper dosage of anaesthesia medication; failure to monitor the patient properly; failure to assess the patient's pre-existing medical conditions properly; failure to use medical equipment (or it was malfunctioning); errors that occurred during intubating and extubating, or negligent positioning of the patient.<sup>254,255,256</sup> All of these shortcomings may have catastrophic consequences for patients, including injury, disability, brain damage, organ failure, paralysis, and death.<sup>257</sup>

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<sup>251</sup> Torsten Herzog and Waldemar Uhl, "Postoperative Peritonitis: Etiology, Diagnosis, and Treatment," in *Abdominal Sepsis: A Multidisciplinary Approach (Hot Topics in Acute Care Surgery and Trauma)*, ed. Massimo Sartelli, Matteo Bassetti, and Ignacio Martin-Loeches, 1st ed. (Gowerbestrasse 11, 6330 Cham, Switzerland: Springer International Publishing AG, 2018), 180, [https://doi.org/https://doi.org/10.1007/978-3-319-59704-1\\_12](https://doi.org/https://doi.org/10.1007/978-3-319-59704-1_12).

<sup>252</sup> "Negligent Post-Operative Care: A Common Cause of Readmission," *Bounds Law Group*, April 2015, <https://boundslawgroup.com/medical-malpractice/negligent-post-operative-care-a-common-cause-of-readmissions/>.

<sup>253</sup> Alayande et al., "A Review of Global Surgery in Rwanda: Global Solutions from Rural Locations."

<sup>254</sup> Prem Jagyasi and Team, "Understanding Anesthesia Errors: Causes, Risks, and Legal Actions," *DrPrem.Com*, March 2025, <https://drprem.com/guide/have-you-developed-complications-resulting-from-anesthesia-errors/>.

<sup>255</sup> "Malpractice Liability for an Anesthesia Error," AllLaw, accessed August 21, 2025, <https://www.alllaw.com/articles/nolo/medical-malpractice/liability-anesthesia-error.html>.

<sup>256</sup> "Anesthesia Malpractice: Errors, Liability, and Patient Rights Anesthesia Malpractice: Errors, Liability, and Patient Rights," Villari Firm, accessed August 21, 2025, <https://www.thevillarifirm.com/2025/04/anesthesia-malpractice-errors-liability-and-patient-rights/>.

<sup>257</sup> "Anesthesia Malpractice," Standards of Care, accessed August 21, 2025, <https://www.standardsofcare.org/medical-malpractice/types/anesthesia-malpractice/>.

Research indicates that such malpractice has occurred and resulted in medical liabilities for some Rwandan health facilities. The following is a summary of an instance of anesthesia malpractice that resulted in medical liability for the University Teaching Hospital of Butare (CHUB).

On July 26, 2011, the spouse of Mr. Munyeshyaka Jean Damascene, Ms. Tuyisenge Marie Christine, had a tonsillectomy at the CHUB for chronic tonsillitis. After this surgery, the patient experienced a major complication arising from premature extubation while still under anesthesia. This caused cerebral anoxia and led to post-anoxic encephalopathy (severe and irreversible brain damage).

After this incident, Ms. Tuyisenge was hospitalized, including a prolonged stay in the Intensive Care Unit (ICU) and continued through specialized departments, including neurosurgery and neurology, at several facilities: CHUB, King Faisal Hospital (KFH), University Teaching Hospital of Kigali (CHUK), CARAES Ndera Neuropsychiatric Hospital, and Rwanda Military Hospital (RMH).

After looking at the events that had occurred regarding the medical negligence and malpractice, the Maison de l'Accès à la Justice (MAJ) determined that CHUB should pay Mr. Munyeshyaka RWF 48 million for the harm suffered by his spouse. The case was settled through the transaction procedure.

#### *4.3.4.4. Incorrect count and retained surgical instruments (RSIs)*

A retained surgical item (RSI) refers to a physical object, such as a gauze, that is inadvertently left inside a patient's body following a surgical procedure.<sup>258</sup> In contrast, an incorrect count denotes a discrepancy or miscalculation in the surgical counting process. This results in a false tally of items within the surgical process, even when no item remains inside the patient.

Although incorrect surgical counts are the leading cause of RSIs,<sup>259,260</sup> other factors can contribute to them, including inaccurate surgical counts, communication breakdowns, complex surgical environments, inadequate procedure standardisation, human error and cognitive overload, technological constraints, failure to use radiopaque materials, and insufficient training and clinical experience.<sup>261</sup>

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<sup>258</sup> King Faisal Hospital Ltd Rwanda v. Mbareba Geoffrey et. al., RCA 00094/2023/HC/KIG- CMB RCA 00108/2023/HC/KIG.

<sup>259</sup> Elizabeth Morell Edel, "Surgical Count Practice Variability and the Potential for Retained Surgical Items," *AORN Journal* 95, no. 2 (2012): 228–38, <https://doi.org/10.1016/j.aorn.2011.02.014>.

<sup>260</sup> Romano P Retained et al., "Retained Surgical Items: Causation and Prevention," *PSNet*, February 2025, <https://psnet.ahrq.gov/primer/retained-surgical-items-causation-and-prevention>.

<sup>261</sup> Retained et al.

RSIs can lead to prolonged hospital stays and other life-threatening outcomes,<sup>262</sup> thereby constituting significant patient harm and grounds for malpractice lawsuits.<sup>263</sup> Even though RSIs are preventable—through measures such as minimising reliance on manual counting and implementing adjunct technologies like barcoding systems—the problem remains prevalent in Rwanda.<sup>264</sup> The following summary of the *Mukakiberwa Eugenie v. Republic of Rwanda* case presents a relevant case and the judicial redress to the associated malpractice claim.

Mukakiberwa Eugenie underwent a medical procedure of fallopian tubes at NETCARE KING-FAYCAL HOSPITAL (a health facility owned by the Government of Rwanda) by Dr. Manzi SUBIRA. They left an instrument (gauze) inside her, leading to other surgical operations to cut her intestines after being damaged by such gauze. Dr. Manzi Subira admitted an error to his employer in a letter dated August 12, 2000, confirming that there was a retained instrument resulting from the nurses’ miscalculating all the surgical instruments before closing the wound. He also apologised to the patient through the letter.

#### 4.3.4.4.1. Mukakiberwa Eugenie v Republic of Rwanda (MINISANTE)

Following the incident, Ms. Mukakiberwa lodged a case in the High Court against the Republic of Rwanda (MINISANTE) seeking compensation resulting from the harm suffered. The Court admitted the case and ruled on it on merit in some issues. The Court held that the Republic of Rwanda (MINISANTE) should vicariously be liable for its employee, Dr. Manzi, who caused harm to the patient in the course of his work. Based on the Supreme Court’s precedent *Nyetera v. CORAR* establishing RWF 2,500 as a reasonable daily wage,<sup>265</sup> and the Presidential Order No. 31/01 of August 25, 2003 on Compensation for Personal Injuries Caused by Motor Vehicles, the High Court, in its ruling of May 16, 2014, ordered the Government of Rwanda (MINISANTE) to pay RWF 3 million for moral damages, RWF 264,000 for non-pecuniary damages, as well as RWF One million consolidating medical expenses and advocate fees.

#### 4.3.5. Lapse in standard medical protocol (lapse of attention)

Standard Medical Protocols refer to evidence-based guidelines and standard operating procedures (SOPs) that healthcare organisations implement to ensure consistent, safe, and effective patient care. These guidelines include diagnostic methods, treatment plans, surgical procedures, medication administration, and infection control measures.<sup>266</sup> ;<sup>267</sup> A lapse in standard medical

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<sup>262</sup> Zach Swartz, “Understanding Retained Surgical Items (RSI): Importance, Prevention, and AORN Guidelines,” August 2024, <https://www.aorn.org/article/understanding-retained-surgical-items-%28rsi%29--importance--prevention--and-aorn-guidelines>.

<sup>263</sup> Edel, “Surgical Count Practice Variability and the Potential for Retained Surgical Items.”

<sup>264</sup> Gilbert Rutayisire Karonkano, “Prevention of Retained Surgical Items : Practice of Surgical Counts In Rwandan Operating Rooms By” (Rwanda, 2017), <https://www.sigmarepository.org/cgi/viewcontent.cgi?article=2859&context=incrc>.

<sup>265</sup> *Nyetera v. CORAR*, RCAA 0202/07/CS (2009).

<sup>266</sup> “Standard Operating Procedure (SOP): A Guide,” *Matrix One*, May 2024, <https://matrixone.health/blog/standard-operating-procedure-sop-a-guide>.

<sup>267</sup> For Coordinating and Event Preparedness, *Standard Operating Procedures For Coordinating Public Health Preparedness and Response in the WHO African Region* (Brazzaville, Republic of Congo: World Health Organization

protocol can occur when a healthcare provider fails to establish, implement, or follow proper protocols and procedures, resulting in harm to patients. Such failure constitutes administrative negligence,<sup>268</sup> a ground for a liability lawsuit in medical practice.<sup>269</sup>,<sup>270</sup>

As Sinikiwe explains, the duty of care requires medical practitioners to demonstrate the level of diligence and skill that a reasonably prudent person would show in similar situations.<sup>271</sup> When there is noncompliance, Cooter and Porat note that “a lapse from a legal standard of precaution is usually sufficient to trigger liability for any resulting harm.”<sup>272</sup> The *Nyandwi Safari Révérien et. al. v. MINISANTE* case illustrates a breach of established medical protocols, showing a failure to meet the required standard of care. The following summary explains the case and how the High Court ruled it.

#### ***4.3.5.1. Nyandwi Safari Révérien et. al. v. MINISANTE***

On November 23, 2015, at night, HABAGUSENGA Benitha was admitted to Munini Hospital in Nyamagabe District for malaria treatment. During the clinical procedure of collecting specimens of blood, the nurse involved, Munyeshyaka Theogene, failed to remove the tourniquet or garrot from the child's arm until the following day. This crucial failure resulted in severe vascular compromise to the extent that the unrelated surgical intervention of amputating the child's right arm became necessary. This patient harm was categorized into the permanence of physical disability with the level of impairment assessed to be 60%. This incident was registered in Report No. 055/LD/NCNM dated April 31, 2016, issued by the National Council for Nurses and Midwives.

After the incident, the child's parents, Nyandwi Safari Révérien and Mukarukundo Donatha, instituted proceedings against MINISANTE in the Intermediate Court of Nyamagabe. The Court ruled in favour of the plaintiffs, awarding them RWF 25 million for compensation for the irreversible harm caused to their child, HABAGUSENGA Benitha, due to medical negligence. The High Court later upheld this in an appeal.<sup>273</sup>

#### ***4.3.5.2. Kabayijuka v. Republic of Rwanda (MINISANTE)***

On December 8, 2000, Mr. Kabayijuka Gaspard attended the Nyarubuye Health Centre, a public institution. He was injected into the thigh by Mr. Hakizimana, who seemed like a medical doctor but was an auxiliary health worker at this Health Centre, as will be claimed later. Afterwards, Mr.

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Regional Office for Africa, 2014), <https://medbox.org/document/sop-standard-operating-procedures-for-coordinating-public-health-event-preparedness-and-response-in-the-who-african-region>.

<sup>268</sup> “When Hospital Protocol Fails: How Administrative Negligence Can Lead to Medical Malpractice Claims Blog.”

<sup>269</sup> Zachary R. Paterick and Timothy E. Paterick, “The Standard of Care: Medical Errors/Violations and the Law,” *The Journal of Medical Practice Management*, 2019, <https://www.physicianleaders.org/articles/standard-care-medical-errors-violations-and-law>.

<sup>270</sup> “Medical Malpractice Claims Due To Inadequate Protocols and Procedures,” MedLeague, accessed August 21, 2025, <https://www.medleague.com/inadequate-protocols-and-procedures/>.

<sup>271</sup> Singini, “An Analysis on the Applicability of Medical Negligence and Its Relevance Under Zambian Health Laws.”

<sup>272</sup> Robert Cooter and Ariel Porat, “Lapses of Attention in Medical Malpractice and Road Accidents,” *Theoretical Inquiries in Law* 15, no. 2 (2014): 332, <https://doi.org/10.1515/til-2014-0204>.

<sup>273</sup> MINISANTE v. NYANDWI Safari Révérien, RCA 00034/2018/HC/NYZ (2018).

Kabayijuka felt severe pain and was referred to Kibungo Hospital, and afterwards went to the Rwamagana Hospital and CHUK, where his health condition deteriorated to a permanent disability.

In this context, Kabayijuka had submitted a complaint to the High Council Chamber of Rwamagana for damage sustained against the Ministry of Health (MINISANTE) due to an employee's negligence, which allegedly caused the injury. The High Council dismissed the complaint on the basis that it had no grounds.<sup>274</sup>

Mr. Kabayijuka appealed to the Supreme Court on the grounds that the lower court had not taken proper notice of the evidence that established vicarious liability on the part of the Ministry. He argued that Mr. Hakizimana, though not qualified, was authorised by the health Centre administration, with the knowledge and acquiescence of his supervisor, to conduct medical activities.

The Ministry specified that there was an absence of an employment relationship between itself and Mr. Hakizimana. Following the written medical report of Medical Doctor Gafurama Claude dated December 12, 2000, stating there was “evidence of suspected paralysis” resulting from “an intramuscular injection to the sciatic nerve by Sylvestre,” the Supreme Court determined that he was solely acting as an employee of the Health Centre when he treated Mr. Kabayijuka. Therefore, having established the Ministry’s vicarious liability, it held that “the employer is liable for the faults of his employee in case they were committed within his or her duties and during working hours”.<sup>275</sup> Besides, while Mr. Kabayijuka could not produce receipts for the costs he incurred because of the injury caused, the Court agreed that the injury did cause him to incur costs. The Court also agreed to award compensation applying the principle of “ex aequo et bono” (equity and fairness).

Using the Supreme Court’s precedent of *Nyetera v. CORAR*,<sup>276</sup> where RWF 2,500 was considered a reasonable daily wage, the Court subsequently determined RWF 60,000 fair (SMIG) for compensation. The Court calculated damage on 12 months’ salary, disability level and how many working years were left until retirement at age 65. The Supreme Court awarded Mr. Kabayijuka RWF 2,240,000, for moral damages, financial damages and compensation for as well as damages for medical and transport expenses.

#### ***4.3.5.3. Mutiganda Fidele v. MINISANTE***

On December 5, 2017, Mutiganda Fidele sought treatment for respiratory complications at Muhima Health Centre. He was then referred to Muhima Hospital and saw a doctor. Mutiganda received Tramadol injection in the left arm administered by Nurse Marie Jeanne Mutuyimana.

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<sup>274</sup> Kabayijuka v. Government of Rwanda (MINISANTÉ), RAD 0003/12/HC/RWG (2012).

<sup>275</sup> Kabayijuka v. The Government of Rwanda, RADA 0054/12/CS.

<sup>276</sup> Nyetera v. CORAR, RCAA 0202/07/CS.

Upon receiving the injection, Mutiganda felt excruciating pain and swelling in the left arm that resulted in permanent disability rated 38.4%.

Even though he continued to receive treatment from several providers, including Munini Hospital, CHUK, and Rwanda Military Hospital, his condition did not improve. Mutiganda requested compensation from MINISANTE on June 18, 2019, for the disability caused by the injection, but received no further support from the Ministry.

As a result, Mutiganda submitted a motion to the Intermediate Court of Nyarugenge, where he was requesting compensation for his accidents: physical, economic, and emotional harm. MINISANTE argued that its internal investigation "revealed no causality linking injection [...] and subsequent adverse consequences." Nevertheless, the court found in favour of Mutiganda. The finding was based in both medical documentation and the precedents of *NYIRABATESI Laurence v. King Faisal Hospital* (July 19, 2019) and *MANIRARORA Jean De Dieu v. RWANDA RUDNIKI LTD et. al.* (June 28, 2022), both decided by the court of appeal and the precedent cited in *Republic of Rwanda v. KABAYIJUKA* (December 12, 2014), where the Court concluded that the injury sustained to his left arm, was causally linked to the injection as set out in medical documents produced and the fact that medical professionals treated her for the events without disputing its origins.

Accordingly, the Court ordered MINISANTE to pay Fidele Mutiganda the following compensation: RWF 10 million for pain and suffering; RWF 6,566,400 for economic loss (loss of income), and RWF 1.2 million for medical and travelling expenses connected to treatment.<sup>277</sup>

#### *4.3.5.4. Institutional failure*

*Although injury prevention initiatives are necessary, identifying health system deficiencies and barriers that hinder access to safe, affordable, good quality, and timely trauma care is key to reducing preventable deaths from people who are inevitably injured.*<sup>278</sup>

Institutional failures or systemic negligence in medical practice refer to situations where harm to a patient result not just from the actions of individual healthcare providers, but from broader problems within the healthcare system or facility. This occurs when the policies, procedures, or culture of a healthcare institution or facility are flawed, leading to patient harm and ultimately resulting in medical malpractice lawsuits.<sup>279</sup> The examples of systemic negligence may include inadequate staffing, negligent credentialing, failure to supervise, faulty policies and procedures,

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<sup>277</sup> Mutiganda Fidele v. MINISANTE, 00138/2022/TGI/NYGE (n.d.).

<sup>278</sup> Pascal Nzasabimana et al., "Barriers to Equitable Access to Quality Trauma Care in Rwanda: A Qualitative Study," *BMJ Open* 13, no. 9 (September 28, 2023): 1, <https://doi.org/10.1136/bmjopen-2023-075117>.

<sup>279</sup> Augustine Kumah, "Poor Quality Care in Healthcare Settings: An Overlooked Epidemic," *Frontiers in Public Health* 13, no. 2 (2025), <https://doi.org/10.3389/fpubh.2025.1504172>.

and poor communication.<sup>280,281</sup> this could result in negligent delay in treatment, which refers to a situation where a healthcare provider fails to act promptly in diagnosing or treating a medical condition, resulting in harm to the patient.<sup>282</sup>

While the case of Nadia is a good example of the previous types of medical malpractice and negligence discussed, including maternal injury, it can also be categorised as systemic/institutional failure resulting in the negligent delay in treatment. The case of Ms. NIYIMUBONA Nadia is a clear example of “negligent delay in treatment” since there was a delayed referral for a cesarean despite the documented fetal distress. As stated by the RMDC report of August 16, 2017, “[i]f the procedure had been done correctly, timely, and with diligence, the baby would not have died. The baby was born dead; this represented a failure to act promptly”. In the same vein, there is delay in supplying medical interventions (including C-section) after the maternal reference to Niyimubona Nadia and the inadequate care provided after the reference, could support an institutional failure or systemic negligence of Muhima Hospital, which resulted from inadequate staffing, or deviation from standard maternal-fetal monitoring protocols, or a lack of emergency medicine preparedness or knowledge to cope with obstetrical/neonatal emergencies.

Another notable case of institutional failure in clinical practice in Rwanda is the baby-swapping incident at Muhima Hospital, which sparked media interest and public concern in 2015. On December 14, 2015, Rukundo's wife went to the facility for maternal care and gave birth to a baby boy (according to the formal birth certificate).<sup>283</sup> Following the birth, the newborn baby was, allegedly, swapped for a baby of a different sex after birth; a case never formally decided by any regulatory or judicial authority. Although rare in Rwanda, this situation highlighted the threats to the neonatal and maternity care systems and increased public awareness of maternal healthcare services. Similar cases occurred in other countries, such as South Africa, illustrating that such errors, while uncommon, are not unprecedented and demand systemic safeguards to prevent recurrence.<sup>284</sup>

#### 4.3.6. Defective drug supply

Defective drug supply generally encompasses product liability, medical malpractice, or negligence. The party that is sued and the suit hinge on where the breakdown occurred in the supply line. This can entail the manufacturer, distributors, and quality control labs that are responsible for confirming the potency and safety of the drug. A strict liability standard can be applied in such circumstances. According to this doctrine, the manufacturer is liable if the drug

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<sup>280</sup> George Zangaro, Cindy Manaoat Van, and Sarah Mossburg, “Impact of System Failures on Healthcare Workers,” *PSNet*, March 2023, <https://psnet.ahrq.gov/perspective/impact-system-failures-healthcare-workers>.

<sup>281</sup> Kumah, “Poor Quality Care in Healthcare Settings: An Overlooked Epidemic.”

<sup>282</sup> “Delay in Medical Treatment – When Is It an Actionable Case?,” *HG.Org*, accessed August 26, 2025, <https://www.hg.org/legal-articles/delay-in-medical-treatment-when-is-it-an-actionable-case-52675>.

<sup>283</sup> JMali, “Rwandan Doctors Accused of Negligence amid Cases of Death, Baby Swap,” *JamiiForums*, 2015, <https://www.jamiiforums.com/threads/rwandan-doctors-accused-of-negligence-amid-cases-of-death-baby-swap.805630/>.

<sup>284</sup> “Cape Town Hospital Baby Switch Discovered 14 Years Later,” *JUTA MEDICAL BRIEF*, September 2022, <https://www.medicalbrief.co.za/cape-town-hospital-baby-switch-discovered-14-years-later/>.

was defective and caused injury to a patient, regardless of whether negligence can be proven. Defective drugs are traditionally categorised into three types: manufacturing defects, design defects, and marketing defects.

A manufacturing defect, for instance, could be contamination, the use of incorrect ingredients, or an incorrect calculation that affects a batch. A design defect—more relevant in the case of medical devices—is when the design of the drug inherently renders it unsafe for its proposed use, even if correctly manufactured. A marketing deficiency includes mislabeling the safety or efficacy of the drug, or warning deficiencies with regard to known hazards, e.g., defective instructions, concealed side effects, or unadvertised drug interactions.

When the defective drug product is imported into the nation and administered by a physician who has no knowledge of its defectiveness, various legal avenues of redress can arise. Under Rwandan law, product liability is imposed upon the drug importer, based on the reasoning that the importer introduced a defective product into the market, which subsequently harmed someone. Licensed importers owe a duty to ensure that the products they bring into the country are safe, registered, and of quality. Therefore, if a drug is found to be defective due to manufacturing errors, contamination, or failure to comply with regulatory standards, the importer is held to have breached this duty, even without actual knowledge of the defect. Under such circumstances, strict liability may be imposed if laboratory tests confirm the defective status of the drug. The plaintiff must establish that the importer supplied the specific drug, that it was defective at the time of supply, and that the defect was the immediate cause of damage suffered.

Doctors are also responsible if their conduct falls below the standards expected in their field of care. This may include such slips as administering the drug without verifying the patient's identity, cross-verifying for allergies, verifying the correct dosage, or inspecting the drug's expiration date. However, a physician who administers a defective drug without having justifiable reasons to believe there is a hidden defect—such as one that requires laboratory testing—would most likely not be held accountable.

While patients usually sue medical professionals in such cases, the fault often lies with the pharmaceutical importer, who is ultimately held responsible for distributing the defective product. The following case summary of *Tukakira et al. v. Hôpital La Croix du Sud et al.* illustrates how these principles are applied in Rwandan law.

#### ***4.3.6.1. Tukakira et al. v. Hôpital La Croix du Sud et al.***

Between February 20 and February 24, 2015, different patients, namely Mr. Tukakira Rugigana Deus, Ms. Mutesi Scola, Ms. Bayitake Angelique, and Mr. Rubagumya Clinton Innocent, underwent treatment at Hôpital La Croix du Sud, during which a 2% lidocaine injection was administered. These patients later developed side effects, including pain, necrosis, and other undesirable reactions. As confirmed by the May 25, 2015, medical Reports of Hôpital La Croix du Sud, the patients' injuries traced back directly to the lidocaine injection, a drug supplied by ABACUS Pharma Rwanda Ltd. Following this accident, all the interested patients who were

enlisted sued in the Intermediate Court of Nyarugenge the Hôpital La Croix du Sud for compensation of the expenses incurred by them on treatment, i.e., transport fees, damages for pain endured after the injection of 2% lidocaine, moral damages, procedural fees, and compensation for being subjected to lawsuits.

On 3 June 2016, the Court ruled that the drug caused health problems and further held that Hôpital La Croix du Sud did not suffer any professional error in administering the drug. Instead, the Court held ABACUS Pharma Rwanda Ltd responsible for supplying the lidocaine that caused side effects, and the subsequent recall of the drug by the company likewise fixed the liability of the company for selling an unsafe drug. The Court instructed ABACUS Pharma Rwanda Ltd to pay damages and legal fees to the claimants of RWF 32,818,808, distributed as follows: RWF 21,184,153 to Mr. Tukakira Rugigana Deus; RWF 3,158,106 to Rubagumya Clinton Innocent; RWF 4,251,641 to Mutesi Scola; and RWF 4,224,908 to Bayitake Angelique. The Court also instructed ABACUS Pharma Rwanda Ltd to pay back RWF 4,883,604 to Hôpital La Croix du Sud for the cost of drug tests.<sup>285</sup> In addition, the Court established that ABACUS Pharma Rwanda Ltd is not liable for compensating damages and ordered the company to refund the court fee to the plaintiffs. The plaintiffs appealed to the High Court of Rwanda against the decision of the Intermediate Court of Nyarugenge. However, the Court in its decision of September 29, 2017, upheld the previous court's ruling.<sup>286</sup>

The High Court ruling was founded on the expert analysis that attested to the fact that ABACUS Pharma Rwanda Ltd 2% lidocaine did not meet the standard and was responsible for the side effects. For this purpose, various laboratory reports confirmed the drug deficiency like that of the University of Rwanda which established that the lidocaine 2% (Batch No. CM4032 LINCOLN PHARMACEUTICAL, INDIA) was below standard and the SGS laboratory in Belgium report dated August 19, 2015, that labeled the same drug as defect because it had the possibility of triggering side effects like allergy and necrosis. Specifically, the medicine was 94.5% pure, whereas the requirement is 95.0% to 105.0%. Additionally, the Court invited the Ministry of Health to participate in the hearing to provide authoritative comments on pharmacy standards and liability mechanisms, and it made it clear that in the event of defective imported medicine, legal liability rests with the licensed pharmacy importer.<sup>287</sup>

#### 4.3.7. Breaches and violations of patient confidentiality

The ethical and legal compliance framework of medical practice demands that all healthcare personnel uphold the confidentiality of personal health information (PHI) during their clinical practice. To reinforce this obligation, governments have enacted data protection laws, and healthcare providers have developed and implemented Standard Operating Procedures (SOPs) to

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<sup>285</sup> Tukakira et al. v. Hôpital La Croix du Sud et. al., RC 0828/15/TGI/NYGE (2016).

<sup>286</sup> Tukakira et al. v. Hôpital La Croix du Sud et. al., RCA00321/2016/HC/KIG, RCA00320/2016/HC/KIG, RCA00322/2016/HC/KIG, RCA00336/2016/HC/KIG (2017).

<sup>287</sup> Tukakira et al. v. Hôpital La Croix du Sud et. al., RCA00321/2016/HC/KIG, RCA00320/2016/HC/KIG, RCA00322/2016/HC/KIG, RCA00336/2016/HC/KIG.

ensure the secure handling of PHI across all medical settings. Patient confidentiality implies trust between patients and healthcare providers and the prevention of serious consequences, such as legal penalties and disruptions in effective healthcare delivery.<sup>288</sup>

Even with such measures in place, possible breaches may occur due to, limited digital infrastructure, inadequate training, and a lack of process uniformity.<sup>289</sup> For example, a recent study at the Rwanda Military Hospital highlighted gaps in implementing privacy standards, especially around Current Procedural Terminology (CPT) codes, which are meant to protect patient data.<sup>290</sup> This creates a CPT-related privacy breach risk.<sup>291</sup>

There is a breach of patient confidentiality when there is an intentional or unintentional disclosure of private health information without consent from the patient.<sup>292</sup> Unlike a breach, a violation of patient confidentiality involves the deliberate and unlawful disclosure of identifiable personal health information.<sup>293</sup> This often occurs through false representations or with the intent to exploit that information for financial gain, personal benefit, or malicious harm.<sup>294</sup> This includes any unauthorised sharing of medical records, conversations, or identifying details. Steve Alder argues that there are numerous breaches of patient confidentiality, and it is impossible to calculate the total number of breaches that occur every year.<sup>295</sup>

Prof. Justin Wane, the former Vice-Chairman of RMDC, underscored that incidents of public disclosure and documentation mismanagement exist in Rwandan medical practice, although they often go unreported.<sup>296</sup> He also added that this concern had been consistently highlighted in various assessments of medical ethics in Rwanda. In particular, poor documentation was identified as a recurring issue. In addition, unauthorised sharing of patient files, especially in administrative disputes, was noted as a form of documentation mismanagement. Such actions exemplify a breach of patient confidentiality and may constitute grounds for a malpractice lawsuit.

#### 4.3.8. Diagnostic errors

Diagnostic errors encompass both misdiagnosis and failure to diagnose. According to Augustine Kumah, these errors constitute a substantial concern leading to a poor quality of healthcare

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<sup>288</sup> Steve Alder, “Breaches of Patient Confidentiality,” *The HIPAA Journal*, August 2024, <https://www.hipaajournal.com/breaches-of-patient-confidentiality/>.

<sup>289</sup> Nemeyimana Patrick et al., “Examining Practicality of Current Procedural Terminology Standard Codes for Privacy of Patients at Rwanda Military Referral and Teaching Hospital and Legacy Clinics,” *MedRxiv*, 2024, 8, <https://www.medrxiv.org/content/10.1101/2024.12.03.24316880v1>.

<sup>290</sup> Patrick et al.

<sup>291</sup> Patrick et al, p. 2.

<sup>292</sup> Alder, “Breaches of Patient Confidentiality.”

<sup>293</sup> Alder.

<sup>294</sup> Alder.

<sup>295</sup> Alder.

<sup>296</sup> Justin WANE, “Medical Litigation” (Kigali, Rwanda: RMDC, 2014), [https://www.rmhc.rw/IMG/pdf/Medical\\_Litigation\\_Presentation\\_KMA.pdf](https://www.rmhc.rw/IMG/pdf/Medical_Litigation_Presentation_KMA.pdf).

setting.<sup>297</sup> Misdiagnosis generally occurs when a healthcare provider incorrectly identifies a patient's condition (either providing the incorrect diagnosis, or missing the patient's actual condition), whereas failure to diagnose occurs when a provider fails to detect a patient's medical condition within an appropriate time frame and/or in an appropriate way (i.e. they either miss the diagnosis completely, or a diagnosis only occurs at a later time). In either case, these failures may lead to serious consequences, including inappropriate or delayed treatment, disease progression, avoidable complications, or irreversible harm to the patient (including death).<sup>298</sup> Choctaw asserts that several diseases such as breast cancer and acute appendicitis are associated with diagnostic errors.<sup>299</sup>

According to Johns Hopkins, misdiagnosis is one of the most common forms of medical malpractice.<sup>300</sup> The common causes of diagnostic failures include failure to obtain a sufficient patient history or examination, misinterpretation of laboratory or imaging test results, failure to order appropriate diagnostic tests, ineffective communication between medical personnel, or systemic issues such as understaffing or lack of necessary equipment.

In the Rwandan context, diagnostic errors, including both misdiagnosis and failure to diagnose, exist despite their limited reporting and legal documentation. A discussed case of *Mugabekazi Assumpta v. King Faisal Hospital Rwanda Ltd et al.* illustrates the misdiagnosis of breast cancer by King Faisal Hospital and a subsequent unnecessary mastectomy by Rwanda Military Hospital, demonstrating the profound impact of diagnostic negligence.

#### 4.3.9. Failure to consider patient history

Patient history is considered the foundation for accurate diagnosis and effective treatment. Indeed, the patient history is part of the medical record,<sup>301</sup> which can support clinical research, drug requisitioning decisions, and health system management.<sup>302</sup> Specifically, the patient history plays a pivotal role in guiding diagnosis and treatment, personalizing care, assessing genetic and teratogenic risks, and enhancing communication between patient and healthcare provider.

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<sup>297</sup> Kumah, "Poor Quality Care in Healthcare Settings: An Overlooked Epidemic."

<sup>298</sup> "Misdiagnosis, Failure to Diagnose & Related Legal Claims," *JUSTICIA*, August 2025, <https://www.justia.com/injury/medical-malpractice/common-types-of-medical-malpractice/misdiagnosis-and-failure-to-diagnose/>.

<sup>299</sup> William T. Choctaw, *Avoiding Medical Malpractice: A Physician's Guide to the Law, Avoiding Medical Malpractice* (Los Angeles: Springer, 2008), p. 7, <https://doi.org/10.1007/978-0-387-73064-6>.

<sup>300</sup> Kim Polyniak, "Johns Hopkins Medicine Researchers Identify Health Conditions Likely to Be Misdiagnosed," *Johns Hopkins Medicine*, November 2019, <https://www.hopkinsmedicine.org/news/newsroom/news-releases/2019/07/johns-hopkins-medicine-researchers-identify-health-conditions-likely-to-be-misdiagnosed>.

<sup>301</sup> World Health Organization, *Management of Patient Information: Trends and Challenges in Member States*, ed. Najeeb Al Shorbaji and Joan Dzenowagis, *Global Observatory for EHealth Series*, vol. 6 (Geneva, Switzerland: World Health Organization, 2012), [https://iris.who.int/bitstream/handle/10665/76794/9789241504645\\_eng.pdf?sequence=1](https://iris.who.int/bitstream/handle/10665/76794/9789241504645_eng.pdf?sequence=1).

<sup>302</sup> Charité Niyitegeka et al., "Synchronization of Patient Data Among Health Facilities Through Electronic Medical Records System: A Case Study of Kabgayi District Hospital," *Rwanda Journal of Medicine and Health Sciences* 2, no. 3 (2019): 281, <https://doi.org/https://dx.doi.org/10.4314/rjmhs.v2i3.12>.

A failure to consider patient history constitutes a form of medical negligence that occurs when a medical provider fails to obtain, review/or take appropriate steps to address historical information (such as reactions to medications, chronic conditions, recent treatments, and prior surgeries) in diagnosis or treatment.<sup>303</sup> If historical knowledge is overlooked, the provider may miss a diagnosis, misdiagnose, make a medication error, or incorrectly determine the appropriate medical intervention. These preventable errors can result in substantial compensation for medical costs and emotional suffering. For example, in a case cited by the online resource Standards of Care, the patient received a settlement of \$450,000 following a physician's failure to diagnose a stroke. Despite the patient disclosing a history of heart valve replacement and an indication that he was not compliant with taking the prescribed blood thinners, and even though the patient had facial palsy as well as a CT scan showing there was no stroke, there was no consideration of the patient's significant history, which delayed treatment and caused the patient significant harm.<sup>304</sup>

In Rwanda, fragmented health records across different health facilities make it difficult for providers to access complete patient information. Besides, although many health facilities have introduced electronic medical records systems, such as OpenClinic EMR, which are particularly useful in resource-constrained environments, some facilities still rely on paper-based records, leaving them vulnerable to loss, damage, or incomplete documentation.<sup>305</sup> Due to those discrepancies, healthcare practitioners can fail to retrieve or even fail to check the patient's history, leading to the issue of test duplication, inconsistent care, or misdiagnoses.

This study's findings indicate that medication errors exist in Rwanda, although there are no data quantifying medical incidents in Rwanda due to limited reporting, associated with various factors such as fearing the associated consequences, the reporter's burden, and a lack of interest in reporting all, resulting from a lack of relevant policies in place to report errors.

#### 4.3.10. Offensive or dehumanising language

Effective communication is essential to establishing a patient-centered approach in the doctor–patient relationship, especially during clinical decision-making.<sup>306</sup> It reflects the principle of “respect for others,” a core principle of professionalism in medical practice.<sup>307</sup> As Kanter et al. emphasize, physicians are expected to uphold high standards of behaviour in their interactions with

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<sup>303</sup> “Failure to Record or Disregarding Patient History,” Standards of Care, accessed August 21, 2025, <https://www.standardsofcare.org/medical-malpractice/types/failure-record-disregarding-patient-history/>.

<sup>304</sup> Standards Of Care, “Failure To Record Or Disregarding Patient History,” Standards of Care, accessed September 2, 2025, <https://www.standardsofcare.org/medical-malpractice/types/failure-record-disregarding-patient-history/>.

<sup>305</sup> Peace Uwambaye et al., “Health Care Consumer’s Perception of the Electronic Medical Record (EMR) System within a Referral Hospital in Kigali, Rwanda,” *Rwanda Journal of Medicine and Health Sciences* 4, no. 1 (2017): 48, <https://doi.org/10.4314/rj.v4i1.7f>.

<sup>306</sup> Shanjeeban Ponnuthurai, Suganthan Navaneethakrishnan, and Rajeshkannan Nadarajah, “Patient Satisfaction toward Doctor Communication in Medical Clinics: A Study from Northern Sri Lanka,” *Academia Medicine* 1, no. 2 (2024): 1–8, <https://doi.org/10.20935/acadmed6200>.

<sup>307</sup> Michael H. Kanter et al., “What Does Professionalism Mean to the Physician?,” *The Permanente Journal* 17, no. 3 (2013): 87–90, <https://doi.org/10.7812/TPP/12-120>.

patients—avoiding offensive or dehumanising language—in a manner that reflects honour, integrity, and ethical responsibility.<sup>308</sup>

Professional standards prohibit the use of dehumanizing expressions, including racial or sexual remarks, aggressive or forceful tones, hateful or malicious allegations, and threatening or offensive gestures or behaviours. Martha Roberts states that “such language confers negative traits such as passivity or petulance onto the patient.”<sup>309</sup> Such transgressions can escalate into harassment or violence, and result not only in the termination of their therapeutic relationship but also turn into a civil or criminal case under the applicable legal and regulatory frameworks.

The use of offensive or dehumanising language is a serious barrier to the delivery of satisfactory healthcare. According to Zimmerman and Stern, “use of offensive language triggers emotions, shapes biases, and elicits myriad behavioral responses—and even legal proscription.”<sup>310</sup> Within clinical practice, such language functions as a double-edged sword, posing risks to both physician and patient. Caitríona and Zoë highlight that outdated medical language that casts doubt, belittles, or implicitly blames patients poses a significant threat to the integrity of the therapeutic relationship.<sup>311</sup>

Although the present study did not identify formally documented cases of offensive or dehumanising language as a form of medical malpractice in Rwanda, such instances are known to occur. For example, a 2018 study conducted on Rwandan women living with HIV found that participants highlighted that women with HIV experience all forms of stigma resulting from various factors, including dehumanising language.<sup>312</sup> The study showed that language questioning a patient’s morality, motherhood, or personal worth can lead to feelings of shame and exclusion.<sup>313</sup>

With the current Rwanda health law, the new healthcare law prohibits and punishes offensive language acts, such as using disparaging, traumatizing language, written remarks, or gestures towards a health service user, and insulting or showing contempt towards him or her.<sup>314</sup> Although the law had not yet been tested in practice, it has laid the groundwork for future punishment of such acts.

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<sup>308</sup> Kanter et al.

<sup>309</sup> Martha Roberts, “The Power of Language in Clinical Practice,” THIS.Institute, May 2022, <https://blog.thisinstitute.cam.ac.uk/the-power-of-language-in-the-clinical-setting>.

<sup>310</sup> Daniel J. Zimmerman and Theodore A. Stern, “Offensive Language in the General Hospital,” *Psychosomatics* 51, no. 5 (2010): 377–85, [https://doi.org/10.1016/s0033-3182\(10\)70719-2](https://doi.org/10.1016/s0033-3182(10)70719-2).

<sup>311</sup> Caitríona Cox and Zoë Fritz, “Presenting Complaint: Use of Language That Disempowers Patients,” *The BMJ*, 2022, 1–4, <https://doi.org/10.1136/bmj-2021-066720>.

<sup>312</sup> D Mukamana et al., “Dehumanizing Language, Motherhood in the Context of HIV, and Overcoming HIV Stigma - the Voices of Rwandan Women with HIV: A Focus Group Study,” *International Journal of Nursing Studies* 135 (2022): 3–8, <https://doi.org/10.1016/j.ijnurstu.2022.104339>.

<sup>313</sup> Mukamana et al.

<sup>314</sup> “Article 84 (1) of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services,” 2025.

#### 4.3.11. Medical record malpractice/ Charting errors

Accurate documentation is critical not only for continuity of care but also for legal accountability, ethical practice, and patient safety. This differs from medical record malpractice, also known as charting errors, which is an underreported concern in Rwanda.

Charting errors are any mistakes, inaccuracies, or omissions in documenting patient clinical information in a patient’s medical record. Charting errors also include errors of omission, such as mislabeling, illegible handwriting, and vague documentation of patients’ information, and can occur in either paper or electronic health records (EHRs). Such errors can lead to potential harm to the patient. An error in charting could result in a wrong diagnosis, a medication overdose, or a delay in treatment, which could cause serious injury or death.<sup>315</sup> Indeed, poor documentation practices, incomplete, inconsistent, and/or inaccurate, have been consistently identified as contributing factors in several malpractice cases reviewed by the Rwanda Medical and Dental Council (RMDC).<sup>316</sup>

#### 4.4. Factors contributing to medical malpractice

The Auditor General’s 2022 report highlights gaps in health service delivery at public hospitals, mainly due to staffing shortages. This leads to long patient wait times, queues, slow responses to complaints, stockouts or shortages of essential medicines, and poor customer service.<sup>317</sup> The report also mentions a shortage of ambulances, unpaid medical bills, and ongoing delays in billing insurance companies, which disrupt hospital operations.<sup>318</sup> The similar report for the year ended in June 2024 documented the non-functioning of health posts, the Rwanda FDA’s delays in service delivery for assessing application dossiers for medicine registration, along with delays in inspecting new premises applied for licensing.<sup>319</sup> All those factors in public health and clinical medicine can result in patient adverse events, as enshrined in the following snippet.

*Medication errors occur when weak medication systems and/or human factors such as fatigue, poor environmental conditions or staff shortages affect prescribing, transcribing, dispensing, administration and monitoring practices, which can then result in severe harm, disability and even death.*<sup>320</sup>

The literature has documented various factors influencing medical malpractice, including deficiencies in medical training, shortages of medical professionals, medical corruption, poor or

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<sup>315</sup> Rafferty Domnick and Cunningham Yaffa, “The Role of Electronic Health Records in Medical Malpractice Lawsuits,” RDCY, accessed September 5, 2025, <https://www.pbglaw.com/blog/the-role-of-electronic-health-records-in-medical-malpractice-lawsuits/>.

<sup>316</sup> WANE, “Medical Litigation.”

<sup>317</sup> “Annual Audit Report for the Year Ended 30 June 2022” (Kigali, Rwanda, 2023), p. 53-57, [https://www.oag.gov.rw/fileadmin/REPORTS/Annual\\_Audit\\_Report\\_2022.pdf](https://www.oag.gov.rw/fileadmin/REPORTS/Annual_Audit_Report_2022.pdf).

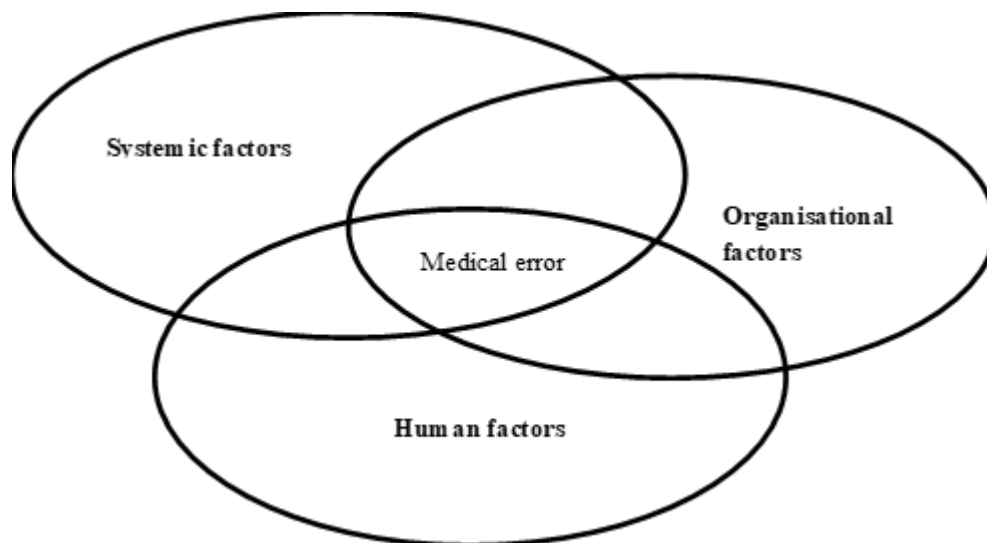
<sup>318</sup> “Annual Audit Report for the Year Ended 30 June 2022.”

<sup>319</sup> Office of the Auditor General, “Annual Report of the Auditor General of State Finances - Year Ended 30 June 2024,” 2025, 26–28, [https://www.oag.gov.rw/fileadmin/REPORTS/ANNUAL\\_AUDIT\\_REPORT\\_2024.pdf](https://www.oag.gov.rw/fileadmin/REPORTS/ANNUAL_AUDIT_REPORT_2024.pdf).

<sup>320</sup> Gloria Shalviri, “Medication Without Harm,” *Journal of Pharmaceutical Care*, 2023, <https://doi.org/10.18502/jpc.v11i1.12632>.

top-down healthcare planning, regulatory gaps,<sup>321</sup> productivity-driven compensation models,<sup>322</sup> and a lack of public awareness of medical rights and accountability mechanisms.<sup>323</sup>

The results of this study have highlighted several factors that contribute to medical malpractice incidents, categorising them into three main arrays: systemic factors, organizational factors, and human factors. Systemic factors include a shortage of medical personnel, outdated infrastructure, regulatory gaps, productivity-driven compensation models, inadequate public awareness of medical rights, and deficiencies in accountability mechanisms and healthcare planning. Besides, organisational factors include shortages and malfunctions of essential medical reagents and equipment, the influence of lack of insurance, and productivity-driven compensation models, which are shared by both categories above. Then, human factors include deficiency in medical training and medical corruption, and broken communication between the patient and provider. The following figure illustrates the three arrays.



*Figure 1. Classification of factors contributing to medical malpractices*

The following section discusses various factors contributing to medical malpractice in Rwanda. Although those factors could be into three categories, the discussion does not classify them. It explores its factors separately.

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<sup>321</sup> Cortez, “A Medical Malpractice Model for Developing Countries ?”

<sup>322</sup> “Medical Malpractice: An Ongoing Crisis.”

<sup>323</sup> Ishimwe, “Assessment of the Status of Medical Negligence and Malpractice in Musanze District, Rwanda.”

#### 4.4.1. Shortage of medical personnel

According to the WHO, the world is expected to experience a shortfall of more than 11 million healthcare workers worldwide by 2030,<sup>324</sup> primarily in low- and middle-income countries.<sup>325</sup> This crisis is driven by a constellation of factors, including insufficient training capacity, unequal distribution of healthcare jobs, burnout and mental health strain, workplace violence, and poor retention policies, coupled with an international migration of health workers, which is cited to exacerbate the situation.<sup>326</sup> In Africa, the situation is particularly dire: by 2030, the continent is projected to lack over 6 million surgical care providers, while the current health workforce density of 0.5 surgeons and 0.1 anaesthetists per 100,000 people has already created a significant burden on healthcare delivery and access.<sup>327</sup>

In 2019, Rwanda recorded a total of 1,492 physicians, resulting in a doctor-to-population ratio of one physician per 8,294 individuals.<sup>328</sup> Compared to the previous year, when there were 1,648 medical doctors, the number of doctors per 1,000 population decreased from 0.134 to 0.1206.<sup>329</sup> Despite projections indicating a potential increase to one doctor per 7,000 people by 2024, these figures remain below the targets established in the Fourth Health Sector Strategic Plan (HSSP IV). The current healthcare worker density stands at approximately 1 per 1,000 population.<sup>330</sup> In the surgical domain, the disparity is even more pronounced: while global standards suggest 20 surgical specialists per 100,000 people, Rwanda currently maintains only 3 per 100,000.<sup>331</sup> The following table illustrates the estimate other doctor-to-population ratio and density in three years (2018, 2019, 2024) from the obtained data.

*Table 5. Rwanda’s estimate of doctor-to-population ratio and density (2018, 2019 & 2024)*

Year	Indicator (Doctor-to-population ratio)	Value (Doctors per 1,000)
2018	1 per 7,465	0.134
2019	1 per 8,294	0.1206

<sup>324</sup> WHO, “Health Workforce,” accessed September 8, 2025, [https://www.who.int/health-topics/health-workforce#tab=tab\\_1](https://www.who.int/health-topics/health-workforce#tab=tab_1).

<sup>325</sup> Mathieu Boniol et al., “The Global Health Workforce Stock and Distribution in 2020 and 2030: A Threat to Equity and ‘universal’ Health Coverage?,” *BMJ Global Health* 7, no. 6 (2022): 1–8, <https://doi.org/10.1136/bmjgh-2022-009316>.

<sup>326</sup> WHO, “Health Workforce.”

<sup>327</sup> Edmund Kagire, “A Surgeon Per District Hospital: African Surgeons Set To Meet In Rwanda To Explore Ways Of Advancing Surgical Care,” *Kigali Today*, February 7, 2025, <https://www.ktpress.rw/2025/02/a-surgeon-per-district-hospital-african-surgeons-set-to-meet-in-rwanda-to-explore-ways-of-advancing-surgical-care/>.

<sup>328</sup> “Rwanda Health Sector Performance Report 2017-2019” (Kigali, Rwanda, 2020), p. 17-18, [https://www.moh.gov.rw/fileadmin/user\\_upload/Moh/Publications/Reports/FINAL\\_Annual\\_Report\\_2017-2019\\_02062020.pdf?form=MG0AV3](https://www.moh.gov.rw/fileadmin/user_upload/Moh/Publications/Reports/FINAL_Annual_Report_2017-2019_02062020.pdf?form=MG0AV3).

<sup>329</sup> Ministry of Health of Rwanda, “Health Labour Market Analysis Report” (Kigali, Rwanda, 2019), p. 15.

<sup>330</sup> Kagire, “A Surgeon Per District Hospital: African Surgeons Set To Meet In Rwanda To Explore Ways Of Advancing Surgical Care.”

<sup>331</sup> Kagire.

2024 (estimated)

1 per 7,000

0.143

Despite the notable progress in strengthening its healthcare system, a severe shortage of medical personnel still subsists.<sup>332</sup> Without targeted and strategic intervention, projections estimate that it would take nearly 180 years to achieve the recommended ratio.

The persistent shortage of medical professionals continues to exert significant pressure on Rwanda's healthcare system, contributing directly to the rising rates of medical malpractice and negligence. This workforce deficit compels healthcare facilities to operate beyond safe staffing thresholds, thereby compromising the quality of care, making it possible for medical malpractice to occur, and leaving organisations, practitioners, and patients open to legal and ethical risks. For example, a 2015 study conducted at a Malawian hospital revealed that professional standards in obstetric care could not be maintained due to a lack of skilled medical staff, resulting in shortcuts in the medical care provided.<sup>333</sup>

Indeed, the excessive workload placed upon medical personnel, primarily driven by patient backlogs, significantly exacerbates medical malpractice.<sup>334</sup> As healthcare providers navigate high-demand environments with limited resources, the strain undermines both the precision and attentiveness required for optimal patient care. This creates diminished clinical attention, delayed emergency responses, inadequate supervision and training, and a high level of human error due to provider burnout. Collectively, these factors contribute to systemic vulnerabilities that undermine patient safety and institutional accountability.<sup>335, 336</sup> Thus, this shortage necessitates the need for strategic workforce expansion and policy interventions to bridge this gap.<sup>337</sup> In response, the Government launched the "4x4 Reform" as a strategic initiative to quadruple the national healthcare workforce by 2027.<sup>338</sup> This program aims to expand training programs, increase investment in medical education infrastructure, and develop new specialty fields to accelerate

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<sup>332</sup> Rajesh Balkrishnan, Owen Selden, and Emmanuel Rusingiza, "Overview, Infrastructural Challenges, Barriers to Access, and Progress for Rwanda's Healthcare System: A Review," *Integrative Journal of Medical Sciences* 12 (2025): 1–7, <https://doi.org/10.15342/ijms.2025.745>.

<sup>333</sup> Susan Bradley et al., "Too Few Staff, Too Many Patients: A Qualitative Study of the Impact on Obstetric Care Providers and on Quality of Care in Malawi," *BMC Pregnancy and Childbirth* 15, no. 1 (2015): 1–10, <https://doi.org/10.1186/s12884-015-0492-5>.

<sup>334</sup> T Ben Sano, "Challenges and Solutions for Improving Healthcare Access in Rwanda: Building on Success," *RwPharma*, November 2024, <https://pharma.rw/2024/11/29/challenges-and-solutions-for-improving-healthcare-access-in-rwanda-building-on-success/?form=MG0AV3>.

<sup>335</sup> Christina Colclough, "How Staffing Shortages in Healthcare Increase Malpractice Risks," *The Future World of Work*, May 2025, <https://www.thefutureworldofwork.org/job/staffing-shortages-healthcare-malpractice-risk/>.

<sup>336</sup> Brenda Ayala, "Ethical and Legal Implications of Healthcare Worker Shortages," *The Journal of Healthcare Ethics & Administration* 11, no. 1 (2025): 1–5, <https://doi.org/10.22461/jhea.1.71649>.

<sup>337</sup> National Academies of Sciences, Engineering, and Medicine *Evaluation of PEPFAR's Contribution (2012-2017) to Rwanda's Human Resources for Health Program (2020)* (Washington, DC: National Academies Press (US), 2020), <https://doi.org/10.17226/25687>.

<sup>338</sup> MOH-Rwanda, "4X4 Reform," accessed September 8, 2025, [https://www.moh.gov.rw/strategic-plans-priorities/4x4-reform?tx\\_news\\_pi1%5Baction%5D=detail&tx\\_news\\_pi1%5Bcontroller%5D=News&tx\\_news\\_pi1%5Bnews%5D=34951&cHash=5805b94d6aacb9e788c54cfefc294980](https://www.moh.gov.rw/strategic-plans-priorities/4x4-reform?tx_news_pi1%5Baction%5D=detail&tx_news_pi1%5Bcontroller%5D=News&tx_news_pi1%5Bnews%5D=34951&cHash=5805b94d6aacb9e788c54cfefc294980).

workforce production and improve service delivery across the country.<sup>339</sup> However, its feasibility requires a concerted effort from various stakeholders and effective enforcement mechanisms to address the systemic challenges.

#### 4.4.2. Deficiency in medical training

The definition of “reasonable care” in the context of medical practice centers on “the application of the skill and knowledge deemed competent among comparable medical providers in the same or similar situation.”<sup>340</sup> This justifies that a medical practitioner needs to undergo thorough education, training, and specialization to deliver reasonable care.

The recent publication of Mahmoud Ali and Branden Tejada in *The Egyptian Journal of Internal Medicine* explores how inadequate training leads to increased medical errors and malpractice. The research has found that deficiencies in clinical training are a major contributor to malpractice incidents.<sup>341</sup> Deficiencies in medical education and clinical training have been widely recognised as substantive contributing factors to medical malpractice and professional negligence. Inadequate preparation of healthcare personnel—whether due to limited access to high-quality training, outdated curricula, or insufficient clinical exposure—may pose diagnostic errors, procedural incompetence, and ethical issues.

Furthermore, failure to uphold professional standards or a reasonable standard of care, resulting from inadequate training, can result in a limitation of duty and potential malpractice. According to the American Bar Association (ABA), malpractice is often the result of the health care provider’s breach of accepted standards of practice where reasonable care was not provided, which may be linked to inadequate training or a lack of specialisation in their scope of practice.<sup>342</sup> The Association notes that expert testimony in malpractice cases frequently usually focusses on whether the practitioner had adequate training to meet expected standards of care normalised by the respected profession.<sup>343,344</sup> This necessitates the importance of CPD programs and adherence to protocols to avoid negligence.<sup>345</sup>

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<sup>339</sup> MOH-Rwanda.

<sup>340</sup> American Law Institute, “A New Legal Standard for Medical Malpractice,” *ALI*, March 2025, <https://www.ali.org/news/articles/new-legal-standard-medical-malpractice>.

<sup>341</sup> Mahmoud Ali and Branden Tejada, “Medical Malpractice’s Impacts and Simulation Training’s Ability to Diminish Its Effects: A Systematic Review,” *The Egyptian Journal of Internal Medicine* 36, no. 1 (2024): 4–7, <https://doi.org/10.1186/s43162-024-00285-w>.

<sup>342</sup> American Bar Association, “Medical Malpractice,” 2016, [https://www.americanbar.org/groups/public\\_education/resources/law\\_issues\\_for\\_consumers/everydaylaw0/health\\_care/personal\\_injury/medical\\_malpractice/](https://www.americanbar.org/groups/public_education/resources/law_issues_for_consumers/everydaylaw0/health_care/personal_injury/medical_malpractice/).

<sup>343</sup> Daniel G. Aaron et al., “A New Legal Standard for Medical Malpractice,” *JAMA* 333, no. 13 (2025): 1161–65, <https://doi.org/10.1001/jama.2025.0097>.

<sup>344</sup> Abigail Zuger, “A New Perspective on Medical Malpractice,” *NJM Journal Watch*, March 2025.

<sup>345</sup> Mitzi Andrade, “Understanding Medical Malpractice: A Training Guide For Healthcare Providers,” *Halt.Org Law Directory*, January 2025, <https://www.halt.org/understanding-medical-malpractice-a-training-guide-for-healthcare-providers>.

In Rwanda, a gap exists in academic preparation and professional standards among allied health practitioners, prompting the implementation of knowledge assessments and disciplinary measures to uphold professional standards. According to the Rwanda Allied Health Professions Council (RAHPC), there is a gradual decline in the knowledge, skills, professional attitudes, core values, and overall appreciation for careers in healthcare across the country.<sup>346</sup> Besides, the National Strategy for Health Professions Development 2020–2030 notes systemic challenges, including limited faculty capacity, under-resourced training institutions, and uneven distribution of clinical mentorship opportunities, which exacerbate these deficiencies.<sup>347</sup> A study assessing medical malpractice in Musanze District further highlights that many healthcare workers lack adequate CPD, which impairs their ability to provide safe and effective healthcare, increasing the likelihood of clinical errors.<sup>348</sup>

To address the deficiencies in medical training, there is a need for a concerted effort involving many aspects, including curriculum reform, investment in faculty development, expansion of clinical training sites, and the integration of ethical and legal education into health professional programs. Without such interventions, the risk of malpractice remains high, particularly in high-risk specialties such as surgery, obstetrics, and emergency medicine.

#### 4.4.3. Shortages and malfunctions of essential medical reagents and equipment

The deficient, substandard, and falsified medical supplies constitute a global public health challenge, particularly in resource-constrained settings such as those in low- and middle-income countries,<sup>349,350</sup> where one in 10 medicines is either substandard or falsified.<sup>351</sup> This issue has been linked to increased rates of medical errors and compromised patient safety.<sup>352</sup> They jeopardise the provision of optimal treatments. The WHO indicates that the supply of ineffective or dangerous products and the lack of essential medicines are contributing factors to significant morbidity, mortality, increased antimicrobial resistance, economic loss, and erosion of public trust in healthcare systems.<sup>353</sup> Besides, the shortage of medical supplies led to delays in chemotherapy,

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<sup>346</sup> RAHPC - Office of the Registrar, “Registry Examinations Policy” (Kigali, Rwanda, 2019), p. 1.

<sup>347</sup> MoH - Rwanda, “National Strategy for Health Professions Development 2020–2030” (Kigali, Rwanda, 2020), p. 37-28, 46-174.

<sup>348</sup> Rosine Ishimwe, “Assessment of the Status of Medical Negligence and Malpractice in Musanze District, Rwanda” (University of Kigali, 2021), p. 27.

<sup>349</sup> Oksana Zirka Pyzik and Ibrahim Abubakar, “Fighting the Fakes: Tackling Substandard and Falsified Medicines,” *Nature Reviews Disease Primers* 8, no. 1 (2022): 1–2, <https://doi.org/10.1038/s41572-022-00387-1>.

<sup>350</sup> Yusuf Hassan Wada et al., “Falsified and Substandard Medicines Trafficking: A Wakeup Call for the African Continent,” *Public Health in Practice Journal* 3 (2022), <https://doi.org/10.1016/j.puhip.2022.100240>.

<sup>351</sup> Maayan Hoffman and Stefan Anderson, “WHO Delays Falsified Medicine Mechanism Reform Amid Health Crisis,” *Health Policy Watch*, May 2025, <https://healthpolicy-watch.news/who-delays-falsified-medicine-mechanism-reform-amid-health-crisis/>.

<sup>352</sup> Biset Asrade Mekonnen, Muluabay Getie Yizengaw, and Minichil Chanie Worku, “Prevalence of Substandard, Falsified, Unlicensed and Unregistered Medicine and Its Associated Factors in Africa: A Systematic Review,” *Journal of Pharmaceutical Policy and Practice* 17, no. 1 (2024): 2–3, <https://doi.org/10.1080/20523211.2024.2375267>.

<sup>353</sup> WHO, “Substandard and Falsified Medical Products,” December 2024, <https://www.who.int/news-room/factsheets/detail/substandard-and-falsified-medical-products>.

incorrect medication dosages, and even surgery cancellations, which constitute a deviation from standard protocols, increasing the likelihood of malpractice.<sup>354</sup>

A 2023 survey by the ECRI and the Institute for Safe Medication Practices (ISMP) indicates that 60% of healthcare professionals reported shortages of over 20 essential medical items, such as single-use supplies or other medical devices, during the six months before the survey, which significantly compromised care in surgery and anesthetics at of 74%, and in emergency care at 64%.<sup>355</sup> Most of those medical supplies include reagents, diagnostic kits, such as pipette tips, blood collection tubes, and other essential equipment, like beds.<sup>356</sup>

Consistency of access to essential medicines has also been a concern in most sub-Saharan countries. The research estimated 10 million deaths annually due to the lack of availability of drugs existing on the list, and the Least and Middle-Income Countries of Africa are the most affected.<sup>357</sup> In Rwanda, the shortage of medical supplies in health facilities is particularly acute.<sup>358</sup> A study conducted at Rwanda Medical Supply Ltd and Medical & Allied Service Solutions Ltd identified systemic factors contributing to the deficiency and presence of substandard and fortified medical products, including poor procurement practices, limited local manufacturing, poor forecasting of medical needs, misalignment between evolving clinical protocols and procurement practices, and the lack of shelf-life requirements in supply contracts.<sup>359</sup> These challenges result in the circulation of expired, damaged, or inappropriate medical commodities, directly undermining the quality of care.<sup>360</sup> To address the problem, the Rwanda Food and Drugs Authority (FDA) has issued guidelines on the safety and vigilance of medical products and technologies,<sup>361</sup> aimed at strengthening post-market surveillance and reducing risks associated with malfunctioning or substandard equipment. Nevertheless, implementation challenges persist, particularly in rural and under-resourced health centers.<sup>362</sup>

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<sup>354</sup> Todd Shryock, “Are Medical Supply Shortages Harming Patients?,” *Medical Economics*, October 2023, <https://www.medicaleconomics.com/view/are-medical-supply-shortages-harming-patients->

<sup>355</sup> ECRI, “Medication, Supply, Equipment Shortages Are Harming Patients,” October 2023, <https://home.ecri.org/blogs/ecri-news/medication-supply-equipment-shortages-are-harming-patients#:~:text=“While medication and supply shortages,Postponement or cancellation of surgeries.”>

<sup>356</sup> Claire E. Knezevic et al., “Rising to the Challenge: Shortages in Laboratory Medicine,” *Clinical Chemistry* 68, no. 12 (2022): 1486–92, <https://doi.org/10.1093/clinchem/hvac179>.

<sup>357</sup> Yenet, Nibret, and Tegegne, “Challenges to the Availability and Affordability of Essential Medicines in African Countries: A Scoping Review.”

<sup>358</sup> L Nditunze et al., “Assessment of Essential Medicines Stock-Outs at Health Centers in Burera District in Northern Rwanda,” *Rwanda Journal* 2, no. 1 (2015): 85–88, <https://doi.org/10.4314/rjhs.v2i1.12f>.

<sup>359</sup> Faustin Kadisi Kotana, “Identification of Factors Leading to Unfit Medical Products and Other Health Commodities, Disposal Management and Related Perceived Consequences to Health Supply Chain in Rwanda: Case of Rwanda Medical Supply Ltd and Medical & Allied Service Solutions Ltd” (EAC Regional Center of Excellence for Vaccines, University of Rwanda, 2022), p. 22-29, <https://dr.ur.ac.rw/handle/123456789/1930>.

<sup>360</sup> Kotana.

<sup>361</sup> Rwanda FDA, “Rwanda FDA Guidelines on Safety and Vigilance of Medical Products and Health Technologies,” 2023.

<sup>362</sup> Op. Cit., “Annual Report of the Auditor General of State Finances - Year Ended 30 June 2024,” p. 26-28.

Additionally, there has been irregular distribution and underutilisation of medical equipment across Rwandan hospitals, where some facilities suffer from acute shortages, while others are oversupplied with medical equipment due to poor planning and logistical failures.<sup>363</sup> Such disparities not only affect service delivery but also expose institutions to legal and ethical scrutiny when patient outcomes are compromised.

The medical supply chain performance is not in line with the market demand.<sup>364</sup> For example, the 2016 USAID-DELIVER Final Report and the Auditor General's reports in the same have consistently highlighted problems with medicine supply,<sup>365</sup> including poor inventory management, stock-outs, and significant losses of expired medicines at the RBC's central medical store<sup>366,367</sup> and Medical Procurement and Production Division (MPPD).<sup>368</sup> Despite the efforts made, the supply has not yet met the demand. In this regard, the Auditor General's report of 2019-2020 indicated that Rwanda Medical Supply (RMS)'s satisfaction was at 29% of health facilities' demand, while it hit 75% of the demand by December 2024.<sup>369</sup> For example, the procurement processes used by the MPPD are also used by the University Teaching Hospital of Kigali (UTHK-CHUK), whose 80% of clients are beneficiaries of the community-based health insurance scheme (CBHI).<sup>370</sup> While the OAG reported that the MPPD supplies essential medicines below demand, clients who rely on public pharmacies without these supplies will experience shortages, as this is the only option available, which is where the CBHI can approve.<sup>371</sup> It requires CBHI beneficiaries to top up for certain prescribed medicines while they are in financial constraints, thus, their insurance subscriptions are paid by the Government.<sup>372</sup>

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<sup>363</sup> Leonce Muvunyi, "Uneven Distribution of Medical Resources Affects Hospital Services," *Rwanda Today*, April 2019, <https://rwandatoday.africa/rwanda/news/uneven-distribution-of-medical-resources-affects-hospital-services-2469484>.

<sup>364</sup> Tshilombo Tshama Sylvain, "Challenges and Solutions of Shortage of Essential Drugs, Supplies and Equipment at the Emergency Department of CHUK: A Mixed Method Study" (2021), p.4-6, [https://dr.ur.ac.rw/bitstream/handle/123456789/1649/Dr.Tshilombo Tshama Sylvain.pdf?sequence=1&isAllowed=y](https://dr.ur.ac.rw/bitstream/handle/123456789/1649/Dr.Tshilombo%20Tshama%20Sylvain.pdf?sequence=1&isAllowed=y).

<sup>365</sup> Theogene HAKUZIMANA, "Institute of Public Health College of Medicine and Health Science" (University of Rwanda, EAC Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management, 2019), p. 3-4, [https://dr.ur.ac.rw/bitstream/handle/123456789/1045/Hakuzimana Theogene.pdf?sequence=1&isAllowed=y](https://dr.ur.ac.rw/bitstream/handle/123456789/1045/Hakuzimana%20Theogene.pdf?sequence=1&isAllowed=y).

<sup>366</sup> Cyril NDEGEYA, "RBC in the Spotlight for Misuse of Funds," *The East African*, August 2020, <https://www.theeastafrican.co.ke/tea/rwanda-today/news/rbc-in-the-spotlight-for-misuse-of-funds--1336238>.

<sup>367</sup> Ibid.

<sup>368</sup> Office of the Auditor General, "Annual Audit Report for the Year Ended 30 June 2023" (Kigali, Rwanda, 2023), p. 52-53, [https://www.oag.gov.rw/fileadmin/REPORTS/Annual\\_Audit\\_Report\\_2023.pdf](https://www.oag.gov.rw/fileadmin/REPORTS/Annual_Audit_Report_2023.pdf).

<sup>369</sup> Daniel Sabiiti, "Rwanda Medicines Agency Turns To Tech To Tackle Drug Shortages," *KT PRESS*, June 12, 2025, [https://www.ktpress.rw/2025/06/rwanda-medicines-agency-turns-to-tech-to-tackle-drug-shortages/#:~:text="Technology makes everything easier in,; Karongi%2C Southern: Huye.](https://www.ktpress.rw/2025/06/rwanda-medicines-agency-turns-to-tech-to-tackle-drug-shortages/#:~:text=Technology%20makes%20everything%20easier%20in%20Kigali%20Southern%20Huye)

<sup>370</sup> Office of the Auditor General, "Performance Audit Report on Procurement and Management of Drugs and Medical Supplies and Its Impact on Health Care at University Teaching Hospital- Kigali (UTH-K / CHUK)" (Kigali, Rwanda, 2016), p. 18.

<sup>371</sup> Arafat Mugabo, "Drugs Shortage Now Pushes Patients to Private Pharmacies," *Rwanda Today*, June 11, 2020, <https://rwandatoday.africa/rwanda/news/drugs-shortage-now-pushes-patients-to-private-pharmacies-2478410>.

<sup>372</sup> Robert MBARAGA, "Patients Face Hard Times as Cost of Medicine Increases in Rwanda," *The East African*, September 3, 2020, <https://www.theeastafrican.co.ke/scienceandhealth/Patients-face-hard-times-as-cost-of-medicine-increases-/3073694-4272068-157quob/index.html>.

To address these issues, Rwanda Medical Supply (RMS) has recently implemented a technological solution by developing platforms that enable the agency to manage and control stock levels in public hospitals. The Systems, Applications, and Products in Data Processing/Enterprise Resource Planning (SAP/ERP) system is expected to integrate with the new Electronic Medical Records (EMR) to oversee stock, supplies, and sales data, which could be crucial for specialized medicine.<sup>373</sup> However, this technological solution requires additional strong mechanisms, such as regulatory oversight and an efficient reporting system, to be effective and beneficial.

Moreover, for drugs to be supplied, they must be registered on the national list of essential medicines. This legal requirement in many countries, including Rwanda, ensures public health and helps inspect, improve, and maintain drug standards, efficacy, and safety. Thus, the registration of pharmaceutical products enables their prescriptions, dispensing, labelling, and availability on the pharmaceutical market. However, the cost and time of the registration process of pharmaceutical industries, entailing medicine registration, good manufacturing practice inspection, and quality testing procedures, have been documented by the Office of the Auditor General to be disproportionate to the existing market demand.<sup>374, 375</sup>

While most pharmaceutical products available in African countries, including Rwanda, are imported, the demand, accessibility, affordability, and effectiveness of medicines depend heavily on the supply by manufacturing companies.<sup>376</sup> Nevertheless, the manufacturing processes of those companies are regulated in other countries, and their supplies are controlled, which may invoke ethical concerns and other implications associated with the medical supply chain in the country of demand, such as health and national security risks, as well as health care costs and medication shortages, as articulated by Senator Cary Peters.<sup>377</sup>

The shortage and malfunction of essential medical reagents and equipment represent a significant operational vulnerability of healthcare systems in developing nations, including Rwanda. Addressing these gaps requires a coordinated cross-border response, robust planning, improved procurement, regulatory oversight, reporting, education, and investment in supply chain resilience to mitigate malpractice risks and safeguard patient safety.<sup>378, 379</sup>

#### 4.4.4. Shortage of up-to-date infrastructure

The shortage of modern and functioning healthcare infrastructure, such as diagnostic equipment, surgical tools, and advanced digital health systems, is common in the low-resource settings of

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<sup>373</sup> Sabiiti, “Rwanda Medicines Agency Turns To Tech To Tackle Drug Shortages.”

<sup>374</sup> Office of the Auditor General, “Annual Report of the Auditor General of State Finances - Year Ended 30 June 2024.”

<sup>375</sup> Yenet, Nibret, and Tegegne, “Challenges to the Availability and Affordability of Essential Medicines in African Countries: A Scoping Review.”

<sup>376</sup> Ibid.

<sup>377</sup> Senator Gary Peters, “Peters Report Finds Continued Shortages of Medications Present Significant Health and National Security Risk,” 2023, <https://www.peters.senate.gov/newsroom/press-releases/peters-report-finds-continued-shortages-of-medications-present-significant-health-and-national-security-risk>.

<sup>378</sup> Pyzik and Abubakar, “Fighting the Fakes: Tackling Substandard and Falsified Medicines.”

<sup>379</sup> Wada et al., “Falsified and Substandard Medicines Trafficking: A Wakeup Call for the African Continent.”

developing countries.<sup>380, 381</sup> For example, the WHO estimated that 50 to 80 percent of medical equipment is non-functional in developing countries,<sup>382</sup> which hinders healthcare providers from delivering adequate care to their patients or other healthcare seekers.<sup>383</sup> About 80 percent of the medical equipment is obtained through donation, but some of its medical devices remain unused in the storerooms due to various infrastructural issues, including unreliable electricity and water.<sup>384</sup> For example, maintenance and repair for a broken-down machine could be beyond the facility's financial capacity, making it impossible. Some new machines cannot be installed due to incompatibility with the available infrastructure, while others are unable to reach remote areas due to transportation issues.<sup>385</sup> Baker argues that “the more delicate and sophisticated the machinery, the more likely it is to fall out of service.”<sup>386</sup>

Inadequate infrastructure compromises diagnostic accuracy, delay treatment, and limit healthcare providers to adhere to clinical standards. These deficiencies are particularly evident in low-resource settings within low- and middle-income countries, where under resourcing and irregular resource distribution exacerbate systemic vulnerabilities. According to the Swiss Re Institute, over 130 countries spend less than the recommended 7 -7.5% of GDP on healthcare infrastructure, resulting in increased morbidity, mortality, and malpractice risks.<sup>387</sup> The report noted that outdated or inadequate facilities limit safe and suitable care at any time, especially during an emergency or when undertaking a high-risk procedure.

In the Rwandan context, infrastructural limitations remain a persistent challenge. There are barriers to access and quality care stemming from outdated facilities, uneven urban-rural distribution of resources, and limited digital integration. The 2020-2021 health sector annual performance report from the Rwanda Ministry of Health indicated that only 60% of the rural facilities meet the

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<sup>380</sup> WHO, *Health Technology Assessment of Medical Devices. Second Edition* (Geneva: World Health Organization, 2024), p. 13, [https://cdn.who.int/media/docs/default-source/medical-devices/health-technology-assessment/hta-for-medical-devices-2024-v1.0-for-consultation.pdf?sfvrsn=d98f6abd\\_3](https://cdn.who.int/media/docs/default-source/medical-devices/health-technology-assessment/hta-for-medical-devices-2024-v1.0-for-consultation.pdf?sfvrsn=d98f6abd_3).

<sup>381</sup> WHO, *WHO Compendium of Innovative Health Technologies for Low-Resource Settings 2021* (Geneva: World Health Organization, 2024), p. 40-41, <https://www.who.int/publications/i/item/9789240032507>.

<sup>382</sup> H Ojwang et al., “Lack of Medical Equipment Is a Hindrance to Universal Health Coverage Utilization; the Case of Seme Sub County in Kisumu County, Kenya,” *World Journal of Innovative Research* 10, no. 1 (2021): 45, [http://62.24.102.115:8080/handle/123456789/9393%0Ahttp://62.24.102.115:8080/xmlui/bitstream/handle/123456789/9393/Ojwang\\_Lack of Medical Equipment is a Hindrance to Universal Health Coverage Utilization%3B the Case of Seme Sub County in Kisumu County%2C K.](http://62.24.102.115:8080/handle/123456789/9393%0Ahttp://62.24.102.115:8080/xmlui/bitstream/handle/123456789/9393/Ojwang_Lack%20of%20Medical%20Equipment%20is%20a%20Hindrance%20to%20Universal%20Health%20Coverage%20Utilization%3B%20the%20Case%20of%20Seme%20Sub%20County%20in%20Kisumu%20County%2C%20Kenya)

<sup>383</sup> Merriam Bautile Moyimane, Sogo France Matlala, and Mokoko Percy Kekana, “Experiences of Nurses on the Critical Shortage of Medical Equipment at a Rural District Hospital in South Africa: A Qualitative Study,” *Pan African Medical Journal* 28 (2017): 803–5, <https://doi.org/10.11604/pamj.2017.28.100.11641>.

<sup>384</sup> Leslie Calman and Jessica Baker, “Lack of Operational Medtech Equipment in Developing World,” *MedTech Intelligence*, November, <https://medtechintelligence.com/column/lack-of-operational-medtech-equipment-in-developing-world/>.

<sup>385</sup> John Kwaku Kutor, Peter Agede, and Rashid Haruna Ali, “Maintenance Practice, Causes of Failure and Risk Assessment of Diagnostic Medical Equipment,” *Journal of Biomedical Engineering and Medical Devices* 02, no. 01 (2017): 2–4, <https://doi.org/10.4172/2475-7586.1000123>.

<sup>386</sup> Calman and Baker, “Lack of Operational Medtech Equipment in Developing World.”

<sup>387</sup> Swiss Re Institute, “Underfunding of Public Health – Harmful to Morbidity, Mortality and GDP,” 2024, <https://www.swissre.com/institute/research/sonar/sonar2024/underfunding-public-health.html>.

minimum standards for infrastructure and staffing.<sup>388</sup> The report notes that gaps remain in equipment availability, maintenance, and utilisation, particularly in district hospitals and health centers.<sup>389</sup> Despite Rwanda's progress in rebuilding its healthcare system post-genocide, disparities in infrastructure continue to hinder clinical performance, increasing the likelihood of medical errors and negligence as well as exposing providers to legal and ethical risks, particularly in remote or rural areas.<sup>390</sup>

Hence, the shortage of up-to-date medical and public health infrastructure is a systemic issue in Rwanda's low-resource settings<sup>391</sup> and can contribute to medical malpractice by undermining the safety, timeliness, and effectiveness of care. Despite the strides made in Rwanda, addressing this issue requires sustained investment in facility modernisation, equitable resource distribution, and strategic planning to ensure that healthcare providers can deliver care that meets professional and ethical standards.

#### 4.4.5. Regulatory gaps

Medical malpractice is exacerbated by weak or inconsistent regulatory environments, which create a lack of accountability for healthcare practitioners.<sup>392</sup> Issues surrounding the legal definition of the term “malpractice” and its classification must also be addressed, including whether it is considered administrative, professional, civil, or potentially criminal fault. Furthermore, the lack of a centralised system for tracking malpractice incidents and regulated oversight poses a significant problem, further impeding enforcement. In this context, LMICs often rely on manual audits and informal deterrents due to resource constraints, which pose a capability challenge for detecting and preventing malpractice.<sup>393</sup> The Rwandan healthcare system suffers greatly from under-reporting by practitioners, often due to fear of litigation and professional repercussions; this limits the feedback loop needed to stimulate regulatory reforms.

Rwanda has made significant strides in health regulatory reform, beginning with the successful passage of relevant laws and regulations. For example, a law creating medical professional liability

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<sup>388</sup> Yves Gashugi et al., “Bridging the Gap: Fostering the Positive Impact of Expanding Medical Training Facilities on Rwanda’s Rural Healthcare: A Review,” *Rwanda Public Health Bulletin* 6, no. 1 (2025): 44–47, <https://doi.org/10.4314/rphb.v6i1.3>.

<sup>389</sup> MoH-Rwanda, “Health Sector Annual Performance Report 2020-2021” (Kigali, Rwanda, 2021), [https://www.moh.gov.rw/fileadmin/user\\_upload/Moh/Publications/Reports/Health\\_Sector\\_Annual\\_Performance\\_Report\\_2020-2021.pdf](https://www.moh.gov.rw/fileadmin/user_upload/Moh/Publications/Reports/Health_Sector_Annual_Performance_Report_2020-2021.pdf).

<sup>390</sup> Rajesh Balkrishnan, Owen Selden, and Emmanuel Rusingiza, “Overview, Infrastructural Challenges, Barriers to Access, and Progress for Rwanda’s Healthcare System: A Review,” *Integrative Journal of Medical Sciences* 12 (2025): 1–7, <https://doi.org/10.15342/ijms.2025.745>.

<sup>391</sup> Balkrishnan, Selden, and Rusingiza, “Overview, Infrastructural Challenges, Barriers to Access, and Progress for Rwanda’s Healthcare System: A Review,” 2025.

<sup>392</sup> Rachael Totz, “Forces That Shape and Constrain Medical Practice,” *The Regulatory Review*, September 2024, <https://www.theregreview.org/2024/09/08/totz-forces-that-shape-and-constrain-medical-practice/>.

<sup>393</sup> Ali Vafae Najjar et al., “A Global Scoping Review on the Patterns of Medical Fraud and Abuse: Integrating Data-Driven Detection, Prevention, and Legal Responses,” *Archives of Public Health* 83, no. 5–23 (2025), <https://doi.org/10.1186/s13690-025-01512-8>.

insurance was passed in 2013, but has not been implemented because there is no mechanism to enforce it. Besides, the Government recently issued a new healthcare law, but its implementation will depend on the Ministerial Orders that have not yet been issued.

Additionally, despite the enforcement of disciplinary sanctions in the Rwandan healthcare system, malpractice cases continue to rise, indicating that these measures are not fully effective due to inconsistencies, weaknesses, or a lack of supportive actions such as awareness campaigns, Continuing Professional Development (CPD), and regulatory upgrades.

Furthermore, poor documentation, lack of standardised procedures, and limited employer accountability have been identified as key issues. Underreporting of malpractice incidents is another primary concern, suggesting that the reported number of incidents may significantly underestimate the true scope of the problem. Additionally, the RMDC's disciplinary decisions are ambiguous to licensed practitioners, and the available appeal options pose issues. In this context, medical practitioners frequently appeal disciplinary decisions, and the Council is often criticized for being either too punitive or too lenient.

These regulatory divides frequently appear as limited enforcement of standards, protracted bureaucratic processes, procurement issues,<sup>394</sup> inadequate oversight and a limited legal framework. These are sometimes related to unsafe medical practice, patient injury, and a loss of trust in the healthcare system. Given these challenges, it is clear that regulatory gaps are a significant factor contributing to medical malpractice in Rwanda.

These factors can lead to system inefficiencies and, in some cases, preventable harm, but could be addressed with a current regulatory divide with vigorous enforcement. The new healthcare regulation is expected to address some challenges if paired with effective enforcement. In Rwanda, while progress is evident, strengthening regulatory bodies like the Rwanda FDA and professional Councils, along with improving regulatory oversight, is crucial to reduce malpractice and improve patient safety. This could be possible with feedback loops and Standard Operating Procedures (SOPs).

#### 4.4.6. Productivity-driven compensation models

In many healthcare systems, physician pay is linked to productivity metrics through models based on Relative Value Units (RVUs) because of fixed low wages.<sup>395</sup> These models appear in various forms. For instance, in the United States, they include fee-for-service (FFS), capitation, pay-for-

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<sup>394</sup> Hudson Kuteesa, "RBC Officials Deny Flouting Procedures in Rwf3 Billion Tender," *The New Times*, December 2022, <https://www.newtimes.co.rw/article/3426/news/crime/rbc-officials-deny-flouting-procedures-in-rwf3-billion-tender>.

<sup>395</sup> Dave Wofford, Maria Hayduk, and Kenneth Robbins, "Revisiting Productivity as a Basis for Compensating Physicians," *Hfm Magazine* (Westchester: Healthcare Financial Management Association, July 2017), <https://www.hfma.org/finance-and-business-strategy/physician-compensation/54579/>.

performance (P4P), case rates or episode-of-illness rates, and bundled payments.<sup>396</sup> These outcomes-based healthcare systems reward physicians according to the volume and complexity of services provided, rather than patient outcomes or quality of care.<sup>397</sup> These models have been adopted worldwide, especially in resource-limited settings. However, this approach can lead to decreased healthcare quality and ultimately harm patients.<sup>398</sup>

In Rwanda, like RVUs, Performance-Based Financing (PBF) is common in public health facilities. These financial incentives are based on data from the Health Management Information System (HMIS), which measures the services delivered during a specific period. This aligns with the “imihigo program” or performance contracts, which provide a benchmark for the government to set targets for the quantity, quality, and timeliness of health services annually, often linked to PBF incentives. Although PBF is recognized for improving patient outcomes, especially in government-incentivized services,<sup>399</sup> it emphasizes quantity more than the quality of healthcare delivery.

While these models may enhance efficiency and resource management, they can also unintentionally create psychological and operational pressures—such as increased workload, task burden, stress, sleep disturbances, and fatigue—that elevate the risk of malpractice.<sup>400</sup> For instance, if doctors are encouraged to be more productive and accept more patients per shift, it likely leads to less thorough diagnostics, documentation, and communication with patients.<sup>401</sup> Additionally, with pay-for-performance (PBF) programs, there is a direct link between billing and payments for healthcare facilities, raising concerns about the overuse of government resources or unnecessary services for patients. This constitutes another form of defensive medicine, as providers aim to maximize service delivery to earn higher bonuses under PBF.<sup>402</sup> When financial compensation is based on “volume, not value,” practitioners are caught in an ethical dilemma, balancing financial interests with professional standards. They must also recognize that persistent productivity

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<sup>396</sup> Alice G Gosfield, “Pitfalls to Avoid in Physician Compensation Models,” *American Academy of Family Physicians* 29, no. 5 (2022): 23–28, [www.aafp.org/fpm](http://www.aafp.org/fpm).

<sup>397</sup> Merritt Hawkins, “RVU Based Physician Compensation and Productivity: Ten Recommendations for Determining Physician Compensation / Productivity Through Relative Value Units,” *Merritt Hawkins* (Texas, 2011), <https://www.amnhealthcare.com/siteassets/amn-insights/whitepapers/rvu-based-physician-compensation-and-productivity.pdf>.

<sup>398</sup> Maria Panagioti et al., “Association between Physician Burnout and Patient Safety, Professionalism, and Patient Panagioti, Maria, Keith Geraghty, Judith Johnson, Anli Zhou, Efharis Panagopoulou, Carolyn Chew-Graham, David Peters, Alexander Hodkinson, Ruth Riley, and Aneez Esmail,” *JAMA Internal Medicine* 4, no. 10 (2018): E2–3, E12, <https://doi.org/10.1001/jamainternmed.2018.3713>.

<sup>399</sup> Costase Ndayishimiye et al., “Performance-Based Financing in Rwanda: A Qualitative Analysis of Healthcare Provider Perspectives,” *BMC Health Services Research* 25, no. 418 (2025): 1–12, <https://doi.org/10.1186/s12913-025-12605-z>.

<sup>400</sup> Mohammad S. Alyahya et al., “The Association between Cognitive Medical Errors and Their Contributing Organizational and Individual Factors,” *Risk Management and Healthcare Policy* 14 (2021): 415–30, <https://doi.org/10.2147/RMHP.S293110>.

<sup>401</sup> Merritt Hawkins, “RVU Based Physician Compensation and Productivity: Ten Recommendations for Determining Physician Compensation / Productivity Through Relative Value Units.”

<sup>402</sup> Ndayishimiye et al., “Performance-Based Financing in Rwanda: A Qualitative Analysis of Healthcare Provider Perspectives.”

pressures are linked to provider burnout, which significantly increases clinical errors and compromises patient safety.

Moreover, not all practitioners can maintain the same pace due to factors such as their age, the issues their patients present, and the tools available. As a result, practices may cultivate a culture of shortcuts in documentation by documenting less or relying on template notes to maintain pace, and increase their risks of miscommunication (e.g., sloppy note-taking) and legal liability.

These systemic issues in healthcare service delivery, which sacrifice quality for quantity, necessitate the need for compensation models that integrate quality metrics, patient satisfaction, and clinical outcomes alongside productivity.<sup>403</sup> Fee-for-service models are suitable for quantity but not for quality in clinical practice. A more balanced approach can help address malpractice risk while preserving practitioners' safety and integrity.

#### 4.4.7. Lack of public awareness of medical rights

For upholding their dignity, human beings should be both aware of and safeguarded in their entitled rights.<sup>404</sup> In the context of public health and clinical practice, patients or service users should be aware of their medical rights.<sup>405</sup> In this light, the current consideration is that patients are consumers whose rights should focus on information, quality, and choice. Particularly, consumer patients have the right to be informed about their rights and the duties of healthcare providers.<sup>406</sup> This transparency is essential for building trust, maintaining ethical standards in clinical care, and allowing patients to participate in shared decision-making in the doctor–patient relationship.

*Providers, especially physicians, know about the right to provide sufficient information about patients' disease and its progress, but they withhold information from patients as they think it can limit the authority of them. Patients' awareness of this right, however, was in moderate level. The disparity in awareness between good providers and weak patient awareness of this right may be attributed to the dominant paternalistic medicine, where medical professionals have the authority to make decisions on behalf of their patients.*<sup>407</sup>

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<sup>403</sup> Merritt Hawkins, "RVU Based Physician Compensation and Productivity: Ten Recommendations for Determining Physician Compensation / Productivity Through Relative Value Units."

<sup>404</sup> Alphonsa B Fernandes, Sweta D'Cunha, and Sucharita Suresh, "Patient Rights: Awareness and Practice in a Tertiary Care Indian Hospital," *International Journal of Research Foundation of Hospital and Healthcare Administration* 2, no. 1 (2014): 25–30, <https://doi.org/10.5005/jp-journals-10035-1011>.

<sup>405</sup> Kumlachew Geta Belete et al., "Patient's Awareness of Their Right and Factors Associated with It: A Scoping Review, 2024," *BMC Medical Education* 25, no. 1 (2025): 2, <https://doi.org/10.1186/s12909-025-07431-0>.

<sup>406</sup> Belete et al.

<sup>407</sup> Zahra Mastaneh and Lotfollah Mouseli, "Patients' Awareness of Their Rights: Insight from a Developing Country," *International Journal of Health Policy and Management* 1, no. 2 (2013): 143–46, <https://doi.org/10.15171/ijhpm.2013.26>.

Although the general public’s limited awareness of their medical rights might be ignored, it could be a significant contributor to medical malpractice. In many healthcare systems, particularly in those of developing countries, patients are not adequately informed about their entitlements. Rwanda is no exception; throughout the interviews, three participants revealed that they have ever dealt with the violation of informed consent as a form of medical malpractice.

Ensuring respectful treatment and equitable access to accurate medical information requires that healthcare providers actively inform consumer patients of their fundamental rights—particularly the rights to informed consent, confidentiality, and access to essential information relevant to their care.<sup>408</sup> These rights are not merely procedural formalities; they constitute the ethical and legal foundation of patient-centered healthcare. Thus, their expectations and needs, wants, and preferences should always be considered.<sup>409</sup> These are enablers that empower citizens to take an active role in their own healthcare. The absence of such information reduces patients’ involvement in health care, which undermines their ability to advocate for themselves, question inappropriate or harmful medical practices, and report violations. As demonstrated by some research, limited awareness of patient rights can be linked to reduced accountability among healthcare professionals and a measurable decline in the quality of health care service delivery.<sup>410</sup>

Furthermore, without a clear understanding of what defines ethical and lawful medical practice, patients may unintentionally accept substandard care or fail to recognise instances of medical malpractice. Thus, this can result into reduced accountability, underreporting of malpractice, and increased vulnerability. This weakness is exacerbated by the lack of public awareness campaigns and institutional systems designed to promote and safeguard patient rights.<sup>411</sup> The systemic neglect of patient education not only threatens individual autonomy but also hinders broader efforts to promote transparency, justice, and dignity within healthcare systems.

#### 4.4.8. Deficiency in accountability mechanisms

Accountability in healthcare means that medical professionals and institutions must deliver quality care, follow ethical and legal standards, and be responsible for their actions or omissions.<sup>412</sup> This has considerable significance in medical practice as it sets an environment that leaves no room for

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<sup>408</sup> Abukari Kwame and Pammla M. Petrucka, “Universal Healthcare Coverage, Patients’ Rights, and Nurse-Patient Communication: A Critical Review of the Evidence,” *BMC Nursing* 21, no. 1 (2022): 1–9, <https://doi.org/10.1186/s12912-022-00833-1>.

<sup>409</sup> Sean P Collins et al., *Achieving Person-Centred Health Systems: Evidence, Strategies and Challenges*, ed. Ellen Nolte, Sherry Merkur, and Anders Anell (New Delhi: Cambr, 2021), p. 1-66, <https://eurohealthobservatory.who.int/publications/m/achieving-person-centred-health-systems-evidence-strategies-and-challenges>.

<sup>410</sup> Fernandes, D’Cunha, and Suresh, “Patient Rights: Awareness and Practice in a Tertiary Care Indian Hospital.”

<sup>411</sup> Edward Maibach and Roxanne Parrott, “Module 13-Effective Public Health Campaigns,” in *Health in All Policies (HiAP) Training Slides: Companion Material to Support HiAP Training Activities* (World Health Organization, 2020), 4–15, <https://doi.org/10.4135/9781452233451>.

<sup>412</sup> Martin Atela and Francis Wafula, *Mapping Accountability Mechanisms: A Review of In-Country Accountability in Health Systems* (Nairobi, Kenya, 2015), p. 3, <https://aidspan.org/wp-content/uploads/reports/Accountability-Mechanisms-Review.pdf>.

negligence and malpractice. On the contrary, a deficiency in accountability mechanisms compromises patient safety.

In this regard, Rwanda has made significant progress in establishing laws and regulatory bodies to oversee healthcare quality and professional conduct. Despite this progress, a deficiency in accountability mechanisms still exists, as manifested by a lack of transparent reporting systems, limited disciplinary frameworks, and lack of defined legal recourse for patient victims, resulting in inconsistent compensation. In the same vein, the RMDC's applicable disciplinary actions, such as suspensions and deregistrations, are rarely applied and often argued to be insufficient, especially when errors lead to death. RAHPC, mandated to regulate and enforce ethical standards among healthcare professionals, itself acknowledges a decline in professionalism, compassion, and clinical competence among practitioners.<sup>413</sup> This might be rooted in institutional issues due to resource constraints and the limited statutory enforcement mandate of regulatory bodies. This can lead to an increase in malpractice and negligence incidents.

Despite ongoing reforms aimed at improving accountability and quality of care, including the introduction of performance-based financing, hospital accreditation, and data systems such as TRACnet and RapidSMS,<sup>414</sup> these mechanisms primarily focus on service delivery metrics rather than individual professional conduct. This necessitates strengthening legal frameworks and enforcement, increasing public awareness of patient rights, ensuring transparent and accessible reporting systems, and providing CPD programs to improve healthcare standards and reduce malpractices to enhance patient safety.

#### 4.4.9. Broken communication between patient/family and provider

As discussed earlier in another section, in patient-centred healthcare, good communication is essential. Without this, providers withhold information from patients, thinking that it can limit their authority.<sup>415</sup> This results in dominant paternalistic medicine, where patients' medical rights are infringed. According to the CRICO report on malpractice risks related to communication failures, such failures account for 30% of all medical malpractice claims. In comparison, 44% of claims involving a communication issue result in serious harm or death.<sup>416</sup> These problems occur in various healthcare settings and involve both provider-provider and provider-patient interactions.

Clinical communication failures often arise from various interconnected causes, such as language barriers, time constraints, heavy workloads, limited interpersonal communication skills, and the embedded hierarchical structures within healthcare settings. These failures can be substantially

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<sup>413</sup> RAHPC - Office of the Registrar, *Registry Examinations Policy* (Kigali, Rwanda, 2019), p. 1.

<sup>414</sup> "Pathway 2: How Did Rwanda Foster a Culture of Accountability and Information Use?," Exemplars in Global Health, accessed September 22, 2025, <https://www.exemplars.health/topics/primary-health-care/rwanda/pathway-2-how-did-rwanda-foster-a-culture-of-accountability-and-information-use>.

<sup>415</sup> Mastaneh and Mouseli, "Patients' Awareness of Their Rights: Insight from a Developing Country."

<sup>416</sup> CIRCO, "Malpractice Risks in Communication Failures," 2015, [https://www.candello.com/Insights/Candello-Reports/Communications-Report?\\_hstc=133161617.a7e699467a0199b4335083d5c3ce4980.1757672924634.1757919120338.1758551616449.3&\\_hssc=133161617.1.1758551616449&\\_hsfp=3203310118](https://www.candello.com/Insights/Candello-Reports/Communications-Report?_hstc=133161617.a7e699467a0199b4335083d5c3ce4980.1757672924634.1757919120338.1758551616449.3&_hssc=133161617.1.1758551616449&_hsfp=3203310118).

reduced by replacing outdated communication systems and adopting electronic health records (EHRs). Evidence of communication failures can sometimes be found in poor or missing documentation, and a lack of or incomplete consent. These communication failures can lead to numerous poor clinical outcomes, including misdiagnosis or failure to diagnose, delays in appropriate treatment, postponement of critical diagnostic testing, prolonged hospitalisation, and medication or surgical errors.<sup>417</sup> This cultural issue has led to various adverse clinical outcomes worldwide.<sup>418</sup> They can also lead to biases about the patients by misinterpreting their needs and withholding some healthcare services.<sup>419</sup>

Patients place great importance on clear and empathetic communication in Rwandan healthcare contexts. If these qualities are missing, patients may feel dismissed or misunderstood, making them more likely to be dissatisfied.<sup>420</sup> These communication issues can compromise the therapeutic relationship and increase the likelihood of formal complaints and potential litigation. Ultimately, these issues underscore the importance of culturally aware, patient-centred communication in fostering trust, adherence, and overall quality care.

In light of both the structural and cultural challenges in patient-provider communication—often with significant clinical implications, there is a distinct need for responsive reforms at the organisational level. A focus on empathy and relational transparency, combined with the use of tools such as electronic health records, can reduce errors, enhance satisfaction, and foster trust. These initiatives are the first step toward improving care quality, safety, and equity, especially within Rwanda's evolving healthcare model.

#### 4.4.10. Faith-based and conscientious constraints

Besides, the beliefs of patients or their families may also contribute to malpractice incidents in various aspects.<sup>421,422</sup> For example, Jehovah's Witnesses' objections to blood transfusions have been a challenge in Rwanda.<sup>423</sup> When healthcare providers' and practitioners' personal or religious

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<sup>417</sup> Steve Alder, "Effects of Poor Communication in Healthcare," *The HIPAA Journal*, 2025, <https://www.hipaajournal.com/effects-of-poor-communication-in-healthcare/>.

<sup>418</sup> Kelvin Quan and Jessica Lynch, *The High Costs of Language Barriers in Medical Malpractice*, ed. Sarah Lichtman Spector and Mara Youdelman (California: National Health Law Program, 2010).

<sup>419</sup> Carol M. Ashton et al., "Racial and Ethnic Disparities in the Use of Mental Health Services," *Journal of Behavioral Health Services and Research* 18 (2003): 146–52, <https://doi.org/10.1007/s11414-007-9097-8>.

<sup>420</sup> Vincent K Cubaka et al., "'He Should Feel Your Pain': Patient Insights on Patient-Provider Communication in Rwanda," *African Journal of Primary Health Care and Family Medicine* 10, no. 1 (2018): 1–11, <https://doi.org/10.4102/phcfm.v10i1.1514>.

<sup>421</sup> Rita Swan, "Faith-Based Medical Neglect: For Providers and Policymakers," *Journal of Child and Adolescent Trauma* 13, no. 3 (2020): 343–53, <https://doi.org/10.1007/s40653-020-00323-z>.

<sup>422</sup> Austen Metcalfe, "Patient v. God: Determining the Standards of Care for Christian Science Practitioners in Medical Negligence Cases," *Dalhousie Journal of Legal Studies* 27 (2018): 137–67, [https://www.canlii.org/en/commentary/doc/2018CanLIIDocs311#!fragment/zoupio-\\_Toepdf\\_bk\\_1/BQCwhgziBcwMYgK4DsDWszIQewE4BUBTADwBdoAvbRABwEtsBaAfX2zhoBMAzZgI1TMAjAEoANMmylCEAIqJCuAJ7QA5KrERCYXAnmKV6zdt0gAynlIAhFQCUAogBl7ANQCCAOQDC9saTB80KTsIiJAA](https://www.canlii.org/en/commentary/doc/2018CanLIIDocs311#!fragment/zoupio-_Toepdf_bk_1/BQCwhgziBcwMYgK4DsDWszIQewE4BUBTADwBdoAvbRABwEtsBaAfX2zhoBMAzZgI1TMAjAEoANMmylCEAIqJCuAJ7QA5KrERCYXAnmKV6zdt0gAynlIAhFQCUAogBl7ANQCCAOQDC9saTB80KTsIiJAA).

<sup>423</sup> Emmanuel Ntirenganya, "New Bill Proposes Treatment without Patient's Consent in Emergency Cases," *The New Times*, May 2025, <https://www.africa-press.net/rwanda/all-news/new-bill-proposes-treatment-without-patients-consent-in-emergency-cases>.

faith deviates from the acceptable standard of care, their doctrine oversteps evidence-based medicine and can result in adverse outcomes. An example is where removing the fallopian tube has been a common practice in Catholic-based hospitals instead of using the less invasive drug like Methotrexate in case of ectopic pregnancy, fearing abortion as a result of the medication.<sup>424</sup> The rationale was that Catholic medical facilities worldwide are bound by binding ethical codes, most notably, the Ethical and Religious Directives to Catholic Health Care Services (ERDs),<sup>425</sup> which restrict or forbid abortion, emergency pregnancy abortions, sterilization, and certain life-saving procedures when those are interpreted as directly killing a fetus.<sup>426</sup>

This applies not only to Catholic health institutions but also to other faith-based providers, some of whom have limited some reproductive health care, including family planning or after abortion services, on the basis of theological teachings. In turn, in areas where such facilities are prevalent, or are the only community providers, the effect of religiously determined refusals can potentially put out the option of patient choice, thus exposing them to potential adverse consequences of delayed or unsuitable care.<sup>427,428</sup>

In Rwanda, the problems associated with the denial of some lawful reproductive health services by faith-based healthcare facilities exist. Some of the church affiliated hospitals and health centres do not provide modern contraception and sterilization or termination of the pregnancy based on their doctrine, despite being part of the national health system. Since the Rwanda reproductive, maternal, newborn, child, and adolescent health (RMNCAH) framework encourages universal access, equity, and emergency obstetric care, its implementation in the faith-based facilities is still limited by negotiated State-church agreements. Although referral is necessary in the lack of services, there is still a gap in referral effectiveness, monitoring, and service continuity, especially in rural areas, and this presents dangers of delayed care and avoidable maternal morbidity.

#### 4.4.11. Insurance forces and effects

Although Rwanda has made significant strides in achieving universal healthcare coverage,<sup>429</sup> some challenges remain.<sup>430</sup> Some citizens are uninsured because they cannot afford premiums. Although

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<sup>424</sup> Metcalfe, “Patient v. God: Determining the Standards of Care for Christian Science Practitioners in Medical Negligence Cases.”

<sup>425</sup> Sarah Varney and Rachel Wellford, “Religious Directives at Catholic Hospitals Complicate Emergency Care for Pregnant Women,” *PBS News*, April 2025, <https://www.pbs.org/newshour/show/religious-directives-at-catholic-hospitals-complicate-emergency-care-for-pregnant-women>.

<sup>426</sup> Quan and Lynch, *The High Costs of Language Barriers in Medical Malpractice*, 2010.

<sup>427</sup> Luciana E. Hebert et al., “Reproductive Healthcare Denials among a Privately Insured Population,” *Preventive Medicine Reports* 23 (2021): 1–6, <https://doi.org/10.1016/j.pmedr.2021.101450>.

<sup>428</sup> “Research on Religious Healthcare Institutions,” University of California San Francisco, accessed January 11, 2026, <https://www.ansirh.org/research/ongoing/research-religious-healthcare-institutions>.

<sup>429</sup> Chukwuemeka A. Umeh and Frank G. Feeley, “Inequitable Access to Health Care by the Poor in Community-Based Health Insurance Programs: A Review of Studies from Low-and Middle-Income Countries,” *Global Health Science and Practice* 5, no. 2 (2017): 299–314, <https://doi.org/10.9745/GHSP-D-16-00286>.

<sup>430</sup> Médard Nyandekwe, Manassé Nzayirambaho, and Jean Baptiste Kakoma, “Universal Health Insurance in Rwanda: Major Challenges and Solutions for Financial Sustainability Case Study of Rwanda Community-Based Health Insurance Part I,” *Pan African Medical Journal* 37, no. 55 (2020): 1–12, <https://doi.org/10.11604/pamj.2020.37.55.20376>.

the government has introduced a tiered premium system based on income levels, which could help more citizens afford insurance, some categories still cannot afford it.<sup>431</sup> This leads to self-medication, resulting in complications. In addition, as Adebayo et. al. indicate, poor quality of care is one of the issues of community-based health insurance schemes (CBHI) in low and middle-income countries (LMICs) that need to be addressed.<sup>432</sup> In the same vein, the Rwandan CBHI, generally available to nonprofessional working groups, does not cover all medications and healthcare services.<sup>433</sup> Additionally, the provision of poor-quality care and long queues for medical services among insured clients has been rampant in Rwanda.<sup>434</sup> This situation necessitates that subscribers incur significant out-of-pocket expenses for medications, like those who are not insured. Such limited coverage of CBHI schemes may discourage individuals from seeking timely medical care, potentially resulting in more severe health outcomes.

Moreover, the complex relationship between care providers and medical insurers exerts a profound influence on clinical decision-making, jeopardising patient-centered care.<sup>435</sup> Financial constraints imposed by insurers routinely curtail physicians' professional autonomy, compelling them to make choices guided more by cost-efficiency than by clinical necessity. For example, a patient referral that requires traveling a long distance from the patient's hospital to a specialised health facility could be denied if the insurer does not cover the ambulance bill. In addition, the doctor may fail to recommend tests or prescribe medication if the patient's insurance does not cover it, and the patient may incur out-of-pocket expenses.

The bureaucratic process of seeking approval from insurers for medications and clinical tests significantly impedes the efficiency of healthcare delivery.<sup>436</sup> This system not only interferes with physicians' autonomy in making medical decisions but also creates unnecessary delays in patient care delivery. The approval process is unpredictable because requests are potentially denied for various reasons, often prioritising financial aspects over medical necessity. This highlights a fundamental conflict between the profit-driven nature of insurance companies and the healthcare needs of patients.

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<sup>431</sup> Benjamin Chemouni, "The Political Path to Universal Health Coverage: Power, Ideas and Community-Based Health Insurance in Rwanda," *World Development* 106 (2018): 87–98, <https://doi.org/10.1016/j.worlddev.2018.01.023>.

<sup>432</sup> Esther F. Adebayo et al., "A Systematic Review of Factors That Affect Uptake of Community-Based Health Insurance in Low-Income and Middle-Income Countries," *BMC Health Services Research* 15, no. 1 (2015), <https://doi.org/10.1186/s12913-015-1179-3>.

<sup>433</sup> Nyandekwe, Nzayirambaho, and Kakoma, "Universal Health Insurance in Rwanda: Major Challenges and Solutions for Financial Sustainability Case Study of Rwanda Community-Based Health Insurance Part I."

<sup>434</sup> Mecthilde Mukangendo et al., "Factors Contributing to Low Adherence to Community-Based Health Insurance in Rural Nyanza District, Southern Rwanda," *Journal of Environmental and Public Health* 1 (2018): 1–8, <https://doi.org/10.1155/2018/2624591>.

<sup>435</sup> Hill et al., *Professional Responsibility: The Fundamental Issue in Education and Health Care Reform*.

<sup>436</sup> Aaron L Schwartz et al., "Measuring the Scope of Prior Authorization Policies: Applying Private Insurer Rules to Medicare Part B," *JAMA Health Forum* 2, no. 5 (2021): E210859, <https://doi.org/10.1001/jamahealthforum.2021.0859>.

The impact of this bureaucratic interference extends beyond simple delays. It can lead to suboptimal treatment plans if preferred medications or tests are not approved, forcing physicians to resort to less effective alternatives. This system also places an additional administrative burden on healthcare providers, diverting time and resources away from direct patient care. The profit-maximization mindset of insurers often clashes with the medical community's goal of providing the best possible care, creating a tension that ultimately affects patient outcomes and the overall quality of healthcare services.

The implications of tradeoffs in healthcare due to insurance are far-reaching. It extends beyond personal patient care and can create an environment that undermines the entire healthcare system. Indeed, when insurance entities interfere with medical decision-making and exert pressure on healthcare providers, it can trigger a series of adverse patient outcomes. Compromised diagnostic accuracy may result from limited access to necessary tests, while delayed interventions can occur when insurance approval processes slow down critical treatments. These factors, combined with the potential for substandard treatment outcomes due to cost-driven compromises, can significantly impact patient health and well-being.

Moreover, the pressure to prioritise cost-saving over providing the highest quality patient care may lead healthcare practitioners to become non-compliant and unethical. This not only compromises the safety of patients but also exposes healthcare professionals to potential lawsuits due to medical malpractice. With all these problems on the rise, patients' trust in their health care begins to decline,<sup>437</sup> and they might start to question the motives of healthcare providers, whether they are receiving the best possible care service or the most cost-effective one.

#### 4.4.12. Poor healthcare planning

Health care planning may have a profound impact on patient care and the quality of healthcare delivery in general. Patient-centred care provision can be dominated by practices like working on performance contracts, which require the public health facilities to work on daily quantitative care measures. This method puts efficiency above medical necessity; thus, it may undermine the quality of care and professional ethics. In this respect, the healthcare system must find a balance between efficiency in terms of volume (operations) and value (patient-centered care). Using quantitative metrics too much may result in a dehumanized approach where patients are treated as numbers, instead of human beings with specific medical needs. To resolve this concern, healthcare planners ought to integrate qualitative evaluations and patient feedback with quantitative information to make healthcare delivery more ethical and inclusive.

Moreover, this issue is complicated by the tension between the medical practitioners' professional rights and the obligation to protect the patients' rights. Although health professionals have a legitimate right to have their legal and ethical privileges acknowledged, they should also ensure

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<sup>437</sup> Hew Hei Choy and Aniza Ismail, "Indicators for Medical Mistrust in Healthcare—A Review and Standpoint from Southeast Asia," *Malaysian Journal of Medical Sciences* 24, no. 6 (2017): 5–20, <https://doi.org/10.21315/mjms2017.24.6.2>.

that these privileges do not disrupt their primary duty of providing quality care. In this balancing, both the needs of practitioners and patients must be considered carefully, and an ethical resolution to the delivery of healthcare must be maintained.<sup>438</sup> Managing these issues will require a more comprehensive healthcare plan that focuses on patient outcomes and respects the rights and responsibilities of medical professionals.

#### 4.4.13. Medical corruption

The WHO claims that corruption is one of the elements undermining the quality of healthcare. Medical corruption prioritises personal gain over patient care. The safety of the patients is at risk since they can undergo needless and detrimental treatment. Numerous forms of medical corruption, including donations, informal payments, bribery, fraud, political influence, research funding, and kickbacks, have been discovered at public health facilities through lobbying efforts, according to the literature.<sup>439</sup> These unethical practices paralyse many nations' healthcare systems, and Rwanda is no exception.<sup>440</sup> They have far-reaching effects that compromise health, including eroding trust, misusing public funding, and raising healthcare costs.<sup>441</sup> Furthermore, medical corruption can exacerbate medical negligence and malpractice, posing a serious risk to patient safety. For instance, the 2023 WHO technical paper documented maternal and child mortality rates to be high in countries with high levels of bribery, with an estimated 140,000 child deaths annually.<sup>442</sup>

A 2017 study by the Basel Institute on Governance on petty corruption in the Rwandan health sector found that certain forms of corruption, including bribery, favouritism, and gift-giving, were prevalent in the sector.<sup>443</sup> According to Transparency International Rwanda, there is a possibility of corruption in several areas related to the delivery of healthcare services. These include Ubudehe categorisation, patient transfers, medical appointments, medical examinations and prescriptions, medical supply chain and procurement, registration, licensing and inspection of health and

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<sup>438</sup> Olaolorunpo Olorunfemi et al., "Achieving A Balance between Ethical and Legal Obligations with Regard to Confidentiality and Patient Privacy," *Amrita Journal of Medicine* 20, no. 3 (2024): 90–93, [https://doi.org/10.4103/amjm.amjm\\_7\\_24](https://doi.org/10.4103/amjm.amjm_7_24).

<sup>439</sup> George J. Kontoghiorghes, "Ethics in Medicines: Exposing Unethical Practices and Corruption in All Sectors of Medicines Is Essential for Improving Global Public Health and Saving Patients' Lives," *Medicines* 8, no. 54 (2021): 2–4, <https://doi.org/10.3390/medicines8090054>.

<sup>440</sup> Marie-Anne Dushimimana, "Cabinet Sacks Entire Division at Rwanda Biomedical Centre for Causing Losses - The New Times," *The New Times*, 2018, <https://www.newtimes.co.rw/article/157143/News/cabinet-sacks-entire-division-at-rwanda-biomedical-centre-for-causing-losses>.

<sup>441</sup> Anas M. Al Quadah, Lara Al-haddad, and Alan A. A. Aljabali, "Combatting Medical Corruption: A Global Review of Root Causes, Consequences, and Evidence-Based Interventions," *International Journal of Innovative Research and Scientific Studies*, 2025, 970, 975.

<sup>442</sup> "Tackling Corruption to Move towards Universal Health Coverage and Health Security," 2023, <https://www.who.int/publications/m/item/tackling-corruption-to-move-towards-universal-health-coverage-and-health-security>.

<sup>443</sup> Claudia Baez-Camargo et al., "Behavioural Influences on Attitudes towards Petty Corruption: A Study of Social Norms, Automatic Thinking and Mental Models in Rwanda," *Basel Institute on Governance*, no. December (2017): 11–12, [https://edoc.unibas.ch/66325/1/20181029120145\\_5bd6e8995192b.pdf](https://edoc.unibas.ch/66325/1/20181029120145_5bd6e8995192b.pdf).

pharmaceutical facilities, clinical trials, drug registration, and authorisation.<sup>444</sup> In addition, Transparency International Rwanda further notes that corruption in Rwanda's healthcare human resource services may likely result in the hiring of underqualified workers, which could have adverse health outcomes.<sup>445</sup>

Establishing strong regulatory measures, implementing strong risk assessments in healthcare organisations, and implementing an integrated multi-stakeholder anti-corruption model are some strategies to combat medical corruption.<sup>446</sup> These strategies aim to enhance collaboration among health regulatory bodies, the national health observatory, and other key health stakeholders. This approach could enable relevant institutions to gather information and tailor suitable mechanisms to address medical corruption, enhancing transparency, accountability, and ethical conduct in medical practice. Transparency International Rwanda recommends several strategies for combating medical corruption in Rwanda's healthcare system, including government audits, integrity training, anonymous reporting of corruption, the adoption of electronic systems to minimise human intervention, and the establishment of independent oversight mechanisms. To address this crucial issue, the WHO recommends that governments implement measures for anti-corruption, transparency, and accountability (ACTA).<sup>447</sup>

#### 4.5. Effects of medical malpractice and negligence

Medical malpractice incidents have enormous and far-reaching consequences for patients,<sup>448</sup> their families, health care professionals, the healthcare system, and the community at large. Beyond the physical pain and emotional distress, individuals often experience considerable financial costs. The human and financial costs of medical errors, including compensation, legal proceedings, and reparation of damages, constitute a heavy burden on the nation. Over time, they can impede overall progress and development. The following discussion outlines those consequences.

##### 4.5.1. Effects on patients and their families

###### 4.5.1.1. Loss of human lives

One of the overwhelming and irreparable effects of medical error is death, whether as a direct outcome or an indirect result of complications. Medical negligence and malpractice accelerate the mortality rate. This has a severe impact on the families, as losing their loved ones impairs their ability to nurture the family. These are compounded by financial hardships associated with unexpected funeral costs and a potential loss of income from the deceased. Additionally, the

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<sup>444</sup> Transparency International Rwanda, "Corruption Risk Assessment of the Health Sector in Rwanda" (Kigali, Rwanda, 2013), p. 18.

<sup>445</sup> Transparency International Rwanda, "Corruption Risk Assessment of the Health Sector in Rwanda" (Kigali, Rwanda, 2013), p. 17.

<sup>446</sup> "Understanding Healthcare Fraud: A Growing Challenge," Alessa, 2025, <https://alessa.com/blog/healthcare-fraud/>.

<sup>447</sup> Theadora Koller, David Clarke, and Taryn Vian, "Promoting Anti-Corruption, Transparency and Accountability to Achieve Universal Health Coverage," *Global Health Action* 13, no. sup1 (2020), <https://doi.org/10.1080/16549716.2019.1700660>.

<sup>448</sup> Madelene J. Ottosen et al., "Long-Term Impacts Faced by Patients and Families after Harmful Healthcare Events," *Journal of Patient Safety* 17, no. 8 (2021): E1145–51, <https://doi.org/10.1097/PTS.0000000000000451>.

emotional toll on families can be devastating and long-lasting. Survivors may experience feelings of anger, betrayal, and distrust towards the healthcare system.<sup>449</sup> Although it seems impossible to quantify the impacts of medical errors in Rwanda, this range of effects underscores their broad impact on both personal and societal levels when they result in death.

#### *4.5.1.2. Iatrogenic injuries*

Patients may experience chronic pain and complications resulting from medical errors such as misdiagnosis, incorrect dosage, or surgical error. When these effects or complications are directly resulting from medical intervention, they are iatrogenic injuries.<sup>450</sup> Although not all iatrogenic injuries are negligent, some injuries are preventable and unacceptable.

#### *4.5.1.3. Emotional and psychological distress*

Medical malpractice can result in emotional and psychological distress, including anxiety, depression, and post-traumatic stress disorder (PTSD).<sup>451</sup> Survivors of medical errors can have resentment toward the healthcare system stemming from their past traumatic experience. These effects often persist long after physical injuries have healed, significantly impairing the patient's quality of life.<sup>452</sup>

While the psychological effects of medical malpractice on individual patients are profound, they often extend to their families, who bear the burden of accompanying their loved ones with social and financial support.

A multidimensional approach to support victims of medical malpractice is essential for their recovery and well-being. Family therapy is essential to repair the relationship strain and enhance communication between victims and their relatives throughout the recovery process. Besides, establishing support groups and counseling services specifically tailored for medical malpractice survivors can play a vital role. These services can provide a safe environment for sharing experiences, gaining valuable insights and practical advice, and learning coping strategies from peers who have faced similar issues. Although these support services are essential for patients and families, educating healthcare professionals about the psychological impact of malpractice is equally essential for creating a more compassionate system of care.

#### *4.5.1.4. Reduced quality of life*

Due to the physical and psychological ramifications resulting from the medical errors, the survivors' ability is significantly impaired so that they cannot perform their daily activities or

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<sup>449</sup> Ottosen et al.

<sup>450</sup> Larry Schlachter, "Iatrogenic Injury and Medical Negligence," accessed October 14, 2025, <https://www.schlachterlaw.com/blog/iatrogenic-injury-and-medical-negligence/>.

<sup>451</sup> "Emotional and Psychological Impact of Medical Malpractice on Patients," Malchow Johnson Injury Lawyers, accessed October 14, 2025, <https://nmjfirm.com/medical-malpractice/emotional-and-psychological-impact-of-medical-malpractice-on-patients/>.

<sup>452</sup> "Emotional and Psychological Impact of Medical Malpractice on Patients."

maintain their lifestyle. As a result, they frequently rely on external support to continue their life journey, which may necessitate continued medical and social care throughout their lifetime.

Such caregiving demands can substantially change family dynamics, introducing additional household roles and responsibilities that may lead to social and financial stress. Family members consider the affected individuals a burden, as the latter might also feel useless and a burden to them. These challenges, coupled with initial trauma, may deteriorate survivors' mental health and complicate their recovery.

#### *4.5.1.5. Prolonged hospital stays and readmissions*

Complications resulting from medical errors, in most cases, necessitate an extension of hospitalization or readmission.<sup>453</sup> For example, when a patient experiences an adverse event due to a medical error, such as misdiagnosis, mistreatment, or incorrect medication, their hospital stay will be extended for further interventions, monitoring, or surgical procedures until they are well diagnosed, treated, or transferred to another hospital. If it is outpatient, she is likely to return for hospital admission for further interventions, which is also a risk factor for further harm to patients.<sup>454</sup>

Shazia Mehmood Siddique and Kelley Tipton highlight the potential trade-offs between reducing hospital length of stay and the risk of post-discharge adverse outcomes, such as readmissions and mortality. Consequently, they advocate for comprehensive discharge planning and multidisciplinary care as appropriate strategies to mitigate extended hospitalizations, particularly for individuals affected by medical malpractice.<sup>455</sup>

The prolonged hospital stays and frequent readmissions increase the healthcare costs and undermine the patient's trust in the healthcare providers. Addressing these issues requires a thorough mechanism of quality assurance, improved diagnostic protocols, and communication among healthcare providers.

#### *4.5.1.6. Economic impact (extra healthcare cost)*

Medical malpractice not only physically and emotionally affects the victims, but also financially.<sup>456</sup> The cost of additional medical care related to hospital stay and corrective procedures while treating the iatrogenic injuries or getting the rehabilitation services is a heavy burden on the

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<sup>453</sup> Lydia E. Pace et al., "Delays in Breast Cancer Presentation and Diagnosis at Two Rural Cancer Referral Centers in Rwanda," *The Oncologist* 20, no. 7 (2015): 780–88, <https://doi.org/10.1634/theoncologist.2014-0493>.

<sup>454</sup> Katie E. Raffel et al., "Prevalence and Characterisation of Diagnostic Error among 7-Day All-Cause Hospital Medicine Readmissions: A Retrospective Cohort Study," *BMJ Quality and Safety* 29, no. 12 (2020): 971–79, <https://doi.org/10.1136/bmjqs-2020-010896>.

<sup>455</sup> Shazia Mehmood Siddique et al., "Interventions to Reduce Hospital Length of Stay in High-Risk Populations A Systematic Review," *JAMA Network Open* 4, no. 9 (2021): E2125846, <https://doi.org/10.1001/jamanetworkopen.2021.25846>.

<sup>456</sup> Bryan Driscoll, ed., *Medical Malpractice Statistics of 2025, 2024*, <https://www.consumersshield.com/articles/medical-malpractice-statistics>.

victim and the family. The issue is exacerbated when malpractice results in chronic conditions or permanent disability.

Beyond the direct costs related to care demands, another high cost is malpractice claims, which involve a lengthy litigation process, expert testimony, legal representation, and administrative costs. The financial impact of medical malpractice is extensive, as affected individuals experience a loss of income, which impoverishes them and places them in dependency on public assistance programmes. Their families experience financial hardship due to caregiving responsibilities and related expenses. These expenses constitute a broader impact of medical malpractices, which need to be addressed by different stakeholders in the healthcare sector with a multidimensional approach.

#### 4.5.2. Effects on the healthcare providers

##### 4.5.2.1. Professional consequences

Malpractice incidents can have significant effects on the healthcare providers' profession.<sup>457</sup> When a medical practitioner or dentist is involved in a negligence or malpractice case, they may face a range of professional consequences, such as disciplinary actions, which can even result in dismissal, and legal liability.<sup>458</sup> For example, depending on the gravity of the fault, the Bureau of the National Council Board of RMDC can impose disciplinary actions varying from a warning to removal from the register of the council members for light faults that do not endanger the life of the patient or the dignity of the medical profession. Beyond those professional sanctions, healthcare providers may also suffer from reputation damage, career disruption, and psychological distress, which can significantly affect their professional lives.<sup>459</sup>

##### 4.5.2.2. Changes in practice/ defensive medicine

By avoiding medical negligence and malpractice incidents and their related consequences, medical providers change their clinical practice, which can lead to either positive or negative outcomes in defensive medicine.<sup>460,461,462,463</sup> Thus, they either order unnecessary tests, procedures, or referrals or avoid high-risk patients and procedures that could result in malpractice litigation. Such a change

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<sup>457</sup> Prinsen, "The Leading Causes of Medicolegal Claims and Possible Solutions."

<sup>458</sup> Saad Dahlawi et al., "Medical Negligence in Healthcare Organizations and Its Impact on Patient Safety and Public Health: A Bibliometric Study," *F1000Research* 10 (2021): 1–12, <https://doi.org/10.12688/f1000research.37448.1>.

<sup>459</sup> Mahmoud Ali and Branden Tejada, "Medical Malpractice's Impacts and Simulation Training's Ability to Diminish Its Effects: A Systematic Review," *The Egyptian Journal of Internal Medicine* 36, no. 1 (2024): 1–4, <https://doi.org/10.1186/s43162-024-00285-w>.

<sup>460</sup> Michelle M. Mello et al., "Malpractice Liability and Health Care Quality," *Physiology & Behavior* 323, no. 4 (2017): 353–65, <https://doi.org/doi:10.1001/jama.2019.21411>.

<sup>461</sup> Junyao Zheng et al., "Prevalence and Determinants of Defensive Medicine among Physicians: A Systematic Review and Meta-Analysis," *International Journal for Quality in Health Care* (OUP Publishing, 2023), <https://doi.org/10.1093/intqhc/mzad096>.

<sup>462</sup> Rana Can Özdemir et al., "Factors Affecting Physician Fear of Malpractice and Defensive Medicine Practices: A Cross-Sectional Study," *Journal of Academic Research in Medicine* 14, no. 2 (2024): 77–83, <https://doi.org/10.4274/jarem.galenos.2024.52386>.

<sup>463</sup> Mohammad Hossein Eftekhari et al., "Exploring Defensive Medicine: Examples, Underlying and Contextual Factors, and Potential Strategies - a Qualitative Study," *BMC Medical Ethics* 24, no. 1 (2023): 1-4,13-20, <https://doi.org/10.1186/s12910-023-00949-2>.

may lead to financial strain due to overutilization of resources. It also includes the refusal of care in complex cases, which reduces access to care for vulnerable people. In addition, the physician may consider patients as future potential plaintiffs and focus on record-keeping and the informed consent process rather than the actual case to treat.<sup>464</sup> Such a change of behaviour always results from the fear of professional and institutional pressure to avoid legal consequences.

#### 4.5.3. Effects on the healthcare system and the community

Medical malpractice incidents can affect the healthcare system and broader community in different ways, such as disrupting care and justice delivery, eroding public trust, and escalating healthcare costs.<sup>465</sup>

##### 4.5.3.1. Burden on the legal system

Medical malpractice litigation is complex and requires expert testimony and thorough documentation, which contributes to the backlog of the legal system, delaying the administration of justice. In addition, malpractice proceedings also involve substantial time and financial costs for both plaintiff and defendant, as well as the judicial organ. As a result, an increase in malpractice lawsuits is a contributing factor to court backlog, which delays justice.

##### 4.5.3.2. Increased cost and erosion of public trust

As previously discussed, the change of clinical practice into defensive medicine, where clinical decisions are mainly influenced by the risk of litigation rather than the patients' needs, accelerates the financial burden on the threefold aspects: medical providers, care services users, and the healthcare system. This can affect vulnerable populations, as some essential services could be excluded to avoid future litigation. Besides, medical errors can result in long-term health consequences affecting the quality of life, prompting the affected families who suffered both psychological trauma and financial burden from either medical complications or legal proceedings to lose confidence in healthcare organisations.

##### 4.5.3.3. Influence on healthcare access and cultural behavioral shift

When the burden of medical malpractice incidents is significant on healthcare consumers and care providers, it often leaves room for searching for alternatives. Beyond its immediate impacts on individual patients and healthcare providers, medical malpractice has broader well-being effects that may influence healthcare access and accelerate behavioral shifts within the community.

Frequent medical malpractice can exacerbate the disparities in healthcare access, particularly in the underserved and remote areas. For example, where malpractice is frequent, healthcare providers may relocate or retire to avoid high litigation costs or insurance costs, which may create “medical deserts,” areas with limited or no access to essential medical services. This phenomenon

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<sup>464</sup> Marta Vizcaino-Rakosnik et al., “The Impact of Malpractice Claims on Physicians’ Well-Being and Practice,” *Journal of Patient Safety* 18, no. 1 (2020): 45–51, <https://doi.org/10.1097/PTS.0000000000000800>.

<sup>465</sup> Sarah Lee, “The Impact of Malpractice on Healthcare: Analyzing the Effects of Medical Negligence on Patients and Providers,” *Number Analytics*, May 2025, <https://www.numberanalytics.com/blog/impact-malpractice-healthcare>.

undermines equitable healthcare delivery and may lead to a cultural and behavioral shift, where people develop a culture of hyper-vigilance and skepticism. Patients may start to second-guess medical advice or seek alternative treatments that are often unverified, such as non-registered traditional healers, or opt for a self-medication lifestyle. Such a culture can significantly result in an increased rate of morbidity and mortality due to misdiagnosis and drug misuse.

#### **4.6.Conclusion**

This chapter has covered the forms, contributing factors, and effects of medical malpractice incidents in Rwanda, as well as the institutions involved in handling related complaints. The analysis of medical malpractice cases summarised in this section has revealed persistent challenges in healthcare accountability, which undermine public trust and compromise the quality of care provided to healthcare service users. Malpractice cases of professional negligence, ranging from delayed or inadequate medical attention leading to fetal death and permanent disability to critical errors during labor and surgical complications, underscore systemic vulnerabilities in healthcare delivery. In addition, other problems like anesthesia-induced hypoxia, absence of essential drugs, and even the use of incompetent staff in clinical practice justify the critical shortage in the enforcement of clinical guidelines and resource allocation. Such incidents cause physical, economic, and psychological harm to patients. They also call for timely medical intervention to prevent these adverse outcomes.

Although negligence and harm to patients are evident, obtaining compensation remains challenging due to a fault-based system, which typically requires a guilty conviction against the defendant to obtain compensation. This model generally places a heavy burden of proof on the plaintiffs, leaving the victims of medical malpractice without an adequate remedy. The issues of professional negligence, patient harm, and gaps in healthcare accountability impose a re-examination of the current medical and legal frameworks to ensure patient safety and justice. This will enable a reduction of both individual practitioners' actions and systemic weaknesses, as outlined in Human Error Theory.

## CHAPTER FIVE

### LEGAL AND REGULATORY FRAMEWORK OF MEDICAL PRACTICE IN RWANDA

This Chapter discusses the Rwandan legal and regulatory framework for medical practice. This legal framework, underpinned by numerous laws, regulations, and codes of ethics, outlines the obligations of healthcare practitioners, the rights and obligations of the healthcare user, and the scope of the roles of the key institutions in healthcare to protect safety. The Chapter outlines how the legal framework is designed to enhance the quality of care, protect the rights of patients, incentivize ethical and legal compliance in practice, and provide accountability for the practitioner. It also outlines the complaint pathways and institutional process in justice delivery to the victim of medical malpractice.

Despite significant achievements in the regulatory context, this Chapter outlines ongoing deficiencies in enforcement, process, and scope that undermine effective implementation. In an in-depth analysis of Rwanda's medico-legal landscape, key legal provisions regarding patient safety, ethical standards in clinical practice, institutional responsibilities, and remedial avenues for healthcare users are connected to the discussion. The Chapter also highlights other areas for reform to foster a more transparent, accountable, and patient-centered healthcare system.

#### 5.1. Overview of the legal and regulatory framework on medical practice in Rwanda

Rwanda has made significant efforts to establish a legal and regulatory framework to enhance the quality of healthcare and harmonise service delivery across public and private providers. Various legal reforms and regulatory initiatives prove such a commitment to strengthening the healthcare system. These include the recent enactment of the healthcare law in 2025, as well as the standardisation and regulation of health facilities in 2022.<sup>466</sup> Adding to that, the issuance of standards for health professional training institutions in 2022,<sup>467</sup> as well as the introduction of pharmaceutical service accreditation standards and performance assessment tools in 2020, this constitutes another step forward. Additionally, integrating reporting systems and inspection protocols across private and public healthcare providers has been another key action to promote data-driven decision-making and accountability. The framework not only upholds patients' rights and safety but also promotes efficiency and accountability in clinical practice. This is under Rwanda's strategic vision to strengthen the health system's resilience during crises and health emergencies,<sup>468</sup> and build an equitable and high-performing healthcare system.

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<sup>466</sup> “Ministerial Instructions No. 20/0002 of 11/10/2022 Governing Private Health Facilities” (2022).

<sup>467</sup> Ministry of Health (MINISANTE) and Ministry of Education (MINEDUC), “Health Professionals Training Institutions Standards in Rwanda” (Kigali, Rwanda, 2022).

<sup>468</sup> Muhammad Arslan Ghaffar et al., “Research on Vehicle-UAV Integrated Routing Optimization Problem to Deliver Medical Supplies,” *Electronics* 3, no. 18 (August 2, 2024): 2, <https://doi.org/https://doi.org/10.3390/electronics13183650>.

Modern medicine is supplemented by traditional medicine, complementary, and alternative medicine.<sup>469</sup> The legal framework for medical practice is designed to ensure the delivery of healthcare services, ethical practice, and the safety of patients and other care service users. In this regard, several laws and regulations, as well as key regulatory bodies, shape the framework. Among others, the statutes establishing major institutions in health care such as the RMDC, NCMC, RAHPC, the Rwanda FDA, and the RBC, play a critical role in defining the standards for medical practitioners. These regulatory bodies, among others, ensure compliance with professional ethics, protect public health, and contribute to the continuous improvement of medical services countrywide.

Besides, the Rwanda FDA has begun to regulate complementary and alternative medicine; however, there are still many issues and, consequently, many malpractices in this field. This necessitates the establishment of a supervisory council and regulatory reform.<sup>470</sup> According to the literature, traditional herbal medicine (THM) is used by many people in sub-Saharan African countries, including Rwanda,<sup>471</sup> in place of modern medication, which leads to a high prevalence of antibiotic resistance.<sup>472</sup> One of the causes is the regulatory offices' inefficiency in regulating THM, which is influenced by a number of factors, including a lack of suitable mechanisms to control THM practices and products, a lack of public support, a lack of legislative enforcement, a lack of financial and human resources, and a lack of basic THM regulatory tools.<sup>473</sup>

Medical professional liability law is the foundation of medical practice, ensuring accountability and protection for practitioners and patients. Although this law lacked an implementing mechanism, it requires healthcare professionals to maintain a coverage policy that provides compensation for patients in cases of negligence, error, or malpractice to minimise the risk in their practice. In addition, the law also safeguards the fundamental rights and freedoms of patients and clearly stipulates the obligation of healthcare professionals in cases of malpractice or negligence that result in harm to patients or other healthcare users.

Moreover, the law establishes a formal compensation scheme under which injured patients can seek redress for harm suffered. Apart from court action, the law provides for ADR through Committees for Conciliation and Compensation for Health Risks at the district and national levels, and court referral, where necessary. Lastly, it provides rigorous supervisory controls to enforce

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<sup>469</sup> Ministry of Health of Rwanda, "Health Sector Policy" (Kigali, 2015), p. 11-12.

<sup>470</sup> Linda M. Kagire, "The Resurgence of Traditional Medicine in Rwanda and Its Impact on Healthcare," *The New Times*, 2025, <https://www.newtimes.co.rw/article/25304/news/health/the-resurgence-of-traditional-medicine-in-rwanda-and-its-impact-on-healthcare>.

<sup>471</sup> Mengxin Tan et al., "Local Experience of Using Traditional Medicine in Northern Rwanda: A Qualitative Study," *BMC Complementary Medicine and Therapies* 21, no. 1 (2021): 1–9, <https://doi.org/10.1186/s12906-021-03380-5>.

<sup>472</sup> Sileshi Dubale et al., "Traditional Herbal Medicine Legislative and Regulatory Framework: A Cross-Sectional Quantitative Study and Archival Review Perspectives," *Frontiers in Pharmacology* 16, no. January (2025): 2–20, <https://doi.org/10.3389/fphar.2025.1475297>.

<sup>473</sup> Dubale et al., p. 16.

compliance with medical liability standards, ensuring adherence to ethical and professional standards.

In the same vein, Rwanda recently enacted the healthcare law that strengthens and expands liability insurance coverage across both the public and private healthcare sectors.<sup>474</sup> The law requires employers to contribute to insurance premiums to help resolve medical disputes.<sup>475</sup> While explicitly excluding criminal acts like sexual abuse from its scope, the legislation sets a five-year deadline for filing malpractice claims.<sup>476</sup> It also adopts a proportional liability approach in cases involving multiple parties.<sup>477</sup> This legal framework addresses the growing complexity and demand in Rwanda's health sector, which is experiencing significant expansion in areas such as medical tourism and specialised services.

The healthcare law constitutes a significant step toward unifying the legal framework with international health standards. However, it could succeed only through practical implementation and the development of institutional capacity. Thus, it consolidates various new health issues that require new skills in both medical and judicial settings. In addition, building strong regulatory enforcement mechanisms is crucial to its success. Besides, public awareness of patient rights is essential in a patient-centred healthcare service delivery.

The regulatory framework of medical practice is based on various policies, including but not limited to the National Strategy for Transformation (NST2), United Nations' Sustainable Development Goals (SDGs), Health Sector Policy 2015, Health Sector Strategic Plan V (HSSP V), Health Sector Strategic Plan IV (HSSP IV), Vision 2050, under which medical practice in Rwanda is underpinned.

One of the pillars of the first National Strategy for Transformation (NST1) is the social transformation. Under this pillar, the strategic interventions were outlined to bring positive change to the people's lives. Among those strategies, ensuring quality health for all, improving health care services at all levels, enhancing the financial sustainability of the health sector, and increasing the capacity of the health workforce were noted.<sup>478</sup> The fifteenth strategic intervention, among others, aims to reach the first of seven priority areas set to deliver the targeted objectives of NST1. This involves supporting the establishment and operationalisation of new and existing centres of excellence, focusing on various sectors, including health. In this regard, the reports on health sector policy actions for the 2022/23 and 2023/2024 fiscal years indicated the following areas needing key policy actions for improvement, including citizen satisfaction with service delivery in the

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<sup>474</sup> “Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services” (2025).

<sup>475</sup> *Ibid.*, Art. 81, par. 2.

<sup>476</sup> *Ibid.*, Art. 107

<sup>477</sup> Emmanuel Ntirenganya, “Parliament Revives Push for Mandatory Medical Liability Insurance,” *The New Times*, August 2025, <https://www.newtimes.co.rw/article/28626/news/health/parliament-revives-push-for-mandatory-medical-liability-insurance>.

<sup>478</sup> “7 Years Government Programme: National Strategy for Transformation (NST1) 2017-2024” (Kigali, 2017).

Health sector.<sup>479,480</sup> Several policy initiatives were proposed to achieve this, including enhancing the efficient and effective delivery of health services at all levels. Other measures include strengthening client feedback systems such as the Patient Satisfaction Survey, Civilian Voice, and Patient Voice Program, and ensuring that all hospital standards, regulations, and procedures are adhered to.<sup>481</sup>

The Rwanda Vision 2050 (The Rwanda We Want) aims to achieve prosperity and a high quality of life and standards for all Rwandans.<sup>482</sup> According to this vision, everyone will have unconstrained access to fair, high-quality healthcare that meets their needs and is without financial hardship. Similarly, among other focuses, the NST2 and the HSSP V aim to enhance healthcare quality.<sup>483</sup> Within this framework, Rwanda has made significant strides in improving healthcare services. For example, the data from the HSSP V indicate that there was a big move in improving various health aspects, including reducing maternal mortality, reducing under-five mortality, stunting among children, and modern contraceptive use.<sup>484</sup>

## 5.2. General foundations of medical ethics and standards of care

Efforts to standardise medical practice have, for centuries, been a bid to improve patient safety. Medical malpractice and negligence have been a concern since medieval times, reflecting the inherent fallibility of human nature. Research indicates that *Stratton v. Swanlond*, recorded in 1374, was the first documented case of medical malpractice, underscoring the longstanding challenges of accountability in healthcare.<sup>485</sup> In this case, a patient's mangled hand was untreated, leading to a petition against the physician for breach of contract. The court did not rule in favour of the plaintiff, but this precedent is thought to have established central principles for medical negligence. Subsequently, a court in London decided a medical malpractice case in 1377, where the physician, Richard Chayndut, was found guilty of failing to properly treat a patient's leg wound that deteriorated due to a lack of expert guidance. In that case, three expert surgeons testified that the patient's leg could have been preserved if specialist assistance had been available.<sup>486</sup> Later in 1794, *Cross v. Guthery* was recorded in Connecticut as the first medical malpractice litigation in the United States. Since then, only twenty-seven lawsuits had been registered by 1861.<sup>487</sup>

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<sup>479</sup> “FY 2023/2024 Forward-Looking Joint Health Sector Review Report” (Kigali, 2023), p.13.

<sup>480</sup> “FY 2022/2023 Forward-Looking Joint Health Sector Review Report” (Kigali, 2022), p.5-9.

<sup>481</sup> “Five Years Government Programme: National Strategy for Transformation (NST 2) 2024-2029” (Kigali, 2024), p. 5-9.

<sup>482</sup> “Rwanda Vision 2050” (Kigali, 2015), p. 7-8.

<sup>483</sup> “Five Years Government Programme: National Strategy for Transformation (NST 2) 2024-2029” (Kigali, 2024), p. 28.

<sup>484</sup> MoH-Rwanda, “Health Sector Strategic Plan” (Kigali, 2024).

<sup>485</sup> L. Kearney et al., “Influence of Socioeconomic Factors on Litigation in Surgery: Addressing the Gap in Malpractice Literature,” *Journal of Plastic, Reconstructive and Aesthetic Surgery* 73, no. 2 (2020): 376–77, <https://doi.org/10.1016/j.bjps.2019.09.030>.

<sup>486</sup> Madeleine Pelter Cosman, “Medieval Medical Third Party: Compulsory Consultation and Malpractice Insurance” (New York: Little, Brown and Company, 1981).

<sup>487</sup> Robert J. Flemma, “Medical Malpractice: A Dilemma in the Search for Justice,” *Marquette Law Review* 68, no. 2 (1985): 237–41.

Furthermore, Justin and Robert underscore that some unskilled practitioners abused the medical practice in London, which prompted the City of London to regulate the surgeons' practice with professional rules and robust enforcement mechanisms.<sup>488</sup> These mechanisms entailed medical inspections, reporting medical faults to the mayor and council members (aldermen), and a licensing process that involved examining professional competence. Medical dishonesty was punishable by a fine and the withdrawal of a license. As a result, the London surgical governance was later considered to ensure professional ethics and consumer protection.<sup>489</sup>

The legal investigation reveals that a medical malpractice claim is essentially the same as a negligence claim.<sup>490</sup> However, by adopting extensive rules, doctrines, and principles applicable to the common law, the nineteenth-century courts generated misunderstandings regarding these features.

Since the eighteenth century, the standards of care in the medical sector have evolved. Substantial scientific discoveries aided the industry's shift from conventional to modern medicine.<sup>491</sup> Scientific and technological advancements have transformed the medical profession into a complex field that demands qualified labour. However, they increased the adaptability of high-risk medical procedures, making them more likely to succeed than low-risk ones but more likely to fail. Also, due to concerns about human rights, medical innovation necessitated systems that did not tolerate the employment of subpar healthcare providers to protect patients' safety. These systems established the guidelines that paved the way for medical malpractice and negligence claims. The concept of medical liability originated from the notion that if medical personnel were held accountable for their malpractice or negligence, they would be more likely to implement the necessary safety measures to enhance healthcare delivery.

### 5.2.1. Core principles governing medical practice

Physicians' adherence to *primum non-nocere* (first, do no harm), also known as non-maleficence, has been at the core of their professional practice.<sup>492</sup> This ethical principle requires healthcare providers to prevent harm by avoiding negligence, unnecessary procedures, and high-risk treatments that could jeopardise patient well-being.<sup>493</sup> In other words, non-maleficence guides

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<sup>488</sup> Justin Colson and Robert Ralley, "Medical Practice, Urban Politics and Patronage: The London 'Commonalty' of Physicians and Surgeons of the 1420s," *English Historical Review* 130, no. 546 (2015): 1105, <https://doi.org/10.1093/ehr/cev261>.

<sup>489</sup> Cosman, "Medieval Medical Third Party: Compulsory Consultation and Malpractice Insurance."

<sup>490</sup> Theodore Silver, "One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice," *Wisconsin Law Review* 1193, no. 4 (1992): 1196.

<sup>491</sup> Christopher McFadden, "15 Medical Inventions And Discoveries of the 1800's That Have Come to Define Modern Medicine," May 2018, <https://interestingengineering.com/health/15-medical-inventions-and-discoveries-of-the-1800s-that-have-come-to-define-modern-medicine>.

<sup>492</sup> James M. Katz, "Understanding Non-Maleficence in Health Care Ethics – AIHCP," *American Institute of Healthcare Professionals*, September 2024, <https://aihcp.net/2024/09/10/understanding-non-maleficence-in-health-care-ethics/?form=MG0AV3>.

<sup>493</sup> Junya Zhou et al., "Moral Dilemmas Regarding Physical Restraints in Intensive Care Units: Understanding Autonomy, Beneficence, Non-Maleficence and Justice in the Use of Physical Restraints," *Journal of Multidisciplinary Healthcare* 17 (2024): 1621, <https://doi.org/10.2147/JMDH.S455910>.

healthcare practitioners to carefully evaluate the potential risks and benefits of all interventions, ensuring treatments do not impose unnecessary burdens while prioritising the best course of action for the patient's overall well-being.<sup>494</sup>

The literature indicates that surgeons could be liable for harming or killing a patient while performing surgery, per the Code of Hammurabi from ancient Babylon, dating to 1754 BCE.<sup>495</sup> For instance, a careless surgeon might lose both hands if the surgery results in permanent injury. Besides, in the fifth century BCE, Roman Law (the Twelve Tables) was strict on personal liability. Under this law, compensation for patient harm was precise. The one who has broken the bone of a freeman was subjected to the Talion law (*lex talionis*<sup>496</sup>) and should pay 300 asses unless they mutually solve the issue.<sup>497</sup> If the victim is enslaved, he should pay 150 asses. However, this later evolved to include the arbitrators who could consider various factors to determine the amount of compensation, including the circumstances and the victim's rank.<sup>498</sup>

The Greek physician, Hippocrates of Cos, instilled medical ethics in the Ancient Greeks in the fifth century BCE (-460 to -370).<sup>499</sup> Since then, physicians have been compelled to take an oath known as the "Hippocratic Oath" to practise their profession and follow medical ethics. Several jurisdictions still employ this custom as a means to assist medical students in transitioning from study to practice.

For the first time, the duty “to aid” and “do no harm” were articulated in *Epidemic I*, the earliest book to address medical ethics. Under this book, ailment, patient, and physician are the three foundations of medicine. The patient is expected to collaborate with the doctor to treat their illness, although the doctor is a servant of the art. In the author's opinion, a competent physician can distinguish between a deadly disease and one that can be treated. For that reason, people will respect him and give their lives to him for medical care.<sup>500</sup>

At the time, Romans used the Latin terms *dolus* and *culpa* to distinguish between two malpractice scenarios.<sup>501</sup> *Dolus*, in this context, alludes to the evil purpose or willful mind, whereas *culpa* combines negligence and clumsiness. In the second situation, a doctor who could practise a medical specialism about which he is uneducated might ultimately lose his ability to practice

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<sup>494</sup> Katz, “Understanding Non-Maleficence in Health Care Ethics – AIHCP.”

<sup>495</sup> Flemma, “Medical Malpractice: A Dilemma in the Search for Justice.”

<sup>496</sup> The *lex talionis* is underpinned by the concept of “*the eye for an eye, tooth for a tooth*”.

<sup>497</sup> David Ibbetson, “Wrongs and Responsibility in Pre-Roman Law,” *Journal of Legal History* 25, no. 2 (2004): 113, <https://doi.org/10.1080/0144036042000276902>.

<sup>498</sup> P. S. Barnwell, “The Past and Present Society Emperors, Jurists and Kings: Law and Custom in the Late Roman and Early Medieval West,” *Oxford University Press* 168, no. 168 (2020): 15–16, <https://www.jstor.org/stable/651304>.

<sup>499</sup> Albert R. Jonsen, *A Short History of Medical Ethics*, The Lancet, vol. 336 (Oxford: Oxford University Press, 2000), p.1-3.

<sup>500</sup> *Ibid.*, p. 27.

<sup>501</sup> Bodenstein H.DJ., “Phases in the Development of Criminal Mens Rea,” *South African Law Journal* 36 (1919): 326–27, 330–31, <http://www.lareau-law.ca/Bodenstein.pdf>.

medicine. In this instance, it is believed that the doctor abused his profession, and once he caused injury, he must be punished.

Another core principle aligned with non-maleficence is beneficence. This is also the foundation of medical ethics, emphasising the duty of healthcare professionals to act in the best interests of their patients.<sup>502</sup> It mandates healthcare professionals to prioritise patient well-being by actively promoting health and preventing harm. This principle is rooted in Hippocratic tradition and evolves with medical progress. It guides clinical decisions, balancing risks and benefits to enhance patient outcomes and navigate complex ethical challenges.<sup>503</sup> Although non-maleficence and beneficence are two distinct principles, they work in tandem to prevent harm and improve the well-being of patients or other healthcare users.<sup>504</sup>

Besides, the principle of autonomy in medical practice underscores a patient's right to make informed healthcare decisions, even when those choices diverge from their clinician's recommendations.<sup>505</sup> It constitutes a foundational tenet of medical ethics, ensuring individuals' control over their treatment choices, free from coercion or undue influence. It also goes hand in hand with other principles, such as non-maleficence and beneficence. It is also related to the normative theory of utilitarianism.<sup>506</sup>

This principle gained prominence in medical ethics following the Nuremberg Trials, which highlighted the importance of voluntary consent in medical research.<sup>507</sup> Today, it plays a crucial role in patient-centred care, ensuring respect for individual rights and dignity in healthcare decisions. Consequently, upholding patient autonomy is essential for mitigating the risks of medical malpractice.

The last core principle in medical practice is Justice. The principle of justice in healthcare requires fair treatment for everyone, regardless of their background, and holds healthcare workers to high ethical standards.<sup>508</sup> This core concept involves distributing resources appropriately,<sup>509</sup> using consistent procedures, and addressing healthcare gaps for underserved populations. Justice also ensures legal fairness for patients and providers. Ethical guidelines based on justice protect

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<sup>502</sup> Zhou et al., "Moral Dilemmas Regarding Physical Restraints in Intensive Care Units: Understanding Autonomy, Beneficence, Non-Maleficence and Justice in the Use of Physical Restraints."

<sup>503</sup> James M. Katz, "Health Care Ethics: The Principal of Beneficence – AIHCP," *American Institute of Healthcare Professionals*, June 2024, <https://aihcp.net/2024/08/29/health-care-ethics-the-principal-of-beneficence/?form=MG0AV3>.

<sup>504</sup> Katz, "Understanding Non-Maleficence in Health Care Ethics – AIHCP."

<sup>505</sup> Mark Moran, "Exploring Autonomy in Healthcare: Ethical Principles and Practice," August 2024, <https://aihcp.net/2024/08/29/exploring-autonomy-in-healthcare-ethical-principles-and-practice/?form=MG0AV3>.

<sup>506</sup> J. Thomas Cook, Constantine Mavroudis, and Constantine D. Mavroudis, "Autonomy and the Principles of Medical Practice," in *Bioethical Controversies in Pediatric Cardiology and Cardiac Surgery* (Springer, 2020), 30–35, [https://link.springer.com/chapter/10.1007/978-3-030-35660-6\\_2?form=MG0AV3](https://link.springer.com/chapter/10.1007/978-3-030-35660-6_2?form=MG0AV3).

<sup>507</sup> Moran, "Exploring Autonomy in Healthcare: Ethical Principles and Practice."

<sup>508</sup> Gillon, "Raising the Profile of Fairness and Justice in Medical Practice and Policy."

<sup>509</sup> Kennelly, "Medical Ethics: Four Principles, Two Decisions, Two Roles and No Reasons."

patients, clarify the duties of providers, and help prevent medical errors and lawsuits. By promoting fairness and ethical choices, justice plays a crucial role in preventing medical malpractice and negligence, fostering trust, encouraging ethical care, and mitigating legal conflicts.

### **5.3. Rwandan legal safeguards on patients' rights**

To protect people's well-being, the right to health is protected under international and regional legal instruments, including the UDHR, ICCPR, ICESCR, CRC, and the Banjul Charter. Additionally, the SDGs, which have become global commitments, did not leave this right behind.<sup>510</sup> In line with this, various national legal systems have incorporated health-related provisions from those legal instruments to secure the right to health and provide means of redress in case of negligence and malpractice. In this regard, the Rwandan Constitution safeguards the right to good health for all Rwandans.<sup>511</sup> This right is also enshrined in the Healthcare Law, comprising five components: promotional health services, disease prevention services, curative and chronic care services, palliative care services, and rehabilitative services.<sup>512</sup> Additionally, there are other health-related laws, regulations, and policies in place to ensure better health for all Rwandans. In the aftermath of the Genocide against the Tutsi, the Government of Rwanda did a tremendous job of improving its health care system by adequately governing the sector, constructing solid healthcare infrastructures, and following a universal health care model that empowers citizens with access to health care services accordingly.

Patients' rights are enshrined in the Constitution of the Republic of Rwanda, which guarantees the right to good health.<sup>513</sup> Besides, the healthcare law outlines the fundamental rights of health service users. Those rights and freedoms are discussed below:

#### **5.3.1. Right to dignity and privacy**

The patient's right to be treated with dignity and respect, as well as their right to privacy, is one of the fundamental principles of healthcare ethics and law. The Rwandan Healthcare Law recognises this right.<sup>514</sup> This right originates from the international human rights instruments, notably the Universal Declaration of Human Rights (UDHR), in Article 1 and the Preamble, which emphasise that all individuals are born free and equal in dignity and rights. Additionally, it is one of the

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<sup>510</sup> United Nations, "Goal 3: Ensure Healthy Lives and Promote Well-Being for All at All Ages," accessed February 12, 2022, <https://www.un.org/sustainabledevelopment/health/>.

<sup>511</sup> Articles 21 and 45 of the Constitution of the Republic of Rwanda, Official Gazette N° Special of 04/08/2023.

<sup>512</sup> Article 52 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>513</sup> "Articles 21 and 45 of the Constitution of the Republic of Rwanda, Official Gazette N° Special of 04/08/2023" (2023).

<sup>514</sup> Article 53 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

principles underlying the International Health Regulations (IHRs), which emphasise full respect for the dignity, human rights, and fundamental freedoms of persons, as outlined in Article 3(1).<sup>515</sup>

This principle covers several critical aspects of the right to health. The concept of human dignity dictates that patients and other healthcare users are treated with respect, regardless of their socio-economic status, medical condition, or cultural background.<sup>516, 517</sup> Healthcare providers are obliged to recognise the inherent worth of each individual and ensure that their practices do not demean or dehumanise the patients they serve.<sup>518</sup> Privacy is another essential aspect of this right, and it includes the protection of personal health information and confidentiality in all medical communications.<sup>519</sup> Besides, privacy extends to physical considerations, ensuring discretion during medical examinations and procedures. Safeguarding privacy is not solely an ethical obligation but also a legal imperative, as many countries have enacted domestic legislation to uphold these rights. The last aspect is the ethical implications, which impose a moral obligation on healthcare practitioners to uphold these rights. Respecting human dignity and privacy fosters trust between patients and healthcare providers, ensuring the equitable treatment of all individuals within healthcare systems.

In the same vein, the Rwandan healthcare law dictates that health professionals discharge their duties with due respect for the human person's life, privacy, and dignity. This right entails respect, care, and treatment with consideration, regardless of the health professional's background, beliefs, or medical condition. Safeguarding patient privacy involves protecting personal information, ensuring confidentiality of medical records, and maintaining a private space for consultations.

To ensure personal health data security, the DPP Law outlines various duties for data controllers, processors, and third parties. Among other responsibilities, they have to keep records of processed personal data, conduct personal data protection impact assessments, provide information during the collection of personal data, notify individuals when there has been a breach of their personal data security and informing them of the breach, and putting in place the necessary organisational and technical safeguards to ensure data security.

This right to be treated with human dignity and privacy imposes legal and ethical obligations on healthcare providers to uphold standards that protect patients from harm, whether resulting from negligence, malpractice, or systemic failures. Violations of patient dignity, such as inadequate

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<sup>515</sup> *The International Health Regulations (2005)*, World Health Organization, 3rd ed., vol. 16 (Geneva, Switzerland: World Health Organization, 2005), <https://iris.who.int/bitstream/handle/10665/246107/9789241580496-eng.pdf?sequence=1>.

<sup>516</sup> Nilüfer Demirsoy and Nurdan Kirimlioglu, "Protection of Privacy and Confidentiality as a Patient Right: Physicians' and Nurses' Viewpoints," *Biomedical Research (India)* 27, no. 4 (2016): 1437–48.

<sup>517</sup> Nurdan Kirimlioglu, "'The Right to Privacy' and the Patient Views in the Context of the Personal Data Protection in the Field of Health," *Biomedical Research (India)* 28, no. 4 (2017): 1464–71.

<sup>518</sup> Pablo Eduardo Pereira Dutra, Laiana Azevedo Quagliato, and Antonio Egidio Nardi, "Improving the Perception of Respect for and the Dignity of Inpatients: A Systematic Review," *BMJ Open* 12, no. 5 (2022): 1–6, <https://doi.org/10.1136/bmjopen-2021-059129>.

<sup>519</sup> Kirimlioglu, "The Right to Privacy' and the Patient Views in the Context of the Personal Data Protection in the Field of Health," p. 1465

care, disclosure of private health information, or denial of necessary treatments, could constitute grounds for liability under both ethical and legal frameworks.

### 5.3.2. Right to healthcare services

The right of access to medical healthcare services constitutes a fundamental aspect of the broader right to health, as enshrined in international human rights law and the Rwandan Constitution. Within the framework of international human rights law, this principle underscores the obligation of states and healthcare systems to guarantee equitable access to essential medical interventions, thereby safeguarding the dignity, autonomy, and well-being of individuals.<sup>520</sup> This right assumes particular significance in contexts where disparities in healthcare access exacerbate the vulnerabilities of marginalised populations.<sup>521</sup>

Key international legal instruments provide the normative foundation for this principle. Article 25(1) of the Universal Declaration of Human Rights (UDHR) explicitly affirms the right to medical care as integral to the realisation of human dignity and well-being. Similarly, the International Covenant on Economic, Social and Cultural Rights (ICESCR) emphasises the right to the highest attainable standard of health, encompassing access to medical procedures and technologies. Article 12 of the ICESCR obligates states to adopt measures that ensure the availability, accessibility, acceptability, and quality of healthcare services, thereby operationalising this right within legal and ethical frameworks.

In Rwanda, the right to access healthcare services is firmly established within the broader framework of patient rights and healthcare ethics, as outlined in national legislation.<sup>522</sup> This right is essential to the realisation of equitable healthcare, as it embodies and promotes the principles of dignity, fairness, and justice. The law guarantees a healthcare service user the right to timely access medical services reinforced by safe medication, mastered techniques and digital health and medical technology.<sup>523</sup> This right imposes an obligation on all healthcare providers to eliminate any form of discrimination during consultations, the delivery of care services, and the execution of paramedical procedures. It encompasses the provision of timely, safe, and effective medical interventions, as well as the obligation to ensure that patients and other healthcare users are adequately informed about their health conditions and available treatment options. Furthermore, healthcare professionals, institutions, insurance organisations, and other entities within the healthcare system are mandated to establish and support mechanisms that facilitate equitable

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<sup>520</sup> Danwood Mzikenge Chirwa, “The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access To Essential Medicine,” *South African Journal on Human Rights* 19, no. 4 (2003): 541–66, <https://doi.org/10.1080/19962126.2003.11865153>.

<sup>521</sup> Edward Halle, “Access to Essential Medicine as Part of the Right to Health in Africa: Access to Essential Medicine Under International Human Rights Law, the Case of Kenya and South Africa,” *Asia Pacific Journal of Health Law & Ethics* 11, no. 3 (2018): 105–38, <http://www.who>.

<sup>522</sup> Article 54 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>523</sup> *Id.*

access to healthcare services and uphold the highest standards of patient safety for all individuals.<sup>524</sup>

The non-observance of this right—particularly in cases where access to medical services is denied or delayed—raises significant concerns regarding medical liability. Under Rwandan law, healthcare providers may be held liable for harm resulting from negligence, errors, or omissions that impede a patient's access to essential healthcare. Such liability extends to instances where the failure to act compromises patient safety or exacerbates health risks. For example, the denial of access to life-saving procedures in emergencies could constitute a breach of professional duty, warranting both legal and ethical scrutiny.

### 5.3.3. Right to free choice of healthcare services and health professionals

The right to choose healthcare services and healthcare professionals is a fundamental aspect of patient autonomy and is acknowledged by many legal systems worldwide, including the Rwandan one. It is a statutory right in civil law jurisdictions like Rwanda,<sup>525</sup> while it originates from the court decisions in the common law system. It is deeply intertwined with the broader objectives of patient-centered care, emphasising respect for individual dignity, autonomy, and equitable access to healthcare services. Without undue influence or pressure, this right guarantees that individuals can choose healthcare services and providers according to their needs, preferences, and trust.<sup>526</sup>

The right free choice of a healthcare professional involves three aspects of consideration. The first one is the autonomy to decide on their healthcare, which is closely related to informed consent, where patients must be fully informed about their options and allowed to make decisions freely. Various international frameworks, such as the Universal Declaration on Bioethics and Human Rights, advocate for this principle. The second involves legal protection, whereby laws safeguard this right. For instance, the law governing healthcare services emphasises patient rights, including the freedom to choose healthcare providers. The third consideration is ethical, where patient preferences are prioritised if they do not compromise healthcare quality or accessibility.

The right of patients to freely choose their healthcare services and health professionals embodies a multidimensional principle, grounded in autonomy, reinforced by legal safeguards, and guided by ethical responsibilities. International legal frameworks and human rights declarations, coupled with domestic legislation, provide substantial reinforcement for this right. When healthcare institutions integrate philosophical views on autonomy with robust legal frameworks and ethical responsibilities, they lay the groundwork for truly empowering healthcare service users' intervention. This approach not only upholds individual choice but also actively fosters equitable

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<sup>524</sup> Ibid.

<sup>525</sup> Ibid., Article 55.

<sup>526</sup> Elizabeth E. Hogue, "Protect Patients' Right to Choose Their Own Provider," *Relias Media* (Burtonsville, February 2015), <https://www.reliasmedia.com/articles/84470-protect-patients-8217-right-to-choose-their-own-provider?form=MG0AV3>.

access to healthcare while building a solid foundation of trust between patients and healthcare providers.

#### 5.3.4. Right to emergency healthcare services

The right to emergency healthcare services entails immediate access to care without discrimination. Thus, all healthcare users must receive urgent medical attention regardless of their nationality, ability to pay, or legal status. The state has an obligation to provide high-quality emergency care.

This right is internationally recognized under Article 12 of the ICESCR. Furthermore, General Comment No. 14 by the UN Committee on Economic, Social and Cultural Rights highlights that emergency healthcare services constitute a core obligation under the right to health. In addition, the WHO emphasizes that emergency care reduces preventable deaths and disabilities and that it should be human rights-based, particularly in developing emergency care systems of LMICs.<sup>527</sup> The 2023 global comparative study reveals that the right to emergency care has been recognized in many countries through constitutional provisions, statutes, or judicial decisions. However, the extent and consistency of enforcement can vary.<sup>528</sup> This study recommends various actions across the chain of survival, such as robust bystander care, pre-hospital and hospital infrastructure, emergency rehabilitation, and funding mechanisms.<sup>529</sup>

The UN Office of the High Commissioner for Human Rights (OHCHR) indicates that during crises such as pandemics, armed conflicts, or natural disasters, the right to emergency healthcare services is at stake and that States should take proactive steps to ensure its accessibility.<sup>530</sup>

In the Rwandan context, the right to emergency healthcare services is documented in the 2025 Healthcare Law.<sup>531</sup> It is complemented by access to referral to another healthcare facility if the receiving healthcare facility cannot provide the required healthcare service.

Despite the Government of Rwanda's efforts in recent years, there are still challenges to address for the successful realisation of emergency healthcare services. These include infrastructural and systemic limitations.<sup>532,533</sup> Emergency medical services (EMS) are still developing, and remote areas often lack rapid response systems, trained emergency care personnel, or ambulatory

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<sup>527</sup> Taylor W. Burkholder, Kimberly Hill, and Emilie J. Calvillo Hynes, “Developing Emergency Care Systems: A Human Rights-Based Approach,” *Bulletin of the World Health Organization* 97, no. 9 (2019): 612–16, <https://doi.org/10.2471/BLT.18.226605>.

<sup>528</sup> SaveLIFE Foundation, “Global Comparative Research on Right to Emergency Medical Care” (New Delhi: Thomson Reuters Foundation, 2023), <https://savelifefoundation.org/wp-content/uploads/2023/10/Global-Comparative-Research-on-Right-to-Emergency-Medical-Care.pdf>.

<sup>529</sup> *Ibid.*, p. 97-110.

<sup>530</sup> OHCHR, “Safeguarding the Right to Health in Crisis,” accessed October 30, 2025, <https://www.ohchr.org/en/health/safeguarding-right-health-crisis>.

<sup>531</sup> Article 56 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>532</sup> Balkrishnan, Selden, and Rusingiza, “Overview, Infrastructural Challenges, Barriers to Access, and Progress for Rwanda’s Healthcare System: A Review,” 2025.

<sup>533</sup> Sudha Jayaraman et al., “Building Trauma and Ems Systems Capacity in Rwanda: Lessons and Recommendations,” *Annals of Global Health* 87, no. 2–10 (2021), <https://doi.org/10.5334/aogh.3324>.

support.<sup>534</sup> Additionally, the EMS teams struggled to easily geolocate emergencies due to limited address systems and inadequate GPS coverage.<sup>535</sup> These challenges are coupled with communication and coordination gaps, such as weak referral systems resulting in care delays and inefficient patient transfers, as well as the lack of a government centralised dispatch system, which limits timely responses and resource allocation.<sup>536</sup> Besides, the out-of-pocket expenses of healthcare service users and geographical disparities pose financial and accessibility barriers that complicate the delivery of emergency healthcare services. The Government needs to reinforce and scale up its emergency care strategies in addition to the established Isange One Stop Centers for gender-based violence (GBV) survivors, which facilitate emergency medical care while providing legal and psychosocial support.

### 5.3.5. Right to human reproductive health

The right to human reproductive health is considered central to gender and equality.<sup>537</sup> It gives individuals the freedom to make informed decisions regarding their reproductive lives. With that, they are guaranteed the necessary healthcare services that support those decisions without discrimination. This right encompasses access to contraception, fertility and infertility services, maternal and antenatal care, safe abortion, and prevention and treatment of sexually transmitted infections (STIs), with a respect for confidentiality and human dignity.<sup>538</sup>

The UN 2030 Agenda for Sustainable Development recognises the right to human reproductive health under Goals 3 (Good Health and Well-being) and 5 (Gender Equality). The Rwandan Healthcare Law also recognizes this right to human reproductive health.<sup>539</sup>

Despite such recognition, the enjoyment of this right has been hindered by various issues such as cultural and religious beliefs, unaffordability, gender-based violence, and the scarcity of reproductive health experts, particularly in rural areas.

As the WHO and Human Reproductive Programme (HRP) advocate for the integration of reproductive health services into universal health coverage to avoid an increasing burden on underserved, marginalised individuals and communities,<sup>540,541</sup> Rwanda has recognised this. For example, healthcare law acknowledges that the eligible person's insurance scheme covers services related to assisted reproductive technology.<sup>542</sup> Besides, the right has also been reinforced by

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<sup>534</sup> Jayaraman et al.

<sup>535</sup> McKenna Hunt et al., “Challenges Locating the Scene of Emergency: A Qualitative Study of the EMS System in Rwanda,” *Prehospital Emergency Care* 28, no. 3 (2024): 501–5, <https://doi.org/10.1080/10903127.2023.2225195>.

<sup>536</sup> Hunt et al.

<sup>537</sup> WHO, “Sexual and Reproductive Health and Rights,” accessed October 30, 2025, <https://www.who.int/health-topics/sexual-and-reproductive-health-and-rights>.

<sup>538</sup> WHO.

<sup>539</sup> Article 57 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>540</sup> HRP et al., *Self-Care Interventions for Sexual and Reproductive Health and Rights to Advance Universal Health Coverage: 2023 Joint Statement by HRP, WHO, UNDP, UNFPA and the World Bank.*, World Health Organisation, 2023, <https://www.who.int/publications/i/item/9789240081727>.

<sup>541</sup> WHO, “Sexual and Reproductive Health and Rights.”

<sup>542</sup> Article 41 (2) of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

various legislation in Rwanda, such as the Law on Prevention and Punishment of Gender-Based Violence (GBV Law), which prevents reproductive coercion and the denial of reproductive autonomy. Hence, although these efforts are crucial for the enjoyment of the right to human reproductive health, there is a continuous need for action to provide those services, align them with emerging technologies, and run awareness campaigns.

### 5.3.6. Right to access information

Information is requisite for decision-making in any healthcare setting. The patient's right to information is also fundamental in healthcare. It is deeply rooted in ethical, philosophical, and legal frameworks to ensure that individuals are adequately informed about their health status, treatment options, and the implications of medical decisions, thereby empowering them to make choices that align with their values and preferences. In this regard, healthcare providers are required to disclose relevant information about diagnoses, treatments, risks, and alternatives.

From an ethical perspective, the right to information is inherently linked to the principle of autonomy, which underscores the capacity of individuals to make informed and independent decisions regarding their healthcare. Upholding this right enables patients to engage in informed consent, a fundamental pillar of ethical medical practice. Within the philosophical realm, Kantian deontology highlights the moral imperative to regard individuals as autonomous agents, endowed with the ability to engage in rational decision-making.<sup>543</sup> This theoretical framework reinforces the ethical obligation of healthcare providers to ensure transparency and respect in the dissemination of information.

Treating patients with respect is a critical component of ethical healthcare practice, as it fosters an environment of emotional support that is free from blame, prejudice, or judgments that may evoke shame or guilt in the patient. By emphasising respect, care providers acknowledge the inherent dignity of each patient, ensuring they are treated as equal individuals and not solely as recipients of medical care. This approach not only enhances the patient's sense of trust and comfort but also strengthens the doctor-patient relationship, promoting effective communication and collaboration in the provision of care.<sup>544</sup>

In the Rwandan legal framework, healthcare professionals are required to provide patients with accurate, reliable, and contextually relevant information regarding their health status and available promotional, preventive, diagnostic procedures, and healthcare service options.<sup>545</sup> This includes disclosure of the potential benefits, frequent or severe risks that are typically predictable,<sup>546</sup> and

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<sup>543</sup> Donaldson, "Using Kantian Ethics in Medical Ethics Education."

<sup>544</sup> Sofia B. Fernandez et al., "How Patients Experience Respect in Healthcare: Findings from a Qualitative Study among Multicultural Women Living with HIV," *BMC Medical Ethics* 25, no. 1 (2024): 4,8-10, <https://doi.org/10.1186/s12910-024-01015-1>.

<sup>545</sup> Article 59 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>546</sup> Emma C. Bullock, "Free Choice and Patient Best Interests," *Health Care Analysis* 24, no. 4 (2016): 375-89, <https://doi.org/10.1007/s10728-014-0281-8>.

the associated costs of the medical interventions under consideration. Such provisions underscore the significance of informed decision-making as a cornerstone of equitable healthcare delivery.

Nevertheless, the law outlines specific scenarios in which the regular disclosure of health-related information to patients may be withheld. These exceptions include emergencies, cases where patients lack full mental capacity, instances where patients cannot be located, or circumstances in which patients explicitly express a desire not to be informed about their condition or its likely outcome.<sup>547</sup> However, the exception to the latter may apply when withholding such information poses a risk of disease transmission to others.

### 5.3.7. Right to protection from health-harming practices

Health service users have the right not to be subjected to health-harming practices or the right to safety, in simple terms.<sup>548</sup> The Rwandan healthcare law stipulates that these practices include those with physical, mental, social, and environmental implications.<sup>549</sup> This right focuses on preventing preventable harm in healthcare service delivery. According to the WHO, patient safety is “the absence of preventable harm to a patient and reduction of risk of unnecessary harm associated with health care to an acceptable minimum.”<sup>550</sup> In a broader sense, the WHO defined it as follows.

*[A] framework of organized activities that creates cultures, processes, procedures, behaviours, technologies and environments in health care that consistently and sustainably lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce impact of harm when it does occur.*<sup>551</sup>

The patient’s right to safety ensures that individuals receive healthcare within environments designed to mitigate risks and prevent harm. In alignment with international frameworks such as the above law, the Patient Safety Rights Charter and the Global Patient Safety Action Plan 2021–2030, this right underscores the imperative to safeguard patients and healthcare users from systemic dysfunctions, adverse events, and medical errors, including medication inaccuracies, surgical complications, and healthcare-associated infections. Additionally, this right encompasses access to medical procedures that conform to established standards articulated by the Minister of Health, thereby reinforcing the necessity of care delivery by qualified healthcare professionals within secure and properly accredited healthcare facilities. In addition, patients are entitled to the right of access to precise and reliable outcomes from diagnostic tests, the provision of appropriately crafted prosthetic devices, the administration of compulsory vaccinations, and the use of safe and effective medical devices and products.

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<sup>547</sup> Bullock., p.388.

<sup>548</sup> Article 58 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>549</sup> Ibid.

<sup>550</sup> WHO, “Patient Safety.”

<sup>551</sup> WHO.

### 5.3.8. The right to receive explanations in an understandable language

Clear and consistent communication between healthcare practitioners and patients is indispensable for efficient and effective healthcare service delivery. The healthcare law provides that healthcare users have the right to be informed about their health status, treatment options, and care plans in a language that they comprehend within the scope of official languages. However, if the service user does not understand any of those languages, he or she has to arrange an interpreter.<sup>552</sup> In case of a healthcare service user's hearing or speech impairment, the law requires a healthcare professional to apply sign language either directly or through an individual with knowledge of sign language to engage them.<sup>553</sup>

This right enhances the healthcare service user's ability to exercise autonomy and make informed decisions about their health, as well as control over their healthcare journey. By ensuring the fulfillment of communication needs, this right particularly upholds the autonomy of service users with disabilities, enabling them to take part in decisions about their health. This inclusion enhances the patient-centered care and overall health outcomes.

### 5.3.9. Right to consent

In the pursuit of strengthening the principle of autonomy, patients and other users of health services must be granted the unequivocal right to provide informed consent for any medical intervention, encompassing both diagnostic and therapeutic procedures.<sup>554</sup> For individuals who possess the capacity to accept or reject a proposed medical procedure, their explicit refusal must be respected by the medical practitioner, provided that comprehensive information regarding the potential ramifications of such refusal is provided.<sup>555</sup>

In circumstances where the patient or health service user is incapacitated and, consequently, unable to articulate their will, healthcare professionals are ethically and legally obligated to abstain from intervention unless emergent conditions necessitate immediate action. In such emergencies, intervention may proceed only after due warning has been communicated to the patient, and the service user's representative has been notified. In the absence of a representative, the intervention must be endorsed by another healthcare professional or the medical facility's management. It should be noted that the representative of a healthcare user may be a parent, child, sibling, legal custodian, or any other individual designated by the healthcare facility in the best interests of the healthcare service user. Any of those must have attained the age of majority.<sup>556</sup>

However, as in many jurisdictions, consent for minors or persons incapable of giving their own consent is typically provided by a parent, legal guardian, or other authorised representative. This

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<sup>552</sup> Article 60 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>553</sup> Article 60 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>554</sup> James F. Childress and Marcia Day Childress, "What Does the Evolution from Informed Consent to Shared Decision Making Teach Us about Authority in Health Care?," *AMA Journal of Ethics* 22, no. 5 (2020): 423–24, <https://doi.org/10.1001/amajethics.2020.423>.

<sup>555</sup> Article 62 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>556</sup> *Ibid.*, Art. 2 (p).

alternative decision-making must prioritise the best interests of the healthcare user.<sup>557</sup> In the Rwandan context, the term ‘minor’ was replaced by the term ‘person incapable of giving consent’ and considered to be under 15 years of age. Otherwise, their consent, similar to that of incapable persons for medical care, requires the intervention of their parents, legal representatives, or guardians.<sup>558</sup> In the latter's absence, the involved health professional can act under the doctrine of implied consent by seeking an opinion from another competent health professional to make a decision. In this case, the intervention must be documented, along with the justification for proceeding without express consent.

The principle of informed patient consent represents a cornerstone of ethical medical practice, underpinning all interactions within the healthcare domain. Its significance becomes particularly important in circumstances involving substantial health risks. In this regard, the informed consent not only upholds patient autonomy but also serves as an indispensable mechanism for safeguarding ethical standards in clinical decision-making, ensuring the effective use of medicine.<sup>559</sup>

#### 5.3.10. Right to refuse treatment and withdraw consent

As consent should be sought from the patient or other health service user before any healthcare examination or treatment procedure, the latter also has the right to refuse treatment or withdraw their consent during the procedure or refuse the continuation of a medical procedure carried out on them.<sup>560</sup> Such a refusal should be in writing and inserted into their medical records.<sup>561</sup>

Any necessary medical intervention should only be carried out in the patient’s best interests in emergencies where uncertainty arises regarding the existence or absence of prior consent from the patient or their representative. Such an intervention must be contingent upon a favourable opinion from another competent health professional or the management of the healthcare facility providing such health care service. Furthermore, the attending physician needs to document all details of the intervention in the patient's medical record.<sup>562</sup>

#### 5.3.11. Right to consult and be given a copy of a healthcare service user’s file

Another essential component of healthcare legislation and ethics is the right to consult with a healthcare provider and request a copy of their medical record within a reasonable timeframe. This right emphasises transparency, accountability, and respect for the patient’s autonomy. Patients are guaranteed access to their personal health information under this right, which empowers them to make informed decisions about their care and, if necessary, seek additional opinions. Rwanda is one of the many jurisdictions that recognise this right through specific legislation. The Rwandan

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<sup>557</sup> T Thirumoorthy and Peter Loke, “Consent in Medical Practice 3 – Dealing with Persons Lacking Capacity,” *SMA News* 12, no. 1 (2013): 16–19, <https://doi.org/10.4038/gmj.v12i1.1082>.

<sup>558</sup> Article 2 (o) of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>559</sup> Rebecca Roache, “Why Is Informed Consent Important?,” *Journal of Medical Ethics* 40, no. 7 (2014): 435–36, <https://doi.org/10.1136/medethics-2014-102264>.

<sup>560</sup> Article 63 (1) of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>561</sup> *Ibid.*, para. 2.

<sup>562</sup> *Ibid.*, para. 3.

healthcare law underscores the importance of patient rights, particularly the right to access their medical records.<sup>563</sup>

In addition, healthcare professionals have an ethical duty to uphold this right, as it fosters cooperation and confidence between patients and providers. Therefore, refusing access without a sound reason might undermine the connection between the patient and the healthcare provider. However, when it seriously jeopardises the patient's health or safety or violates the privacy of others, this right may be restricted.<sup>564</sup>

#### **5.4. Obligations of healthcare service users**

If the law were to only bind healthcare providers and professionals without imposing corresponding obligations on healthcare service users, it would undermine fairness and reciprocity. Such an asymmetric approach could result in systemic imbalance and injustice in healthcare service delivery. It is in this regard that the healthcare law imposes the following set of obligations on healthcare service users to ensure they actively participate in receiving appropriate healthcare services.

During consultation, they have an obligation to provide accurate and comprehensive information about their health, including their past and current health status, symptoms, and any concurrent ongoing medications and healthcare services. Additionally, they must adhere to the advice, instructions, and treatment plans provided by healthcare providers. Among other things, they should take prescribed medications, follow recommended lifestyle changes, attend scheduled appointments, and adhere to recommended therapies or rehabilitation programs.<sup>565</sup>

Besides those treatment-related obligations, healthcare service users must treat healthcare service providers, healthcare facility staff, and fellow service users with respect and dignity. They must also avoid any harm to their own health and to that of others. Furthermore, service users must comply with the regulations of the healthcare facilities when accessing their services and must pay for the chargeable services received.<sup>566</sup>

#### **5.5. Rights of healthcare practitioners**

Healthcare professionals are also entitled to a range of rights and protections under the Rwandan Healthcare Law.<sup>567</sup> The law stipulates that healthcare service providers must be treated with respect and dignity by healthcare service users, the healthcare facilities, and fellow employees within those facilities.<sup>568</sup> The provision outlines these rights and freedoms, including the protection from all forms of discrimination, violence, and harassment. The same law mandates healthcare

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<sup>563</sup> Article 61 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>564</sup> Nerissa Ferrie, "Can Patients Access Their Medical Records?," *Royal Australian College of General Practitioners*, June 2021, <https://www1.racgp.org.au/newsgp/professional/can-patients-access-their-medical-records?form=MG0AV3>.

<sup>565</sup> Article 66 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services (2025).

<sup>566</sup> Ibid.

<sup>567</sup> Ibid., Article 64 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>568</sup> Ibid.

professionals to operate in a safe and supportive environment that ensures their physical and mental well-being.

Within this legal framework, healthcare practitioners are also afforded the freedom to exercise their professional expertise and autonomy in delivering healthcare services. Additionally, they are entitled to remuneration and other benefits as provided by applicable laws. The provision further grants healthcare professionals access to the necessary tools and provides them with appropriate training on their effective use in the course of performing their professional duties.

### **5.6. Duties and responsibilities of medical practitioners**

This section outlines the general duties of physicians as outlined by the World Medical Association in the International Code of Medical Ethics. The Code outlines duties for healthcare practitioners by emphasising the role of preserving patients' lives with compassion and respect for human dignity.<sup>569</sup> By doing so, they are required to exercise their independent professional judgement with conscience, honesty, integrity, and accountability while maintaining the highest standards of professional conduct. Additionally, a physician has a duty to treat patients and colleagues with honesty and to report other physicians who practice unethically and incompetently, or engage in fraudulent or deceptive actions, to the applicable authorities.<sup>570</sup>

It is also prohibited for physicians to receive any financial benefits or incentives for referring patients or prescribing medications. They have to respect patients' rights and preferences. They must certify what they have personally verified. They must endeavour to use healthcare resources in the best interest of patients and their community by balancing medical necessity with respect for their dignity and rights. Physicians must also adhere to local and national codes of ethics. Among other duties, healthcare professionals are required to engage in continuous professional development (CPD) throughout their professional practice to enhance their knowledge and skills. They must never participate in or facilitate acts of torture, or other cruel, inhuman, or degrading practices and punishments. Additionally, they must endeavour to adopt medical practices that are environmentally sustainable to minimise the environmental risks to current and future generations.<sup>571</sup>

The International Code of Medical Ethics also enumerates various duties of physicians towards patients, including the following.<sup>572</sup>

- Respect the patient's dignity, autonomy, and rights;
- Commit to the primacy of patient health and well-being and act in the patient's best interest when providing medical care by minimising harm to the patient and seeking a positive balance between the expected outcome and any potential harm;

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<sup>569</sup> World Medical Association, "WMA International Code of Medical Ethics" (Berlin, German, 2022), <https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/>.

<sup>570</sup> World Medical Association.

<sup>571</sup> World Medical Association.

<sup>572</sup> World Medical Association.

- Respect the patient’s right to be informed on every step of the medical care process by seeking informed consent prior to any medical care;
- Involve the patient as much as possible in medical decisions when the patient's ability to make decisions is significantly limited, underdeveloped, impaired, or fluctuating if available, the physician has to cooperate with the patient’s representative in decision-making by prioritising the patient’s preferences;
- Owe their patients their undivided allegiance by consulting with or sending patients who are unable to receive the examination or treatment to another qualified medical professional;
- Provide emergency care as a humanitarian obligation unless they are certain that others are capable and willing to do it;
- Ensure that the patient is fully informed of the situation when operating on behalf of a third party;
- Ensure accurate and timely medical documentation;
- Respecting the patient’s privacy and confidentiality even after the death of the patient;
- Refrain from inappropriate marketing and advertising, and make sure that all of the material the physician uses is accurate and not misleading;
- Avoid any commercial, financial, or other conflicting interests that could affect their professional judgment;
- Ensure medically justifiable forms of communication and necessary provision of medical care when providing medical services remotely;
- Maintain appropriate professional boundaries by refraining from engaging in any abusive or exploitative relationships, including sexual ones, with their current patients.

In addition to the above list of duties, as a member of the medical profession, a medical practitioner must adhere to, protect, and promote the ethical principles outlined in the International Code of Medical Ethics.

The WMA Declaration of Kigali on the Ethical Use of Medical Technology, also known as the Declaration of Kigali, emphasises the importance of beneficence, privacy, confidentiality, human dignity and rights, patient autonomy, and fairness as guiding principles in the development and application of medical technology.<sup>573</sup>

In the Rwandan legal framework, healthcare practitioners are bound by a set of obligations articulated in the Healthcare Law.<sup>574</sup> These obligations include providing efficient healthcare services and emergent care. They also have to disclose all necessary information enabling healthcare service users to make an informed decision regarding their treatment. Additionally, they have an obligation to consistently respect the autonomy of healthcare service users and provide healthcare services without any form of discrimination. Besides, they must ensure non-discrimination while providing healthcare services, avoiding the use of any form of violence

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<sup>573</sup> WMA, “WMA Declaration of Kigali on the Ethical Use of Medical Technology” (Kigali, Rwanda, 2023), <https://www.wma.net/policies-post/wma-declaration-on-medical-ethics-and-advanced-medical-technology/>.

<sup>574</sup> Article 68 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

against healthcare users. The law also requires them to establish and maintain files for healthcare service users, containing accurate and comprehensive information.

Those obligations are coupled with adherence to principles, standards, and protocols governing the healthcare profession, ensuring the integrity and quality of healthcare service delivery.<sup>575</sup> The Rwanda Medical Code of Ethics also emphasises the principles of the International Code of Medical Ethics, such as acting in the healthcare users' best interest, respecting patient autonomy and privacy, and upholding confidentiality. It also highlights the significance of informed consent, effective communication, and respecting one's professional boundaries.

Furthermore, in addition to what the healthcare law and other international health law instruments provide, the statute establishing the NCNM provides various responsibilities toward nurses and midwives. For example, nurses and associate nurses have a duty to promote health through preventive and curative care.<sup>576</sup> By doing so, they are required to protect individuals, families, and the community from illnesses, infections, accidents, and other complications.<sup>577</sup> Additionally, they are obligated to provide curative, rehabilitative, and palliative services through consultations and treatments for patients, responding to the population's needs by applying their professional knowledge and skills in accordance with the professional code of conduct.<sup>578</sup> Mental health nurses are obliged to provide curative care,<sup>579</sup> rehabilitative,<sup>580</sup> and palliative care.<sup>581</sup> Besides, midwifery professionals are responsible for promoting health by preparing and caring for women, families, and the community throughout their reproductive life cycle. They are also responsible for delivering preventive care such as immunisations,<sup>582</sup> providing midwifery care,<sup>583</sup> and promoting the health of women, families, and the community.<sup>584</sup>

## **5.7. Role of major health institutions in ensuring healthcare service users' safety**

### **5.7.1. Ministry of Health in Rwanda (MINISANTE)**

The Government of Rwanda aims to deliver accessible, efficient, and integrated health services that address the needs of its population and strengthen global health security. In pursuit of this goal, the Ministry of Health (MoH) plays a crucial role in ensuring patient safety and preventing medical malpractice through strategic planning, regulation, oversight, capacity building, and collaboration with other health organisations.<sup>585</sup> Rwanda's Ministry of Health is responsible for

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<sup>575</sup> Ibid.

<sup>576</sup> Ibid., Art. 16.

<sup>577</sup> Ibid., Articles 20, 30, 34 and 36.

<sup>578</sup> Ministerial Order N° 20/25 of 18/04/2012 determining the Code of Professional Conduct for Nurses and Midwives, Official Gazette n° 21 of 21 May 2012.

<sup>579</sup> Ibid., Article 40.

<sup>580</sup> Ibid., Article 41.

<sup>581</sup> Ibid., Article 42.

<sup>582</sup> Ibid., Articles 25 and 39.

<sup>583</sup> Ibid., Article 26.

<sup>584</sup> Ibid., Article 28.

<sup>585</sup> Article 3 of the Prime Minister's Order No. 011/03 of 26/02/2024 Determining Mission, Responsibilities and Organisational Structure of the Ministry of Health (2024).

enhancing the health of its people through preventive, curative, and rehabilitative services.<sup>586</sup> This mandate is grounded in and guided by the constitutional right to health. The ministry aligns its goals with Rwanda’s Vision 2050, the NST 2, and the SDGs to realize its long-term vision of building a resilient, equitable, and high-quality healthcare system.

Within the context of ensuring legal and regulatory compliance, the Ministry of Health plays a pivotal role in licensing and accrediting health facilities. It also supports established accountability mechanisms through various activities, such as regulatory oversight and pharmacovigilance, which are primarily carried out through its affiliated agency, the Rwanda Food and Drugs Authority (FDA).<sup>587</sup> Additionally, the Ministry has a strategic vision and governance that support the development of the Rwanda healthcare system. For example, with the Health Sector Strategic Plan V (2024/25–2028/29), the ministry aims to achieve universal health coverage by 2030, focusing on, among other things, the quality of healthcare, which directly supports the delivery of safe healthcare and reduces the risk of malpractice.

Another key role of the Ministry of Health as a policymaker is to develop a surveillance and reporting system by developing the national guidelines for pharmacovigilance and medicine information.<sup>588,589</sup> To attain this, the Ministry of Health established the National Pharmacovigilance and Medicine Information Center, which is the Pharmacovigilance and Safety Monitoring Division in the Rwanda FDA.<sup>590</sup> The primary function of this Center is to collect and analyse data on adverse drug reactions (ADRs), manage the national ADR database, and communicate safety information to the public to protect public health. This role ensures the safety of patients as consumers of medical products.

Furthermore, the Ministry has another responsibility of building and enhancing the capacity of both health providers and care service users. In this regard, the Ministry improves the providers’ clinical skills and compliance with ethical standards. Additionally, the Ministry also promotes the population’s health literacy.<sup>591</sup> It supports compliance campaigns and public health education initiatives, including public awareness campaigns and feedback mechanisms, to reduce the likelihood of malpractice.

To fulfill its responsibilities, the Ministry of Health in Rwanda collaborates with other stakeholders in the healthcare sector. In this regard, the Ministry collaborates with the private sector, civil society, and other development partners to promote transparency and accountability in the delivery

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<sup>586</sup> Ibid., Article 2.

<sup>587</sup> Abimana Rwandenzi Eugene et al., “Strengthening Pharmacovigilance in Rwanda: Introducing PViMS for Spontaneous Reporting of Adverse Drug Effects,” *USAID Medicines, Technologies, and Pharmaceutical Services (MTAPS) Program* (Kigali, Rwanda: USAID, 2023).

<sup>588</sup> Ministry of Health of Rwanda, “Guidelines for Pharmacovigilance and Medicine Information in Rwanda” (2024).

<sup>589</sup> Rwanda FDA, “Regulations Governing Pharmacovigilance of Pharmaceutical Products and Medical Devices” (2024).

<sup>590</sup> *Marketing Surveillance Control, Medicines Safety Bulletin* (Kigali, Rwanda: Rwanda Food and Drugs Authority, 2022), p. 36.

<sup>591</sup> Generis Global Legal Services, “Understanding Public Health Compliance Standards in Rwanda,” Generis Legal Intelligence, 2025, <https://generisonline.com/understanding-public-health-compliance-standards-in-rwanda/>.

of healthcare services. It also empowers the healthcare service users through public awareness campaigns.

#### 5.7.2. Rwanda Biomedical Centre (RBC)

RBC is a statutory institution with various health-related responsibilities.<sup>592</sup> Its mission is to promote quality, affordable, and sustainable health care services for the population.<sup>593</sup> The governing Presidential Order further details this mandate and determines the Ministry of Health as its supervising authority.<sup>594</sup> To promote patient safety and prevent medical malpractice, it coordinates health programmes, enforces clinical standards, and monitors healthcare delivery across Rwanda. Within this framework, RBC employs innovative and evidence-based interventions and practices that adhere to ethical and professional standards.

Among other things, RBC has responsibilities for monitoring various health programmes aimed at health promotion, disease prevention, diagnosis, and treatment. It also coordinates and monitors the implementation of those programmes. It is also responsible for preventing and controlling epidemic diseases and other public health emergencies. Additionally, RBC coordinates the planning of all activities related to pharmaceutical products and medical equipment in Rwanda. Contributing to the financial sustainability of the health sector in Rwanda, as well as to the vital regional and global health activities, constitutes another essential task in fostering the healthcare sector.<sup>595</sup>

To attain its mission, RBC has a surveillance system and takes a significant role in developing and enforcing various guidelines and structures, including clinical management protocols, pharmacovigilance systems, hemovigilance systems (for blood safety), and antimicrobial stewardship guidelines.<sup>596</sup> These tools enhance patient safety by helping healthcare providers adhere to safe practices and accurately report adverse events.

#### 5.7.3. Rwanda Food and Drug Authority (Rwanda FDA)

The Rwanda FDA is a statutory institution with a mandate to protect public Health and conduct pharmacovigilance and post-marketing surveillance of medical products in the Rwandan territory, ensuring the safety, quality, and efficacy of medicines and health technologies.<sup>597</sup> This institution was established to address the issue of substandard or falsified products that were in the market.<sup>598</sup> In this regard, it issues guidelines for reporting medication errors and adverse events, which support the prevention of medical malpractice and promote the safety and rights of healthcare

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<sup>592</sup> Article 5 of the Law No. 013/2019 Governing Rwanda Biomedical Centre (2019).

<sup>593</sup> *Ibid.*, Article 4.

<sup>594</sup> *Ibid.*, Article 3.

<sup>595</sup> Article 5 of the Presidential Order No. 032/01 of 06/05/2022 Governing Rwanda Biomedical Centre (2022).

<sup>596</sup> “National Antimicrobial Stewardship Guidelines” (2024), [https://www.rbc.gov.rw/fileadmin/user\\_upload/Signed\\_National\\_AMS\\_GUIDELINES\\_FOR\\_HC\\_SETTINGS.pdf](https://www.rbc.gov.rw/fileadmin/user_upload/Signed_National_AMS_GUIDELINES_FOR_HC_SETTINGS.pdf).

<sup>597</sup> Article 9 of the Law No. 003/2018 of 09/02/2018 Establishing Rwanda FDA, 2018.

<sup>598</sup> Ministry of Health of Rwanda, “National Pharmaceutical Sector Strategic Plan (NPS -SP) 2018–2024” (Kigali, 2018), p. 14.

users. Additionally, the Rwanda FDA has a responsibility to harmonise national health standards with the WHO and the East African Community (EAC) frameworks. This regulatory framework helps prevent harm from falsified, substandard, or improperly used medicines.

#### 5.7.4. Health professional Councils

In Rwanda, five health professional councils play a crucial role in safeguarding patient safety and reducing preventable adverse events. These councils include the Rwanda Medical and Dental Council (RMDC), the National Council of Nurses and Midwives (NCNM), the Rwanda Allied Health Professional Council (RAHPC), and the National Pharmacy Council (NPC). Each of these councils has a statutory mandate to regulate respective personnel through licensing practitioners, accrediting relevant training institutions, enforcing ethical standards, and monitoring their compliance with professional guidelines. These councils serve as custodians of clinical competence and ethical conduct within Rwanda's healthcare system. They significantly contribute to patient safety and the prevention of medical errors and adverse events through various mechanisms, including incident and near-miss reporting systems, quality assurance audits, and CPD programs. These councils work together, and the Ministry of Health (MINISANTE) supports their operations and professional development.

##### 5.7.4.1. Rwanda Medical and Dental Council (RMDC)

RMDC plays a central role in ensuring professionalism and ethics in Rwanda's health care sector. Its establishing law has significantly impacted the policy and legal environment of medical practice in Rwanda.<sup>599</sup> Harmonisation with the East African Community (EAC) standards has been especially beneficial to both patients and practitioners, offering quality medical care and promoting consistency in qualifications, practice guidelines, and ethical standards within the region. Additionally, the Council has a robust complaints mechanism that allows patients or their representatives to file cases of professional misconduct, unethical behaviour, or substandard care, including negligence and malpractice. The Council, as a regulator, plays an investigative role in all malpractice cases brought before its Complaints Committee. After a preliminary investigation and gathering of evidence, the Council is able to discipline members who have been found guilty of misconduct.

##### 5.7.4.2. National Council of Nurses and Midwives (NCNM)

The National Council of Nurses and Midwives (NCNM) is a statutory institution with a primary mandate to safeguard the public by ensuring that nurses and midwives delivering care are both professionally competent and ethically responsible. It is responsible for protecting the public from

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<sup>599</sup> Law No 44/2012 of 14/01/2013 on Its Organisation, Functioning and Competence of Rwanda Medical and Dental Council (2012).

harm resulting from the deeds of nurses and midwives.<sup>600</sup> As a guardian of ethical rules,<sup>601</sup> it operates through a comprehensive regulatory framework.

The Council is responsible for licensing and registering Nurses and Midwives, defining the scope of practice, setting and enforcing professional standards, and monitoring the practices of its licensed members. Through curriculum oversight, the Council accredits the nursing and midwifery training schools to ensure consistency and quality education.<sup>602</sup> Additionally, the Council identifies practitioners who meet the standards through its licensing mechanism before they enter the workforce. To ensure their consistent practice, the Council has CPD programs.

To uphold legal and ethical compliant practice and improve patient safety, NCNM collaborates with various stakeholders in healthcare, including educational bodies, the Ministry of Health and its affiliated agencies, as well as other local and international health institutions. The Council makes professional standards publicly accessible. By doing so, it promotes public awareness and empowers healthcare users through community outreach programs to recognize and report unsafe practices.

To promote access to remedial avenues, the NCNM has a formal complaint mechanism through which victims of nurses' and midwives' actions, or their representatives, can submit their claims and seek redress. It investigates claims related to professional misconduct or unethical behaviour and imposes sanctions on practitioners found guilty of posing risks to patient safety.

#### *5.7.4.3. Rwanda Allied Health Professions Council (RAHPC)*

The RAHPC is a statutory organization with a mandate to protect public health through various activities, including the regulation of allied health professionals.<sup>603</sup> It registers and licenses qualified and competent professionals who want to practice, sets education standards and ensures their compliance, provides ethical oversight, and establishes disciplinary mechanisms to ensure patient safety and prevent malpractice.<sup>604</sup>

Besides, the Council promotes public awareness through various channels, engaging healthcare users. In this regard, it provides the mechanism for reporting misconduct to ensure transparency and accountability in healthcare service delivery. To achieve its mission, the Council operates through professional advisory boards representing specific allied health fields, which help to set standards for each profession and address unique risks.

Additionally, the Council is responsible for providing CPD programs to enhance its practitioners' professionalism.<sup>605</sup> To uphold accountability and ethical practice, the Council imposes disciplinary

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<sup>600</sup> Article 6 (1) of the Law N°25/2008 of 25/07/2008 Establishing the National Council of Nurses and Midwives and Determining Its Organisation, Functioning and Competence (2008).

<sup>601</sup> Ibid., para. 3.

<sup>602</sup> "Function of NCNM," accessed November 5, 2025, <https://www.ncnm.rw/Function.php>.

<sup>603</sup> Article One of the Law N°46/2012 of 14/01/2013 Establishing the Rwanda Allied Health Professions Council and Determining Its Organisation, Functioning and Competence (2013).

<sup>604</sup> Ibid., Article 5.

<sup>605</sup> Ibid., Article 21.

sanctions on practitioners who contravene the ethical code of conduct.<sup>606</sup> In this light, the Council offers remedial avenues, which enable it to institute a disciplinary procedure on its initiative or upon request by an interested party.<sup>607</sup> This approach enhances access to justice for victims of malpractice by allied health professionals.

#### 5.7.4.4. *Rwanda National Pharmacy Council (NPC)*

Similar to other professional health Councils, NPC is a statutory institution.<sup>608</sup> Its mandate is to ensure the protection of public health by ensuring adherence to the rules, honour, and dignity of the pharmacy profession.<sup>609</sup> Within this context, it regulates pharmacy practice in Rwanda and enhances ethical practice. This enables the delivery of safe pharmaceutical services and reduces the risks of malpractice.

Within the scope of regulating pharmacy practice, the NPC registers, licenses, and authorizes qualified and competent pharmacists to dispense medications and provide other pharmaceutical care in Rwanda after assessing their qualifications. Additionally, the Council advises higher learning institutions on pharmacy academic programs to align their curricula with national health needs and international standards.

To enhance ethical and legal compliance, it offers internships and mandates CPD programs to its members as a condition for renewal. This enables its members to be up-to-date and address the emerging risks in their practice. In the event of a violation of the code of ethics for the pharmacy profession, the Council imposes disciplinary measures against pharmacists,<sup>610</sup> depending on the classification of the malpractice.<sup>611</sup> The Council also provides accessible channels for reporting misconduct, which enhances access to justice for victims of pharmacists' malpractice and promotes professional accountability.

### 5.8. **Legal and regulatory loopholes in Rwanda's medical liability system**

Despite highlighted admirable initiatives, Rwanda's medical liability framework endured numerous legal and regulatory challenges, particularly during the enforcement phase. The primary source of medical liability is statutory provisions and court precedents. But such laws are often constrained by a lack of institutional capacity, inadequate procedural principles, and difficulties in acquiring and presenting expert testimony. All these factors may contribute to the difficulty of resolving medical liability cases in a timely and proper manner, which in turn affects the general observance of patient rights and medical standards.

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<sup>606</sup> Ibid., Article 32.

<sup>607</sup> Ibid., Article 39.

<sup>608</sup> Article One of the Law No. 45/2012 of 14/01/2013 on Organisation, Functioning and Competence of the Council of Pharmacists (2013).

<sup>609</sup> Ibid., Article 3.

<sup>610</sup> Ibid., Article 27.

<sup>611</sup> *Article 4 of the National Pharmacy Council Disciplinary Measures' Guidelines*, 2nd ed. (Kigali, Rwanda, 2023), p. 8.

To add to this, the provisions of the statute are largely complemented with ethical standards and doctrinal principles that dictate the conduct of healthcare professionals and define their duties to a greater extent than the law itself. These ethical standards also foster a culture of professionalism and patient-centred healthcare service delivery. Thus, the medical liability system in Rwanda is regulated by laws and regulations, legal precedents, and morality, although enforcement is another concern that must be strengthened. *These prevalent problems can be addressed to encourage medical accountability by enhancing regulatory oversight, establishing professional training on legal and ethical duties as part of CPD programs, and making enforcement processes more transparent.*

Furthermore, every institution is recommended to regularly review and adopt best practices within its sphere of practice. This is particularly the case in healthcare service delivery in developing countries, such as Rwanda. The issue of copying from best practices is positive but may have negative implications. When the institutional theory governs a healthcare provider, isomorphic factors may push it to imitate other institutions with greater capacity to some extent in order to gain legitimacy.<sup>612</sup> Legal and regulatory coercion, normative standards, and mimetic pressure could prompt the organization to do so while implementing certain structures, strategies, and processes, which always require both human and financial resources that it does have in place. This situation may lead to organizational collapse or failure in healthcare delivery.

Even though laws and regulations reflect patients' rights, they are not adequately implemented or developed. Even those institutional structures established to protect the interests of health service users are often breakable, with insufficient operational or legal capacity. The agencies charged with oversight, including professional councils, frequently do not have the authority to conduct a detailed investigation or sanction the wrongdoer practitioner. This regulatory gap limits the deterrent accountability required to ensure compliance in the health care system.

On top of this, these agencies have financial and human resource limitations, which increase the enforcement divide. They also lack sufficient funds and cannot retain qualified staff and facilities to carry out efficient monitoring and enforcement. This situation has had an effect of leaving victim patients unsupported in cases where their rights have been infringed, particularly those from rural areas. A larger population is unaware of the rights and protections afforded to them. They are also not guided on the measures to be undertaken in seeking redress, thus, a continued disparity between the law in text and the actual empowerment of patients. This fact demonstrates that more action is essential to strengthen enforcement mechanisms, enhance regulatory capabilities, and better educate patients to turn legal rights into practical protection.

Moreover, the absence of disclosure of medical malpractice (code of silence) has been identified as a regulatory problem that may compromise the feedback loop that is critical in enhancing

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<sup>612</sup> Katy Ellis Hilts et al., "Institutional Factors Associated with Hospital Partnerships for Population Health: A Pooled Cross-Sectional Analysis," *Health Care Manage Review* 47, no. 3 (2022): 254–261, <https://doi.org/10.1097/HMR.0000000000000325>. Institutional.

supervision in the healthcare system. The inability to regulate bodies through correctional measures and effective prevention of hazards is the absence of accurate and comprehensive data, which is not provided by an inadequate reporting procedure. The existence of such a gap is an obstacle to regulatory reforms that would advance patient safety and, at the same time, hold professionals accountable. Additionally, public mistrust among healthcare providers, patients, and regulators stemming from underreporting needs to be addressed. The absence of visible reporting systems, as well as insufficient incentives or safeguards for whistleblowers, might lead to healthcare workers' reluctance to report mistakes or negative occurrences, lest they run afoul of the law or lose their careers. Such reluctance not only helps avoid identifying the patterns that might shape policy change but also negatively affects the development of a safety and learning culture in healthcare institutions. Thus, it is essential to address underreporting to maintain the integrity of the regulatory feedback loop and foster an environment that supports the continuation of reforms and improved healthcare outcomes.

Also, there is a legal ambiguity surrounding the concepts of medical malpractice, error, and negligence, stemming from the absence of explicit definitions or statutory guidance that clarifies which acts or omissions fall under these categories. This regulatory gap creates challenges in judicial and professional settings, where determining liability or fault requires a nuanced understanding of professional standards rather than relying on rigid legal criteria. Consequently, the determination of whether a particular act constitutes malpractice or negligence must be grounded in an expert assessment of what is considered commendable or acceptable practice within the relevant professional community. This approach emphasises the role of prevailing professional norms and consensus as the benchmark against which conduct is measured.

The dependence on expert analysis emphasises how dynamic and context-sensitive malpractice and negligence assessments are. As the community's knowledge and practices evolve with time, what is deemed negligent may no longer be so tomorrow. Also, professional standards change in tandem with technological and knowledge advancements, as well as social expectations. Because of this, court decisions in this area usually call for the assistance of specialists who can evaluate acts in accordance with current best practices to ensure liability is determined based on contextually relevant information rather than solely on statutory language. The situation also necessitates CPD programs and the enforcement of clear, current guidelines from the medical profession regarding these complex determinations, even though there is a reliance on experts. This will help practitioners and the legal system better understand the complexities involved. Relatedly, although there is a reliance on experts, the situation also calls for the enforcement of clear, up-to-date guidelines from the medical profession regarding these complex determinations, so that practitioners and the legal system can better understand the details involved.

Moreover, there is no binding strategy for amicable settlement of medical malpractice claims.<sup>613</sup> Initially, there were the Prime Minister's Instructions governing the organisation and functioning of the committee in charge of out-of-court settlements.<sup>614</sup> This committee was responsible for resolving disputes between the state and its institutions without resorting to litigation, reducing court congestion, and promoting amicable settlements. This legal instrument contributed to the settlement of numerous malpractice claims involving the Ministry of Health or its affiliated entities. However, following various legal and administrative reforms, the instrument was repealed. The structure was redefined, and such a mandate was shifted to other mechanisms, such as ADR and court-annexed mediation. One can say that the instructions were instrumental to the government, but they were not inclusive, as private healthcare providers had no comparable approach to redress.

To reach an amicable settlement, there would be a *prima facie* organ mandated to adjudicate malpractice claims before reaching the court. For example, labour disputes from both the public and private sectors could reach the court after exhausting all available avenues. If the dispute arises from the public sector, it should first be exhausted through gracious recourse and hierarchical appeal. If it were from the private sector, it should have first exhausted the labour inspectors' offices. Thus, there should be a harmonised mechanism for resolving medical malpractice claims that is affordable and easily accessible to victims. Romanian procedures for resolving medical malpractice complaints out of court and commissions for monitoring and professional competence in malpractice cases could serve as best practices.<sup>615</sup>

There is another challenge related to the implementation of medical laws. While various provisions in the Healthcare Law provide for ministerial orders to facilitate its enforcement, these Orders have not been issued, leaving a gap between the legal text and practical implementation. For example, the law provides for a minister's order establishing a committee to address disciplinary issues in healthcare facilities,<sup>616</sup> but such a committee has not been established because that ministerial order has not been issued. This leads to different legal regimes being applied to public and private sector health facilities when dealing with disciplinary matters.

Furthermore, to align medical practice with international standards and emerging technologies, address misalignments in healthcare delivery, modernise, and scale up Rwandan healthcare delivery, the healthcare law introduced additional healthcare services. It also provided more than 10 ministerial Orders under various provisions that will regulate those services, as well as some existing ones. In this regard, Minister's Orders will determine the healthcare services provided at

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<sup>613</sup> Protais Byiringiro, Pie Habimana, and Eugene Silas Seminega, "Medical Malpractice Liability in Rwanda: Aligning Legal Theories with Judicial Practices," *Lwati: A Journal of Contemporary Research* 22, no. 3 (2025): 3, <https://www.ajol.info/index.php/lwati/article/view/307838>.

<sup>614</sup> Prime Minister's Instructions N° 005/03 of 16/12/2015 Governing the Organisation and Functioning of the Committee in Charge of out-of-Court Settlements.

<sup>615</sup> Hanganu et al., "Reasons for and Facilitating Factors of Medical Malpractice Complaints. What Can Be Done to Prevent Them?"

<sup>616</sup> Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services, Art. 106.

each of the three healthcare levels,<sup>617</sup> as well as the prices for those services provided by healthcare facilities.<sup>618</sup> The same situation applies to the licensing of a private healthcare facility,<sup>619</sup> the inspection of a healthcare facility,<sup>620</sup> marketing of healthcare services by a healthcare facility,<sup>621</sup> as well as the amount of insurance premium share payable by the healthcare professional and the amount payable by the employer.<sup>622</sup> This also regards the determination of procedures for the provision of care to a person suspected of, or diagnosed with, a mental health condition subject to criminal proceedings.<sup>623</sup> For assisted reproductive technology services, there should be an Order of the Minister establishing a committee in charge of their supervision and determining its structure and functioning.<sup>624</sup> In this light, the fee for storing gametes and embryos,<sup>625</sup> the maximum allowable age for a gamete donor,<sup>626</sup> the surrogacy contract,<sup>627</sup> as well as standards and protocols governing the provision of healthcare services through digital health and medical technology,<sup>628</sup> are also expected to be provided by the respective prospective Ministerial Orders. Nevertheless, most of those ministerial orders have not been issued, leaving a gap in the implementation of the current healthcare legal regime.

Moreover, although expert testimony does not bind the judges, they attribute evidentiary weight to their findings. Due to a lack of defined standards of care, which results in unclear benchmarks for what constitutes malpractice or acceptable clinical practice, courts may vary in their judicial interpretation of expert opinions. However, such ambiguity may also make expert testimony more subjective. This is coupled with a conflict of interest in the medical community, which prompts practitioners to refuse to testify against their peers, particularly in public hospitals. This necessitates a standardized process for vetting and accrediting medical experts for litigation. Additionally, the expert testimony should be logically reasonable and consistent with the facts of the case, which establishes a ‘reasonable medical probability,’<sup>629</sup> as stated in *Paric v. John Holland Constructions Pty Ltd*. Nevertheless, courts have on multiple occasions requested that experts revise their reports due to a lack of definitive conclusions.

Furthermore, the weight of expert opinion is also doubtful in medical malpractice cases. In the case of *Prosecutor v. Dr. MUGEMANSHURO Alfred and Another*, the appellate court set aside

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<sup>617</sup> Article 5 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>618</sup> *Ibid.*, Article 40 (2).

<sup>619</sup> *Ibid.*, Article 74 (2).

<sup>620</sup> *Ibid.*, Article 75 (2).

<sup>621</sup> *Ibid.*, Article 80 (2).

<sup>622</sup> *Ibid.*, Article 81 (4).

<sup>623</sup> *Ibid.*, Article 35 (2).

<sup>624</sup> *Ibid.*, Article 23 (2).

<sup>625</sup> *Ibid.*, Article 22 (5).

<sup>626</sup> *Ibid.*, Article 25 (3).

<sup>627</sup> *Ibid.*, Article 30 (2).

<sup>628</sup> *Ibid.*, Article 38 (2).

<sup>629</sup> Damian Capozzola and Jamie Terrence, “Appeals Court Clarifies Standard for Admissibility of Expert Opinion in Medical Malpractice Case,” *Clinician.Com* (Morrisville, December 2023), <https://www.clinician.com/articles/appeals-court-clarifies-standard-for-admissibility-of-expert-opinion-in-medical-malpractice-case>.

the autopsy report concerning the patient's death, which indicated that the cause of death resulted from hypoxia after laryngospasm, due to anesthesia. Despite dismissing the testimonies, the appellate Court did not thoroughly investigate the cause of the hypoxia or whether the clinical protocols were adequately followed. This situation creates confusion about the weight of the expert opinion in malpractice trials.

Besides, the current healthcare law aggravates sanctions in cases where medical faults have resulted in serious consequences, but it does not specify what constitutes serious consequences arising from those faults.<sup>630</sup> In addition, the same law allows the treatment of a healthcare service user without their consent if it is in the public interest.<sup>631</sup> The provision also raises another question: how will a facility assess what constitutes "public interest" to decide whether to treat a healthcare service user without their consent or that of their representative? This lack of clear criteria is likely to enable professionals to exercise excessive discretion, potentially compromising the foundational principles of informed consent and human dignity.

Another challenge is a disconnect between how lawyers formulate legal arguments and how medical professionals interpret clinical decisions. This issue presents a lack of collaboration between the medical and legal sectors to enhance their personnel. Legal professionals require a sufficient level of medical literacy to cross-examine experts or interpret technical testimony effectively.

### **5.9. Complaint pathways and institutional process**

If a patient is harmed at a clinic, hospital, or any other health facility (health provider), the aggrieved patient or their representative may file a complaint directly with the facility, the Ministry of Health, the council, or the court. If the complaint is filed within that health provider's administration, the latter conducts an internal review through an Ethical Committee to determine whether the harm is linked to the practitioner's or the provider's act or omission. The Committee's assessment aims to identify the incident and decide whether it could be managed at the health provider level. If it finds it to be a disciplinary fault, the Ethical Committee may transfer it to the provider's disciplinary committee for disciplinary proceedings against the suspect medical practitioner. If the Ethical Committee finds the complaint falls within its mandate, it can make a decision, recommend a course of action to the health provider, and report to the hospital Quality Improvement Committee. If it finds the case manageable, the provider may issue an apology to the aggrieved patient or choose to ignore the complaint. Such ignorance has various factors, including the fear of paying compensation, self-incrimination, or providing evidence for future litigation.<sup>632</sup> However, due to an informal culture of shielding peer doctors from medical malpractice, known as the "code of silence,"<sup>633</sup> complaints regarding medical malpractice are

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<sup>630</sup> Article 83 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>631</sup> Ibid., Article 64.

<sup>632</sup> George Miaoulis and Ivan M Manev, "Personal and Organizational Responsibility in the Delivery of Healthcare Services: Breaking the Code of Silence," *Health Services Insights* 18, no. 1–12 (2025), <https://doi.org/10.1177/11786329251356095>.

<sup>633</sup> Miaoulis and Manev.

rarely brought before the hospital administration where they occurred. Even if they are, the health provider may have no capacity to investigate the matter or no specific funds for compensating for medical malpractice.

Apart from professional and administrative liability, aggrieved patients or their representatives can file complaints against the health providers through the professional council. This could be directly from the complainants or indirectly through the Ministry of Health. In this case, the council investigates the matter and reports its findings to the Ministry of Health. If the matter is found to be a medical malpractice, the Ministry may negotiate with the aggrieved party to avoid court litigation and issue an apology to the patient. At this point, the Ministry’s attorney and the patient or their representative schedule a meeting to discuss the matter. The hospital where the patient experienced the malpractice is convened, and if they reach an agreement, the Ministry pays the agreed amount, or the Hospital pays it upon the Ministry's demand. Such a negotiation may involve a mediator or a conciliator to facilitate the amicable dispute settlement. The compensation is not only based on the payment of a certain sum of money; it may also involve repairing the damage caused by such malpractice, such as treating iatrogenic injuries free of charge. If the parties do not agree on the compensation, the complainant may seek relief in court.

If the matter is gross or overwhelming negligence, mostly involving the death of a patient, various organs, including the Council, RIB, and the prosecution, cooperate. Although the criminal court could handle the case, the victims can separately petition for civil damages. In civil matters, the court determines the amount of compensation based on the severity and surrounding circumstances, including moral harm and financial loss. Unlike most US states, Germany, the UK, Canada, and India, the court’s damage in Rwanda is not subject to any caps that would otherwise violate the right to trial. In criminal matters, the court either acquits the suspect if found innocent or imposes a term of imprisonment if found guilty. In most cases, there was an overwhelming negligence of involuntary manslaughter, or when there was an intention to harm the victim.

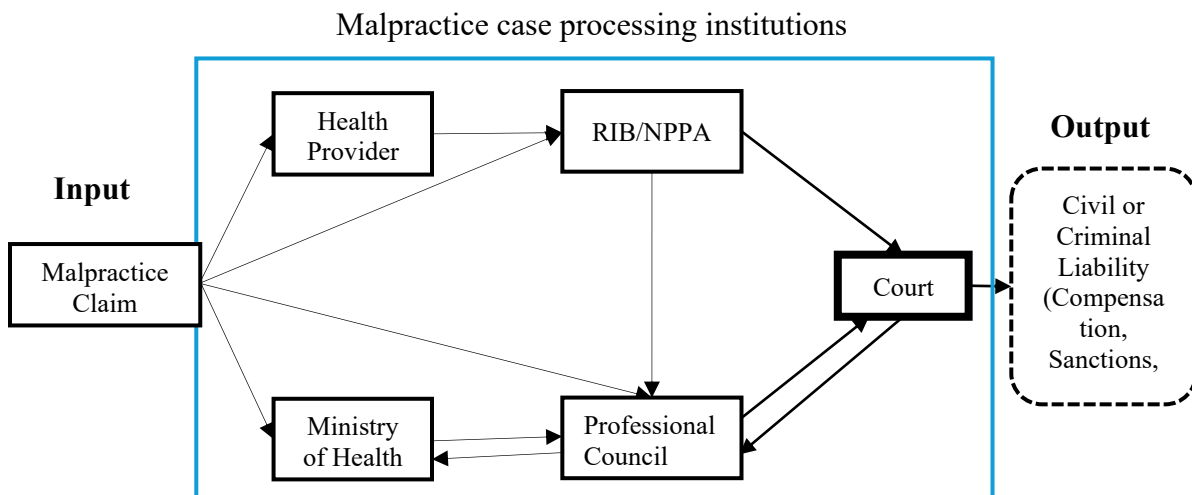


Figure 2. Process flowchart of medical malpractice accountability

Despite the availability of a remedial process for medical malpractice complaints, their resolution is limited by resource and evidentiary challenges. The case investigation process is constrained by resource and evidentiary deficiencies resulting from documentation failures. Documented delays occur between the submission of a complaint, the investigation, and the decision. Besides, the results reveal strong legal frameworks for patient rights but uneven awareness, persistent gaps in informed consent, and non-operational professional liability insurance despite statutory provisions.

### **5.10. Conclusion**

The purpose of medical practice and medical liability structure in Rwanda is to ensure the safe and compliant delivery of healthcare services. They are underpinned by statutory provisions, code of ethics, professional councils, and government institutional oversight mechanisms. This legal landscape also protects the autonomy of healthcare service users and fosters accountability among medical practitioners. Despite the existence of this framework, its practical implementation remains impractical. The lack of ministerial orders necessary to operationalize the healthcare Law represents a significant divide between the statutory objectives and their operational enforcement. Additionally, there are other challenges resulting from the insufficient operational capacities of oversight bodies, which hinder their ability to conduct investigations and impose disciplinary measures. There are no comprehensive procedural mechanisms in place to handle medical malpractice claims effectively. These shortcomings in the enforcement undermine the accountability of healthcare professionals and the interests of healthcare users, particularly in underserved and rural or remote areas. Besides, various institutions, including health facilities, the Ministry of Health, professional councils, the RIB, the NPPA, and courts, are involved in resolving malpractice cases; however, delay remains a challenge in the compensation process.

To address these issues, there is a need for the promulgation of ministerial orders to implement the healthcare law and regulations. Reforms are also essential in critical areas, such as extending the regulatory agencies' powers and reinforcing their operational capacities, both in terms of human and financial resources. Additionally, it is necessary to foster a culture of legal and ethical compliance, accompanied by public awareness reinforcement. These measures are essential to transform legal provisions into real protections, thereby promoting ethical and legally compliant medical practices. Such an environment will help repair the eroded public trust, ensure the accountability of healthcare professionals, and uphold patients' rights and safety in Rwanda's dynamic healthcare system.

## CHAPTER SIX

### LIABILITY OF MEDICAL MALPRACTICE IN RWANDA

Medical liability is fundamental to healthcare governance, as it upholds accountability, protects patient rights, maintains professional integrity, and ensures legal compliance in clinical practice. In Rwanda, the medical liability framework is primarily fault-based, focusing on the duty of care and the principle of negligence as central determinants of liability. It has evolved from informal, community-based mechanisms in the pre-colonial era to a structured legal regime underpinned by statutory provisions influenced by international norms and comparative jurisprudence.

This chapter begins by discussing the historical background, rationale, and ethical dilemmas associated with medical liability. It further explores Rwanda's medical liability system from various dimensions, encompassing professional, civil, administrative, and criminal liability, while outlining the operational mechanisms that ensure effective enforcement. Its overarching aim is to evaluate whether the current liability scheme offers the desired outcomes in terms of justice delivery to the victims of medical malpractice, patient safety, systemic integrity, and equitable healthcare delivery, while identifying gaps and opportunities for reform.

The discussion situates Rwanda's approach within a global context, comparing fault-based and no-fault compensation models to evaluate their respective advantages in achieving deterrence, accountability, fairness, and efficiency in the justice delivery process. Additionally, the researcher integrates doctrinal analysis with comparative perspectives from jurisdictions such as France, Hungary, South Africa, and Canada to explain normative foundations and practical challenges of Rwanda's liability regime. This analysis also helps illustrate how liability standards, including negligence, strict liability, and professional accountability, may influence outcomes for healthcare users and providers. In the end, the chapter underscores the importance of a comprehensive, patient-centered liability system that strikes a balance between deterrence and fairness, while promoting systemic improvements in healthcare delivery.

#### 6.1. History of medical liability

Medical liability originates from both written and unwritten laws that have evolved over time. Historically, medical liability was often imposed both civilly and criminally through corporal punishment. From the Law of Hammurabi in 1794 BC, medical malpractice was recognised under Rule 218, where a physician who could kill a patient or cut out one of his eyes was subject to having his hands cut off.<sup>634</sup> This punishment was imposed without trial or presumption of innocence.

In the same vein, Cumulative Egyptian Hieroglyphics, dating back to around 2700 BC, provided a basis for holding physicians accountable for contravening the standards of practice as agreed upon by the royal physician priesthood. Before the introduction of the castle system of punishment

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<sup>634</sup> Petroula Mandilara, Spyridon P Galanakos, and George Bablekos, "A History of Medical Liability : From Ancient Times to Today," *Cureus* 15, no. 7 (2023): 1–7, <https://doi.org/10.7759/cureus.41593>.

in India, the Indian Laws of Punishment were also imposed around 1500 BC to punish medical malpractice.<sup>635</sup>

In China, the Chinese Confucian precepts (515-476 BC) dictated that doctors follow “The Tao” or the right action, and if not, to refrain from practice. Under the reign of Genghis Khan (1206-1227 BC), the violation of “The Tau” was subject to prosecution and trial, and if guilt was proven, the wrongdoer was punished by death.<sup>636</sup>

In Ancient Greece, medical liability can be traced back to the legislative texts of Draco, dating to 621 BC, and Solon, between 639 and 559 BC. However, these texts were linked to theocracy, which mitigated the harshness of previous punishments, such as the death penalty for physicians.<sup>637</sup> Hippocrates (460–377 BC) contributed significantly to the development of modern medical practice, but it was more ethical than legal.

Moreover, due to immoral acts between 1932 and 1945 that humiliated the medical profession, German doctors were prosecuted and tried by the Nuremberg Tribunal, and 16 of them were found guilty, and 7 of them were sentenced to the death penalty.<sup>638</sup> Concurrently, various approaches were developed in the UK to harmonise medical liability, including the use of medical expert opinion in the contractual approach and the tort principle. The most well-known approach is the “Bolam Test,” which has since become the foundation for liability in medical litigation.

Furthermore, there were doctors’ inhuman acts in history that necessitated an emergent action in medical practices. For example, various atrocities committed by Unit 731 members towards prisoners of war and civilians during their experiments after World War II reflect the state of a lack of accountability and liability in medical practice. These Japanese medical personnel were not held accountable in the International Military Tribunal for the Far East (Tokyo Trials), unlike the case of the Nazi doctors in the Nuremberg era.<sup>639</sup> This horrible act prompted the International and bioethics experts to call for “moral repair” for this injustice, whereby the permanent memorial to the victims was established, Japan issued a policy against human experimentation without informed consent, and the U.S. was requested to issue an official apology for its complicity in those medical atrocities.<sup>640</sup> These acts also prompted an immediate call for international legal instruments of human rights and medical ethics to include clauses prohibiting all forms of complicity in unethical medicine, whether before or after the fact, by any state or group, for any reason.

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<sup>635</sup> Mandilara, Galanakos, and Bablekos.

<sup>636</sup> Henry Buchwald, “The History of Medical Liability: Where Did It Come from, and Where Is It Heading?” (Minneapolis, U.S., 2023), <https://www.ifso.com/pdf/henry-buchwald.pdf>.

<sup>637</sup> *Ibid.*, 5.

<sup>638</sup> Buchwald, “The History of Medical Liability: Where Did It Come from, and Where Is It Heading?”

<sup>639</sup> Jing-bao Nie, “The United States Cover-up of The United States Cover-up of Japanese Wartime Medical Atrocities: Complicity Committed in the National Interest and Two Proposals for Contemporary Action,” *The American Journal of Bioethics* 6, no. 3 (2006): 21–33, <https://doi.org/10.1080/15265160600686356>.

<sup>640</sup> Doug Hickey et al., “Unit 731 and Moral Repair,” *Journal of Med Ethics* 43, no. 4 (2016): 1–7, <https://doi.org/10.1136/medethics-2015-103177>.

In Rwanda, the history of medical liability is relatively short. During the pre-colonial kingdom era, medicine was dominantly traditional and provided by healers (abavuzi) and herbalists. During this period, any disputes that may arise over harm caused by treatment could be resolved through a community-based process, handled by elders or local councils applying customary law. If a healer's actions were deemed negligent or harmful, compensation (indemnity) could be imposed in kind (cattle or goods). There were no codified laws or written standards governing medical practice, and no formal courts existed to apply them.<sup>641</sup>

Modern medicine began with the German colonial period and expanded during the Belgian colonial period, particularly with the involvement of missionary doctors in Rwanda.<sup>642</sup> During colonial periods, medical liability in Rwanda followed European civil and penal codes (Belgian law), applied mainly to Europeans and formal institutions. Native patients rarely accessed courts; disputes were still settled informally, as in pre-colonial periods.<sup>643</sup> Although there was no specific medical liability framework in place during that time, medical malpractice and negligence cases were typically treated under general negligence or criminal provisions of Belgian law. However, those doctors and trained health workers were considered sacred at one point, as their clinical practice was often intertwined with evangelism. This sense could limit daring to hold them accountable for wrongful acts or even lessen harsh penalties against them.

Later, after the independence in 1962, medical matters were considered either civil or criminal issues, regulated by different laws stemming from the colonial legacy.<sup>644</sup> Furthermore, the regulation of the art of healing in Rwanda took shape after the 1994 Genocide against the Tutsi, and subsequently, the medical council was established in 2003. Clinical practice kept being governed by a series of provisions embodied in various health-related laws and regulations, as well as the former Civil Code, which was repealed as part of the reform of all laws enacted under the colonial legacy. The criminal code could also intervene in cases of malpractice that involve a criminal aspect. Recently, the foreign precedents and doctrines have been playing a pivotal role in Rwanda's medical liability system.

## **6.2. Rationale for medical liability**

Before discussing various aspects of medical liability in Rwanda, it is crucial to begin with its rationale. The ultimate goal of the medical profession is to save human lives by relieving suffering and preserving the welfare of the body.<sup>645</sup> This lead role makes it noble. Yet, dissatisfaction with health care delivery can discredit its nobility and impair its enormous contribution to society.

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<sup>641</sup> Binagwaho, Freeman, and Sarriera, "The Persistence of Colonial Laws: Why Rwanda Is Ready to Remove Outdated Legal Barriers to Health, Human Rights, and Development."

<sup>642</sup> "Church, John Edward (1899-1989): Prominent Leader of the East African Revival," School of Theology History of Missiology, accessed December 22, 2025, <https://www.bu.edu/missiology/missionary-biography/c-d/church-john-edward-1899-1989/>.

<sup>643</sup> Binagwaho, Freeman, and Sarriera, "The Persistence of Colonial Laws: Why Rwanda Is Ready to Remove Outdated Legal Barriers to Health, Human Rights, and Development."

<sup>644</sup> Binagwaho, Freeman, and Sarriera.

<sup>645</sup> Pandit and Pandit, "Medical Negligence: Coverage of the Profession, Duties, Ethics, Case Law, and Enlightened Defense - A Legal Perspective."

Indeed, a derelict medical professional who fails to comply with standards of care can cause unimaginable patient harm or premature death and a socio-economic burden to the entire community.

Before assessing the logic of medical liability, it is worth briefly answering the following question, although further details will be provided throughout the subsequent discussions. When is a physician at fault? The physician is at fault for failing to adhere to the standards of care and ultimately breached the duty of care towards the patient. Such a failure can include misdiagnosis and administering the wrong or unnecessary procedure or treatment to a patient. The health care provider is also at fault for not respecting the patient's rights.<sup>646</sup> A physician's error can result from negligence, lack of skill, inaccurate information, communication breakdown, and bureaucracy in healthcare.

Danzon argues that the liability of healthcare service providers can encourage the most effective treatment for patients.<sup>647</sup> Nonetheless, a clash is likely to arise between medical experts and compensation authorities if all remedial measures for medical injuries focus solely on economic compensation. Such compensation would prioritise the future quality of healthcare, in addition to the financial loss already suffered. All forms of liability ultimately aim to prevent medical malpractice by providing victims of medical injuries with a flexible remedy and successful compensation. Indeed, one of the goals of medical liability is to create "deterrence," whereby medical practitioners must tread cautiously in their professional endeavours to prevent medical errors that subject them to liability. The liability also promotes another objective of "accountability," where health care professionals should be accountable to the public to maintain their trust.

Therefore, the overall objective of medical liability is to ensure healthcare providers are accountable, protect patient rights, and compensate the victims of medical negligence and malpractice,<sup>648</sup> and promote high standards of medical practice by encouraging compliant, diligent, and ethical care. Within this framework, various purposes are implied, including the protection of patients' rights and safety, compliance with health regulations and policies, the prevention of future malpractices, and the delivery of justice to victims. Additionally, liability prevents unacceptable and detrimental social behaviour by keeping professional, ethical values and practice standards, and establishing normative responsibility standards.<sup>649</sup>

#### 6.2.1. Protection of health users' rights and safety

Establishing medical liability mechanisms, such as strict health laws and regulations, can enhance the protection of patients' and other healthcare users' rights and safety. In this regard, enhancing

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<sup>646</sup> Pr Herman Nys, "Report on Medical Liability in Council of Europe Member States: A Comparative Study of the Legal and Factual Situation in Member States of the Council of Europe Professor in Medical Law Universities of Leuven and Ma" (Strasbourg, 2005).

<sup>647</sup> Patricia, "Liability For Medical Malpractice."

<sup>648</sup> Michelle M. Mello et al., "Malpractice Liability and Health Care Quality."

<sup>649</sup> Durbin, "Torts – Nature of Tort Law and Liability."

legal frameworks that clearly define the responsibilities and accountability of healthcare professionals is critical. When the Government establishes accessible and transparent complaint and redress mechanisms for the victims of medical malpractice and promotes rigorous adherence to ethical standards and clinical guidelines, there will be collective justice for all healthcare users.

Moreover, CPD is always essential in any professional practice, as it ensures that service providers are well-equipped to deliver safe and competent care. In this view, empowering the culture of transparency and accountability in service delivery can help build public trust. Additionally, implementing effective risk management systems, fostering open communication between patients and healthcare providers, and enforcing strict penalties for negligence can further safeguard patient rights and improve overall healthcare quality and safety in Rwanda.

#### 6.2.2. Compliance with health regulations

Adhering to the health regulations is a crucial reason for medical liability. Indeed, without a robust medical liability framework with strict sanctions for medical malpractice, it would enable a culture of impunity and poor service delivery in the system. However, with strict professional, civil, and criminal sanctions, healthcare providers will strive to comply with applicable legal and ethical standards, as well as established protocols in the profession, to avoid legal consequences, financial penalties, or loss of their professional reputation. This approach will ultimately enhance patient safety and improve the quality of care.

In this regard, the Government has a duty to establish a comprehensive legal framework that entails well-defined responsibilities and sanctions for breaches, as well as an awareness campaign, enabling practitioners to comprehend their responsibilities and the repercussions of non-compliance with these rules.

#### 6.2.3. Prevention/Deterrence

Prevention of future malpractice is another vital purpose of medical liability. Sanctions serve as a deterrent against professional misbehaviours. In medical practice, the fear of lawsuits or disciplinary action motivates practitioners to provide high-quality care, document their practices thoroughly, and follow evidence-based protocols,<sup>650</sup> engage in continuous education, and stay up-to-date with the latest clinical guidelines. These efforts improve overall practice standards and minimise medical errors. This proactive approach fosters a culture of safety and accountability within the healthcare system,<sup>651</sup> thereby reducing the likelihood of future negligence and ultimately enhancing patient trust and the quality of care.

#### 6.2.4. Justice/reparation

One of the critical roles of justice delivery for the victims is reparation. In medical malpractice situations, remedial resources are essential for delivering justice to patients who have suffered harm from an adverse event and for providing them with appropriate compensation as reparation. This is a fundamental purpose of medical liability. Liability in this regard helps restore fairness by

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<sup>650</sup> Kapaki and Souliotis, p. 66.

<sup>651</sup> Kapaki and Souliotis.

holding health professionals accountable. This enhances trust in the healthcare system as it demonstrates that there are mechanisms in place to protect patients' rights and ensure that those harmed are compensated. This promotes a culture of responsibility and integrity in medical practice.

### **6.3.Ethical dilemma in healthcare accountability**

There is an ethical dilemma in healthcare accountability rooted in two key concepts. The first concept, "*injuria sine damnum*", involves a consideration of breach of duty or wrongful act, even though no actual harm is inflicted on the patient, while the second, "accountability without injury", entails holding healthcare practitioners accountable for 'near-misses' or lapses, even when no direct injury results. The following discussion centers on the two concepts.

#### **6.3.1. Injury without damage (*Injuria sine damnum*)**

Medical liability can extend beyond the medical intervention's outcome, even to the physician's choice of procedure itself. This raises an important question: what are the implications if the doctor opts to use a procedure that will inflict pain on the patient despite the availability of other alternatives? Could such a decision constitute grounds for legal action without causing harm to the patient?

Even in cases where there is no bodily harm, a doctor's decision to undergo a painful procedure when there are less painful options may give rise to a claim. This is covered by the legal doctrine of "*injuria sine damnum*," or "injury without damage."<sup>652</sup> It essentially means that a legal right has been violated without resulting in bodily injury.<sup>653</sup> In these situations, the patient may argue that the physician violated their duty of care by not considering less painful alternatives, which could be construed as medical malpractice or negligence. It would be the patient's responsibility to prove that the doctor's actions were unreasonable and fell below the standard of care expected in the medical profession.<sup>654</sup>

On the contrary, a person can suffer a loss or damage without violating their legal rights. This doctrine is known as "*damnum sine injuria*" or damage without injury. A patient can experience a painful procedure or bodily harm, such as uncomfortable scars, but may lose any cause of action if a physician has adhered to all existing standards of procedure and protocols. This may occur if pain or a scar is unavoidable for a patient who undergoes such a procedure. However, this would be chosen as the best alternative. This concept, however, raises an issue of whether the imposed sanctions are appropriate merely based on procedural or technical errors that do not result in tangible harm.

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<sup>652</sup> Kunal Jain, "Damnum Sine Injuria & Injuria Sine Damnum: All You Must Know," [ipleaders.in](https://blog.ipleaders.in/damnum-injuria/?form=MG0AV3), 2020, <https://blog.ipleaders.in/damnum-injuria/?form=MG0AV3>.

<sup>653</sup> Jain.

<sup>654</sup> Seth Gladstein, "Cause of Action? Personal Injury," 2020, <https://gladsteinlawfirm.com/what-is-a-cause-of-action-personal-injury-101/?form=MG0AV3>.

### 6.3.2. Accountability without injury: sanctioning medical lapses?

Despite established standards of liability, one may ask the following question: What could be done if a medical practitioner fails to act with due diligence, but fortunately, no harm occurs, although there is a likelihood of it happening next time? Shall this behaviour be subject to punishment even if there is no harm?

This question centers on the intersection of medical ethics, legal liability, and professional accountability. The concept of accountability without injury raises an issue of “near misses” in healthcare delivery, highlighting the importance of maintaining high standards of care and preventing future adverse events by specifically sanctioning medical lapses or near misses.

Ordinarily, the legal approach is “no harm, no liability,” in which most legal systems, including Rwanda, establish liability by assessing four key elements: the duty of care, breach of that duty, an injury, and the causal link between the injury and the breach of that duty. Thus, if the fourth element is missing, no liability could be invoked in the medical compensation system. However, jurisdictions like Nigeria and Rwanda permit disciplinary or regulatory action, even in the absence of harm, particularly if there was a foreseeable risk to the patient. However, a negligence claim merely based on that breach (error) is not likely to be successful in court, as articulated by Oludamilola and Oluseyi.<sup>655</sup> This approach emphasizes the ethical principle of non-maleficence (do no harm), as an act or omission posing a risk of harm, even if there is no immediate harm, should be sanctioned. This is because it constitutes a pattern of reckless care that can erode public trust and endanger future healthcare safety. In Rwanda, professional bodies can impose preventive measures to protect the public welfare, such as issuing warnings, mandating retraining, suspending, or revoking licenses in severe cases or instances of recidivism.

Near misses are valuable opportunities for systemic learning and risk management in modern medical practice, thereby improving the healthcare system. They enable hospitals to identify the root causes of adverse events and promote a culture of safety by encouraging reporting without fear of sanction. However, accountability without injury could raise a further inquiry about whether potential harm should be the basis of punishment, such as the outcome. Although this could be the topic for future discussion, it should be looked at from both the pros and cons angles.

Nevertheless, it is worth noting that consequences are not only resulting from tangible injury. They are, instead, necessitated by any act or omission that violates the acceptable standards of care or poses potential risks. Thus, instead of corrective action that involves punishments, these concepts necessitate professional accountability for prevention, education, and safeguarding public trust. Both situations show the tension between legal and ethical dimensions in healthcare. They both ensure accountability, safety, and professional integrity in healthcare delivery.

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<sup>655</sup> Adejumo and Adejumo, “Legal Perspectives on Liability for Medical Negligence and Malpractices in Nigeria, p. 2.”

## 6.4. Models of medical liability

Medical liability models encompass tort-based systems, no-fault compensation, and a hybrid approach. Their applicability can vary from jurisdiction to jurisdiction. In Rwanda, courts have developed various approaches falling within this spectrum, based on which victims of medical negligence and malpractice can seek redress. Among other things, the central liability system is fault-based, encompassing vicarious liability, corporate liability, and criminal liability. The following discussion concerns these liability models.

### 6.4.1. No-fault compensation system

Contrary to the adversarial litigation in courts, the ‘no-fault system’ is a compensation model in which healthcare users can receive compensation without having to prove negligence through the technicalities of a court case. Many OECD countries, including Denmark, Finland, New Zealand, and Sweden, have adopted this model.<sup>656</sup> A no-fault system aims to provide compensation for suffered injuries without necessarily assessing the negligence of a healthcare provider.<sup>657</sup> This system was introduced in different states based on the employees’ working injury compensation structure. In Virginia and Florida, the no-fault plan was introduced to compensate birth-related neurological injuries.<sup>658</sup>

The no-fault system is primarily administered by the government or insurance companies, focusing on injury rather than fault. Under this system, claims are not taken to court. Instead, they are adjudicated by the designated administrative agencies to reduce the delay and expense of the courts’ claims adjudication.<sup>659</sup> This approach makes it faster and less adversarial, reducing both the financial and emotional burden. The system was previously known to focus on birth-related litigation.<sup>660</sup> Then, it expanded to incorporate general medical liability. Similar to the UK, Rwanda does not apply a no-fault medical liability system.

Contrary to the tort-based compensation model, which is claimed to be expensive, time-consuming, focusing on medico-legal technicalities, promoting defensive medicine, the no-fault compensation model is recognised as patient-centred, time-effective, and offers fair compensation if the harm was avoidable. It also encourages the culture of reporting additional medical errors, enabling healthcare institutions to take appropriate measures to prevent them.<sup>661</sup> Thus, the no-fault compensation system is believed to encourage transparency in compensating victims of medical

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<sup>656</sup> Nys, “Report on Medical Liability in Council of Europe Member States: A Comparative Study of the Legal and Factual Situation in Member States of the Council of Europe Professor in Medical Law Universities of Leuven and Ma.”

<sup>657</sup> Patricia, “Liability For Medical Malpractice.”p. 64-65.

<sup>658</sup> Saša Nikšić, “Understanding Medical Liability,” in *Legal and Forensic Medicine*, ed. Roy G. Beran (Springer, 2013), 691, 701–2, [https://doi.org/10.1007/978-3-642-32338-6\\_53](https://doi.org/10.1007/978-3-642-32338-6_53).

<sup>659</sup> Patricia, “Liability For Medical Malpractice.”

<sup>660</sup> Matthew M. Rice, *Medical Professional Liability Insurance* (American College of Emergency Physicians, 2004).

<sup>661</sup> Vicki Swanton, “No Fault Compensation,” 2021, <https://dwfgroup.com/en/news-and-insights/insights/2021/2/no-fault-compensation>.

iatrogenesis resulting from adverse treatment outcomes, leading to fair, efficient, and equitable compensation.<sup>662</sup>

However, another side of the no-fault system is that most jurisdictions also impose compensation caps to control costs and balance the compensation fairness and efficiency, ensuring the sustainability of the compensation fund. Consequently, these caps deprive the plaintiffs of seeking full compensation, as they do not allow them to present evidence to justify it, which contradicts the right to a trial by a judge or a jury. This system contravenes the constitutional principle of the separation of powers, as it vests judicial prerogatives in the legislature, which passes laws setting limits on damages.<sup>663</sup>

#### 6.4.2. Fault-based compensation system

The fault-based system of compensation is an approach in which the victim can only receive compensation if they can prove the fault of the wrongdoer. In the medical liability context, the healthcare user can only obtain compensation for the harm suffered upon proving the fault of the healthcare provider. The fault should be understood as negligence, error, or omission, which directly caused that harm. This is also known as malpractice, without which the court could not grant compensation. In other words, there is no compensation or liability for medical providers, even if the harm is severe, as long as there is no fault.

Fault-based claims are expensive in terms of procedure and stressful in proving the breach of duty of care owed.<sup>664</sup> Additionally, they are slow, as they require investigations to gather the facts. Consequently, they could limit access to justice. Although the fault-based system places the burden of proof on the plaintiff, it is, however, known to prioritise accountability and deterrence over universal coverage. Despite these challenges, it is the foundation of all compensation recourses in Rwanda, including courts, committees responsible for dealing with disciplinary faults, and direct insurance claims.

The current healthcare law outlines various faults for which a healthcare professional or healthcare facility could be sanctioned, including those based on professional responsibilities whose breach invokes accountability, but this list is not exhaustive. The law focuses on compensation for harm resulting from substandard healthcare services and administrative penalties for systemic failures, such as poor hygiene that results in infections. Although it maintains the fault-based liability regime introduced by the 2013 law on medical professional liability insurance, which was repealed, it does not overhaul it. For example, it does not define the categories of errors or faults or mention any reference for excusable errors in the context of medical liability.

The healthcare law avoided any tendency towards no-fault compensation, as it did not recall the compensation approach introduced by the previous law in a situation of excusable error. Thus, the

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<sup>662</sup> Troyen A. Brennan and Michelle M. Mello, "Patient Safety and Medical Malpractice: A Case Study," *Annals of Internal Medicine* 139, no. 4 (2003): 272.

<sup>663</sup> Frank A. Sloan and Lindsey M. Chepke, *Medical Malpractice* (London, England: The MIT Press, 2008).

<sup>664</sup> Swanton, "No Fault Compensation."

law on professional liability insurance, in its Article 6, paragraph 2, enabled minors under the age of fourteen (14) to obtain compensation for excusable error, even if this error shielded the medical professional from liability.

The current law does not focus on the liability of healthcare professionals and healthcare facilities. It instead prioritises the preventive measures, such as mandatory training and quality audits, over liability defences. This approach aims to reduce errors through regulation rather than address them after the harm has occurred. However, the current liability system supports the fault-based liability mechanism through mandatory insurance and the establishment of committees responsible for addressing disciplinary faults in healthcare facilities.

#### *6.4.2.1. Grounds for excluding medical practitioner fault and liability*

When can medical practitioners be shielded from liability despite the occurrence of an error and harm? Finding the answer to this question requires an exploration of some aspects. One can ask the following sub-questions. Is liability exempted when errors occur during the exercise of their professional duties? Or is the exemption granted when they have satisfied all the requisites, such as adherence to the accepted medical standards of care, the unavailability or unforeseeability of an adverse outcome, and the absence of negligence, recklessness, or breach of duty?

The answer lies in balancing two conceptual contexts: committing an error while performing the boss's task in good faith or making an error despite the exercise of optimal professional care. The latter introduces a concept of "excusable" or "forgivable" error, while the former invokes "vicarious liability". Consequently, medical professionals will not be held liable if they have exercised their competence, exercised due diligence, and followed the accepted standards of care at the time of treatment.<sup>665</sup> This position is substantiated by the principle that medical practice is exercised under means-based standards rather than results-based guarantees. The former sub-question, which involves committing an error within the scope of diligent standard-compliant healthcare service delivery, is regarded as an inherent risk of medical practice and supplements the latter. However, it does not shield the practitioner in the event that it could be proven that there was a malicious intent to cause harm. The practitioner could also be held personally liable for personal fault through administrative or professional mechanisms. However, if there is no direct link between the harm and the error, even if the latter occurred, a medical practitioner is exempt from liability.<sup>666</sup> In this regard, the burden of proof lies on the shoulders of the plaintiff to establish the causal link between the act or omission and the damage.

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<sup>665</sup> Mirela Carmen Dobriță, "Medical Malpractice: Exonerating Cases of Medical Liability," in *The European Proceedings of Social & Behavioural Sciences*, 15th ed. (Future Academy, 2016), 295–304, <https://doi.org/10.15405/epsbs.2016.09.38>.

<sup>666</sup> André T Mees, "Medical Liability and the Burden of Proof: An Analysis of Recent Quebec Jurisprudence," *McGill Law Journal* 16, no. 1 (1970): 163–72, <https://lawjournal.mcgill.ca/issue/volume-16-issue-1-1970/>.

Nevertheless, it should be noted that the exoneration of the medical professional's liability does not preclude the liability of the healthcare provider or the health facility employing that practitioner if all necessary conditions are met under a fault-based liability system.

### **6.5. Application of tort liability in malpractice cases**

The liability for medical malpractice or negligence is underpinned by a tortious principle rooted in the renowned case of *Donoghue v Stevenson* (1932), in which Lord Atkin established the principles of negligence law and the duty to take reasonable care.<sup>667</sup>

No person can be held liable in tort unless the act or omission with which he or she is charged was a breach of a duty owing by that person to the plaintiff or to a class to which the plaintiff belongs, and the plaintiff has suffered individual damage therefrom.<sup>668</sup>

As summarised in the snippet above, to establish a case of medical negligence under the tortious principle, there are three key considerations. It must be proven that the duty of care was owed; whether that duty was breached; and whether the harm suffered is directly linked to that breach.<sup>669</sup> In this regard, hospitals owe healthcare users a duty of care through their personnel and ostensible agents, who are committed to providing care and treatment to patients. This duty should be well observed in three situations: (a) when deciding to engage in delivering healthcare services to a particular healthcare user; (b) when deciding what treatment to administer; and (c) when administering that treatment to the patient.<sup>670</sup> If they accept the patient, medical professionals are expected to provide the necessary healthcare services employing all their knowledge and skills, with due diligence, and under accepted standards of care. On July 19, 2019, in the *N.L v King Faisal Hospital* case,<sup>671</sup> the Court of Appeal assessed the three components to determine the liability of King Faisal Hospital.<sup>672</sup>

Concurrently, healthcare providing institutions are also expected not to harm healthcare users due to negligence, carelessness, or a reckless attitude among their staff.<sup>673</sup> Thus, medical practitioners should apply all their competence reasonably to save the patient at their disposal, although they

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<sup>667</sup> Oludamilola Adebola Adejumo and Oluseyi Ademola Adejumo, "Legal Perspectives on Liability for Medical Negligence and Malpractices in Nigeria," *Pan African Medical Journal* 35, no. 44 (2020): 2, <https://doi.org/10.11604/pamj.2020.35.44.16651>.

<sup>668</sup> Durbin, "Torts – Nature of Tort Law and Liability."

<sup>669</sup> Geoff Manley, "What Is Medical Malpractice?" (Atlanta: American Board of Professional Liability Attorneys, 2020), <https://www.abpla.org/what-is-malpractice>.

<sup>670</sup> Pandit and Pandit, "Medical Negligence: Coverage of the Profession, Duties, Ethics, Case Law, and Enlightened Defense - A Legal Perspective."

<sup>671</sup> This is a medical malpractice and negligence case on appeal level following the case No RCA 0187/12/HC/KIG ruled by the High Court on November 1, 2013, and the case No RC 0290/09/TGI/GSBO ruled by the Intermediate Court of Gasabo on March 08, 2012. The case involved a mother who attended the hospital for labouring, but due to the hospital's negligence, she suffered an adverse event that resulted in iatrogenic injuries including a fistula among others.

<sup>672</sup> *N.L v King Faisal Hospital*, RCAA 00073/2018/CA (2019).

<sup>673</sup> Pandit and Pandit, "Medical Negligence: Coverage of the Profession, Duties, Ethics, Case Law, and Enlightened Defense - A Legal Perspective."

have no obligation to cure them. In the event that an adverse medical outcome results from the negligence of healthcare providers, they are liable under the law of negligence.

In the U.K., tort has five elements: conduct, causation, fault, duty of care, and injury. However, three of them are central in the context of this research, including fault, duty of care, and injury.<sup>674</sup> They are the most common in many jurisdictions, including Rwanda. From the fundamental principles underpinning the negligence law, there should be further observations apart from the fault, damage, and causal link. This is because the objects that constitute harm vary on a case-by-case basis. Indeed, the victim should have incurred physical or mental injury. This is a harmful change in the healthcare user's physical or psychological condition, weakening or damaging the functional role of their tissue, organ, or entire life. In medical liability, an organ or tissue might have been negligently damaged so that it can no longer serve its role, apart from the change of physical characteristics.<sup>675</sup> To be precise, the physical difference may not be noticeable even though the damage occurred. This reflects the dysfunctional role of that tissue or organ resulting from specific medical treatments. However, in all circumstances, the compensation degree depends on the victim's harm.<sup>676</sup>

Without this, healthcare professionals could be held liable for unwanted scars or physical changes (including plastic deformation) resulting from their clinical procedures, even though those scars are inherent risks of such treatments. This invokes the Latin maxim "*minimis non curat lex*," meaning that the court does not deal with minor issues or unimportant things for which a reasonable person would not be complaining.

#### 6.5.1. Liability standards

Liability standards vary depending on the jurisdiction and can be established under theories of intention, negligence, and strict liability.<sup>677</sup> In some jurisdictions, such as Canada, establishing liability for specific causes of action requires the plaintiff to prove that the defendant intended to cause harm as a result of their action or inaction.<sup>678</sup> This approach underscores the importance of the defendant's attitude, ensuring that liability reflects deliberate conduct rather than unintended harm. Additionally, the plaintiff is required to prove that the defendant would have believed their actions or inactions were risky and likely to result in harm. This means that the plaintiff must prove not only that the defendant's actions or inactions resulted in harm but also that the defendant had a deliberate will to cause it or had recklessly disregarded the foreseeable consequences despite the likelihood of harm. In this context, the defendant's conduct falls into the category of wanton or

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<sup>674</sup> David Simonsz, "In Search of International Tort Law: Civil Liability of Arms Manufacturers for Indirect Sales to Embargoed Conflict Zones" (2007). p. 26.

<sup>675</sup> Christian Witting, "Physical Damage in Negligence," *Cambridge Law Journal* 61, no. 1 (2002): 189–92, <https://doi.org/10.1017/S0008197302001587>.

<sup>676</sup> Victor Tadros, "What Might Have Been," in *Philosophical Foundations of the Law of Torts*, ed. John Oberdiek (Croydon: Oxford University Press Inc., 2019), 171–73.

<sup>677</sup> Durbin, "Torts – Nature of Tort Law and Liability."

<sup>678</sup> Durbin.

willful misconduct. Consequently, the defendant's mindful choice to engage in harmful actions is central to liability in intentional torts, such as assault or fraud.

On the contrary, negligence is another liability standard that requires the plaintiff to prove that the defendant failed to exercise the same level of care that a reasonable and prudent person would exercise under similar circumstances, resulting in unintended harm. This diverges from intentional torts. Negligence has two essential aspects: "foreseeability of the risk of harm" and "negligence calculus".<sup>679</sup>

In the medical liability context, the foreseeability of the risk of harm is assessed by responding to this question: had the medical professional taken the precautions, would the situation not have been this, or would the patient's life have been saved? This inquiry highlights that medical negligence is determined based on the professional's foreseeability of the harm. Thus, the unforeseeability or unintentionality of the professional's conduct breaches the duty of care owed to the patient. In other words, the defendant's failure to take necessary precautions to prevent the risk of harm compels them to be held liable. The rationale for assessing the probability of foreseeability is that not all adverse events (such as malpractice) constitute medical negligence.

However, the mere foreseeability does not justify the defendant's reasonableness, which should be coupled with a causal link to the injury in the determination of the defendant's negligence and liability. The reasonableness may be assessed differently depending on the specific situation at hand. For example, the situation in which a medical practitioner acts has significant implications for determining what is reasonable and what is not. The situational factors here may include the urgency of the treatment, the complexity and risk of the treatment, the patient's condition (capacity and understanding), the medical setting, applicable protocols, the professional specialty, and available resources. However, for the judge to determine negligence, the assessment of reasonableness is always done in comparable scenarios. This falls within the standards acceptable to peers in the practitioner's professional community. If the practitioner has deviated from those acceptable norms and caused unintended but foreseeable harm, they were negligent and should be held liable. This liability spectrum would inform medical practitioners that they operate within the framework of accountability and that they should be aware that adverse events and liability do not necessarily derive from malicious intent. Therefore, they should operate responsibly in their clients' best interests, protecting them from avoidable harm.

After determining the foreseeability of the risk of harm, another step of the "negligence calculus" follows.<sup>680</sup> The principle of negligence calculus, also known as the Hand formula, is rooted in the *T.J. Hooper case* of 1932, a landmark case involving two barges carrying coal that were lost in a storm while being hauled by tugboats, including the T.J. Hooper. Due to their lack of radios, the

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<sup>679</sup> David Andrew et al., "Review of the Law of Negligence Final Report" (Canberra: Commonwealth of Australia, 2002), p. 102-03.

<sup>680</sup> Negligence calculus is a term that was coined by Henry Terry in 1915 and developed by Justice Learned Hand in *U.S. v. Carroll Towing*, 159 F.2d 169 (2d Cir. 1947) see Stephen G. Gilles, "On Determining Negligence: Hand Formula Balancing, the Reasonable Person Standard, and the Jury," *Vanderbilt Law Review* 54, no. 3 (2001): 825-26.

tugboats were unable to receive weather warnings and could have escaped the storm. The barge owners sued the tugboat operators for negligence. Judge Learned Hand of the Second Circuit Court of Appeals suggested a balancing test to assess negligence and determine the standard of care, using three variables: the probability that the vessel will break away, the gravity of the resulting injury if it occurs, and the burden of taking adequate precautions. By ruling on this case, the court found that the tugboat operators were negligent because the burden of equipping the vessels with radios was minimal compared to the potential harm they could have prevented.<sup>681</sup>

The calculus of negligence provides a basis for choosing the nature of precautions that should have been taken to prevent the damage that occurred. At this stage, there must be an assessment of the appropriate decision that a reasonable medical professional would be expected to take. That decision should be aligned with the standard of a responsible, logical, and defensible body of medical opinion. Then, for the negligence calculus, some components should be analysed to determine the necessary precautions that should have been taken to prevent harm. In the calculus situation, it is worth noting that the first two components are weighted against the remaining two.

- i. The probability of the occurrence of harm if due care were not taken;
- ii. The likelihood of the harm's seriousness;
- iii. The burden of taking precautions to prevent injury; and
- iv. The utility of the opted choice (action or inaction).

Negligence calculus is closely related to the 'but for' test and the 'likelihood of survival' test adopted by various courts to determine factual causation. In this regard, the reasonableness of the health professional is the sole concern. However, some negligence courts do not undertake this thorough assessment to come to a verdict. Instead, they only consider what a reasonable health professional would have done or not done to prevent the harm. However, this would not be sufficient to conclude that negligence or malpractice had occurred, and ultimately, to impose liability. Other means, such as the "proximate cause doctrine," the "acceleration theory," "novus actus interveniens," and the "eggshell skull rule" could play an essential role in assessing causation related to the negligence calculus, similarly in tort liability.

Nevertheless, to establish the defendant's negligence for liability, the plaintiff can only justify the defendant's failure to abide by the standards of care and common medical practice without proving the defendant's intention. This failure and injury incurred must fall within the scope of remediable damages, as per the fundamental elements of tort law. However, it should be noted that the burden of proof is not always placed on the plaintiff's shoulders. If the plaintiff has established the essential elements of the cause of action, the defendant also must disprove his intention to cause harm. However, there is a constrictive intent as a liability standard without evidence. Additionally, the defendant can be held accountable for the intentional tort under the doctrine of transferred intent. For example, defendant **A** intended to harm individual **B** but failed and, unwillingly, harmed

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<sup>681</sup> United States Court of Appeals for the Second Circuit, *The T. J. Hooper*, 60 F.2d 737 (2d Cir. 1932) (1932).

another individual C. So, the intention to cause injury to B will be transferred to C and become the cause of the latter's action against the defendant.

Furthermore, it is also important to note that liability is not always based on the establishment of the defendant's intention or negligence. In some cases, it is sufficient for the plaintiff to prove that their injury results from the defendant's action or inaction. This is another standard of liability under the law of tort known as strict liability. Strict liability is another standard that holds individual health practitioners and institutions accountable for their actions or inactions, regardless of their intent, negligence, or lack of care. In some cases, it is considered no-fault liability.<sup>682</sup> The central element in this regard is that the prohibited result or adverse event has occurred despite the precautions taken and the absence of wrongful intent. The strict liability standard promotes optimal care and accountability in professional activities, such as medical practice, which are inherently risky and often make it difficult or impossible to prove fault. In other words, strict liability constantly shifts the burden of proof to the medical professionals and providers (defendants) to ensure the safety of healthcare users and protect them against harm. This is not only related to the medical interventions provided or non-interventions (inactions), but also to the product liability of pharmaceuticals for warning and defective claims,<sup>683</sup> as both aspects necessitate the protection of public welfare. So, strict liability serves as a deterrent against risky behaviour and as a means to simplify compensation for the victims of adverse events.

#### 6.5.2. Liability principles and rules

Medical liability framework encompasses various considerations to ensure justice delivery to all parties involved. In this regard, a range of principles and rules have been developed over time to assess the defendant's fault and ultimately determine liability. In certain cases, the defendant can also invoke those doctrines as defense. This discussion is about three principles entailing "*novus actus interveniens*", "*eggshell skull rule*" and "*Bolam test*" that have been useful and remain relevant in both civil law and common law systems despite the differences in their doctrinal framing and practical application.

##### 6.5.2.1. The doctrine of "*novus actus interveniens*" and its application

*Novus actus interveniens* is a Latin doctrine that refers to "new intervening act". In other words, the occurrence of a new act or event in the causal chain between the initial event and a clinical outcome breaks the continuity of that chain.<sup>684</sup> In medical negligence cases, this doctrine may be invoked by a defendant as a defense tool. Thus, if an external factor or event occurs in treatment and the adverse outcome of such treatment is not directly linked to the medical practitioner's negligence,

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<sup>682</sup> M Nöthling Slabbert and Michael S Pepper, "The Consumer Protection Act: No-Fault Liability of Health Care Providers F Orum," *South African Medical Journal (SAMJ)* 101, no. 11 (2011): 800–801.

<sup>683</sup> Mary J Davis, "Time for a Fresh Look at Strict Liability for Pharmaceuticals," *Cornell Journal of Law and Public Policy* 34, no. 2 (2019): 400–433, [https://uknowledge.uky.edu/law\\_facpub/685/](https://uknowledge.uky.edu/law_facpub/685/).

<sup>684</sup> Abhaykumar B Dheeraj, Sandeep K Giri, and Bedanta Sarma, "Doctrine of Novus Actus Interviens Not Always a Defense: Analysis of Case," *Indian J Crit Care Med* 24, no. 10 (2020): 983–85, <https://doi.org/10.5005/jp-journals-10071-23634>.

this doctrine may permit the latter to be exempted from liability despite the initial wrongdoing.<sup>685</sup> In this regard, the adverse outcome is attributed to such a novel factor. To be considered, the novel or intervening factor must appear in the form of negligence. It may result from another medical personnel's actions or inactions, from the patient, or may be of a natural character in the course of treatment.

The rationale for the defendant's exemption from liability is grounded in the principle of direct causation. Liability is limited to only harm constituting proximate and foreseeable consequences of the defendant's conduct, which excludes any liability that does not directly flow from their actions. In other words, the legal cause of liability deposits that defendants should not be held accountable for the consequences arising from acts or events that are excessively remote from their conduct or that result from independent intervening causes.<sup>686</sup> Therefore, the doctrine of *novus actus interveniens* limits liability by reducing the causal remoteness in the chain of events that resulted in an adverse outcome.

This principle underwent progressive refinement to include specific situations, such as those in which victims attempt to escape from danger originated by the defendant. It serves as a threshold test to determine whether the victim's reaction meets the following conditions:<sup>687</sup>

- i. Within the scope of responses reasonably anticipated from a victim under comparable circumstances;
- ii. Reasonably foreseeable considering the prevailing circumstances;
- iii. Corresponding with the degree of the perceived threat.

#### 6.5.2.2. *The eggshell skull rule and its applicability*

The eggshell skull rule is another vital consideration in medical malpractice lawsuits. This common law principle dictates that the defendant accepts the victim as they find them.<sup>688</sup> Contrary to the doctrine of *novus actus interveniens*, where any act or event that interrupts the causal chain between the defendant's original event and outcome excludes the defendant's liability, under the eggshell skull rule, the defendant is held liable for the full extent of the claimant's unforeseeable and common reaction to the defendant's negligent or intentional wrongful acts, as long as they constitute a proximate cause.<sup>689</sup> For example, if an individual already has an inherent unusual medical condition, and the latter is worsened by the defendant (physician)'s surgical error, the physician will bear full liability for the harm.

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<sup>685</sup> Dheeraj, Giri, and Sarma.

<sup>686</sup> Will Chen, "Novus Actus Interveniens," Lawprof, 2025, <https://lawprof.co/definition/novus-actus-interveniens/>.

<sup>687</sup> Chen.

<sup>688</sup> "How the Eggshell Skull Rule Affects Personal Injury Claims in Massachusetts," brandonjbroderick.com (Massachusetts), accessed December 29, 2025, <https://www.brandonjbroderick.com/massachusetts/how-eggshell-skull-rule-affects-personal-injury-claims-massachusetts#:~:text=Understanding the Eggshell Skull Rule,damage under the same circumstances.>

<sup>689</sup> "Eggshell Skull Rule," Legal Information Institute, accessed December 29, 2025, [https://www.law.cornell.edu/wex/eggshell\\_skull\\_rule.](https://www.law.cornell.edu/wex/eggshell_skull_rule.)

This principle reflects the concept of a good samaritan as a medical professional who provides reckless intervention. In this case, liability arises, despite the act being voluntary, without compensation, and in a therapeutic relationship. Thus, the Samaritan must act with good faith and apply necessary knowledge and skills to prevent an adverse outcome. Otherwise, worsening the situation of the one in danger could result in liability for the full extent of the injury.

One can argue that holding the defendants liable for unusual consequences arising from latent vulnerabilities that they are not aware of may accelerate an inequitable burden and defensive medicine, as well as discourage professional engagement at times. However, the rationale for such liability may be underpinned by the ideal for corrective justice, which imposes that a wrongdoer must bear the entire burden irrespective of the victim's inherent vulnerability. Additionally, if negligence or tort is established as a proximate cause, the degree of damage (whether foreseeable or not) cannot limit the liability. Thus, the eggshell skull rule remains crucial in protecting vulnerable individuals and upholding integrity and accountability in clinical practice.

#### 6.5.2.3. *Bolam test*

The “Bolam test” is a common law doctrine comparable to objective standards of care in civil law. It originates from the famous 1957 *Bolam v Friern Hospital Management Committee* case. In this case, Mr. Bolam voluntarily underwent electro-convulsive therapy in a mental health institution which was under the control of the Friern Hospital Management Committee. After Bolam suffered serious injuries, he sued the Committee seeking compensation for being negligent as they did not do three things: muscle relaxation before the procedure, body control during the procedure, and disclosure of the associated risks. After noting the expert witnesses, the court did not decide in favour of Bolam because the muscle relaxant medication and the manual restraint could have increased the risks. Additionally, the court confirmed that disclosing all risk-related information to patients was not a common practice in the medical profession. In this case, the court established the standard of reasonable care in cases involving medical professionals. This rule is underpinned by the medical professional custom, which is considered the “standard of a responsible body of medical opinion”.<sup>690</sup> If a physician has worked to the extent that meets the reasonable standard of care, he will not be held to account for any medical negligence. In the opposite situation, the physician should be held liable.

It is worth noting that the Bolam test has been applied in various cases and adapted to the specific circumstances. For example, the 1998 *Bolitho v City and Hackney Health Board* case modified the test, adding that the medical opinion under the Bolam test must be logical, defensible, and based on a reasoned assessment of risks and benefits.<sup>691,692</sup> Additionally, the test was replaced by the patient-centered test in informed consent-related claims, as established in the UK's 2015

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<sup>690</sup> Timms Solicitors, “Clinical Negligence - The Bolam Test,” accessed November 13, 2025, <https://www.timms-law.com/clinical-negligence/the-bolam-test/>.

<sup>691</sup> *Bolitho v City and Hackney Health Authority*, AC 232 (1997).

<sup>692</sup> Ash Samanta and Jo Samanta, “Legal Standard of Care : A Shift from the Traditional Bolam Test,” *Clinical Medicine* 3, no. 5 (2003): 443–46.

*Montgomery v Lanarkshire Health Board* case and the 1989 Irish *Dunne v National Hospital* case.<sup>693</sup> In this light, medical practice dictates that medical practitioners disclose all possible risks associated with any medical procedure or treatment that a reasonable patient would want to know.<sup>694</sup> If they fail to do so, they are held liable for being negligent.

It must be well understood that healthcare professionals practice under the “obligation of means,” under which they must apply their knowledge and skills with due diligence in treating their patients. They are not bound by the need to effectuate recovery for their clients. Thus, if an unexpected medical outcome occurs, the doctor will not be liable if they have acted within the standards of care. Although Rwandan courts do not recall the Bolam test, their practice reveals it as they assess the defendant’s conduct against the standards of professional norms by scrutinizing medical expert reports.

Nonetheless, the tort-based system has been criticised for being time-consuming and expensive, for focusing on medico-legal technicalities, and for promoting defensive medicine. Besides, Brennan and Mello argued that it incites emotional provocation among litigants, leaving psychological scars on those involved rather than advancing patient safety.<sup>695</sup>

## **6.6. Forms of liability in medical malpractice cases**

Several strategies could be employed to hold medical practitioners accountable for medical malpractice. Depending on the circumstances and severity, liability may be either professional, civil, or criminal. Moreover, healthcare service organisations can be held accountable for the faults and negligence of their employees and agents, as well as for contract violations, fiduciary breaches, and violations of patient rights. In the case of medical negligence, they can also be liable under tortious principles within the context of tort law.

### **6.6.1. Medical professional liability**

The power to impose professional liability is vested in the medical professional bodies to which medical professionals belong. Their internal rules and regulations categorise faults depending on their seriousness. After the investigations’ findings, these bodies can impose professional sanctions, also known as professional disciplinary measures, based on the nature of the fault.

For medical doctors and dentists practicing in Rwanda, the Bureau of the National Council Board within RMDC has the authority to impose those sanctions.<sup>696</sup> If the fault does not endanger the life of a healthcare user or the dignity of the medical profession, the Bureau sanctions the practitioner

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<sup>693</sup> Mary Hough, “Dunne’ Principles Remain the Appropriate Legal Test for Medical Negligence in Ireland,” Hayes-Solicitors, 2020, <https://hayes-solicitors.ie/news/dunne-principles-remain-the-appropriate-legal-test-for-medical-negligence-in-ireland/>.

<sup>694</sup> Guy B. Faguet, “From the Patient’s Perspective,” in *The War on Cancer: An Anatomy of Failure, A Blueprint for the Future* (Dordrecht: Springer Nature, 2005), 127–42, [https://doi.org/https://doi.org/10.1007/978-1-4020-3617-0\\_11](https://doi.org/https://doi.org/10.1007/978-1-4020-3617-0_11).

<sup>695</sup> Brennan and Mello, “Patient Safety and Medical Malpractice: A Case Study.”

<sup>696</sup> Article 27 of the Law N°44/2012 of 14/01/2013 on the Organisation, Functioning and Competence of the Medical and Dental Council, Official Gazette N° 02 of 14/01/2013 (2013).

with a warning or reprimand.<sup>697</sup> If the fault poses a risk to the patient's life or the dignity of the profession, the Bureau sanctions the wrongful practitioner with temporary suspension from practice. Such suspension period must not exceed six (6) months, and this fault, which falls into the third category, should be communicated to the Minister of Health.<sup>698</sup> For faults that are seriously incompatible with the profession, the Bureau punishes them with a removal from the register of members of RMDC. The disciplinary measures taken against these faults under this category are communicated to the public.<sup>699</sup>

Additionally, the imposition of those sanctions has other implications: a member of the Council serving them is deprived of other rights, such as voting and being elected to any organ of the Council, for a period of four years.<sup>700</sup> In the event that the practitioner was already exercising such a function and had been punished with any of these sanctions, they should be removed from office automatically, similarly to those who were criminally sentenced to a term of imprisonment of six months or more.<sup>701</sup> The National Council Board decides to remove an elected practitioner from office, the supreme organ of the Council,<sup>702</sup> either on its own initiative or at the request of Council members.

Furthermore, nurses and midwives may also be held liable for professional misconduct, with disciplinary action imposed by the NCNM. Under the statute establishing NCNM, there is room for complaints related to professional misconduct. The Council has a complaint mechanism in which any aggrieved health service user or other interested person may submit a complaint of professional misconduct against a registered nurse or midwife.<sup>703</sup>

A complaint remains valid and may be submitted in writing within 30 days of the day the misconduct is identified.<sup>704</sup> The complaint should be submitted to the health supervising authority of the alleged professional's workplace. Then, the alleged nurse or midwife is informed on the day of appearance for defense. The addressed authority has 15 days to take a decision upon the reception of the complaint.<sup>705</sup> If the referred organ lacks the authority to resolve the complaint, it is forwarded to the Registrar of the Council within 15 days of the end of the previous period.<sup>706</sup> If the referred organ has the authority to resolve the complaint and the decision is not satisfactory, either the complainant or the defendant has 30 days from receipt of the decision to initiate hierarchical recourse to the register, which, in turn, submits the appeal to the Board of Directors

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<sup>697</sup> Ibid., para 2.

<sup>698</sup> Ibid., para 3.

<sup>699</sup> Ibid., paras 4 and 5.

<sup>700</sup> Article 28 of the Law N°44/2012 of 14/01/2013 on the Organisation, Functioning and Competence of the Medical and Dental Council, Official Gazette n° 02 of 14/01/2013.

<sup>701</sup> Ibid., Article 29.

<sup>702</sup> Ibid., Article 8.

<sup>703</sup> Article 27 of the Law N°25/2008 of 25/07/2008 Establishing the National Council of Nurses and Midwives and Determining Its Organisation, Functioning and Competence (2008).

<sup>704</sup> Ibid., para 2.

<sup>705</sup> Ibid., para 4.

<sup>706</sup> Ibid., para 5.

for a decision.<sup>707</sup> Similar to court litigation, the accused nurse or midwife has the right to defense and legal representation in this process.<sup>708</sup>

In the event that a nurse or midwife is accused of serious misconduct, the Board of Directors may suspend them for investigation and communicate this decision to the respective authority.<sup>709</sup> After the Board's hearing, it can impose professional disciplinary action if the accused is found to be at fault, and the decision is communicated to the concerned nurse or midwife within 15 days after the hearing.<sup>710</sup> Such a decision could be appealed within 15 days of its receipt. The National Council for Nurses and Midwives can impose any of the following sanctions, based on the gravity of the fault, including verbal warning, written warning, reprimand, suspension, or cancellation from the Register.<sup>711</sup> These sanctions could only be approved when the right to defense was given to the accused.<sup>712</sup> However, the decision could be taken in absentia, when the accused was notified appropriately.<sup>713</sup>

It is worth noting that professional disciplinary action is distinct from judicial prosecution.<sup>714</sup> Thus, the case may be dealt with by the Council and be subject to criminal prosecution. In this case, the Board of Directors can inform the concerned authorities of the criminal process and is required to facilitate the process by indicating all criminal acts committed by the nurse or midwife, except in cases of professional secrecy.<sup>715</sup>

For pharmacists, the law establishing the Rwanda National Pharmacy Council (NPC) includes a disciplinary mechanism in place for addressing professional misconduct. This mechanism does not prevent court proceedings or other disciplinary proceedings before the pharmacist's superior in the administrative hierarchy.<sup>716</sup> Among other things, the Council's organs responsible for dealing with complaints related to the pharmacists' misconduct can impose any of the following disciplinary actions against a wrongful pharmacist, including a warning, reprimand, temporary suspension of practice for a period not exceeding twelve (12) months, and removal from the register of members of the Council.<sup>717</sup>

The Rwanda Allied Health Professionals Council (RAHPC) has a similar mechanism in place for addressing professional misconduct. The disciplinary sanctions that could be imposed are the same

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<sup>707</sup> Ibid., para 6.

<sup>708</sup> Ibid., para 7.

<sup>709</sup> Article 29 of the Law N°44/2012 of 14/01/2013 on the Organisation, Functioning and Competence of the Medical and Dental Council, Official Gazette n° 02 of 14/01/2013.

<sup>710</sup> Ibid., Article 31, para 1.

<sup>711</sup> Ibid., Article 30.

<sup>712</sup> Ibid., Article 33 para 1.

<sup>713</sup> Ibid., Article 33 para 2.

<sup>714</sup> Ibid., Article 28, para 1.

<sup>715</sup> Ibid., Article 28, para 2 and 3.

<sup>716</sup> Article 33 of the Law N° 45/2012 of 14/01/2013 on Organisation, Functioning and Competence of the Council of Pharmacists (2013).

<sup>717</sup> Ibid., Article 27.

as those imposed on pharmacists.<sup>718</sup> The complaint can be initiated by the respective organ of the council or by a submission from an interested person, while the right to defense is, in all cases, provided by law.

Hence, these councils also have the post-knowledge assessment measures to enhance professionalism in their members. After assessments, members who do not meet the required standards may be subject to continued training programs, work under supervision, suspension of practicing, or removal from the register of the council's members. Although these assessment measures are not considered sanctions for misconduct, they establish a sense of legal and ethical compliance in the daily healthcare service delivery and thereby prevent medical malpractice.

All four medical professional councils have professional codes of conduct and nearly identical mechanisms for addressing complaints related to professional misconduct or breach of professional ethics. They provide the right to defense for the accused members and provide a recourse for appeal in case of dissatisfaction. However, their operationalisation may differ due to various factors, such as the number of skilled personnel available for medical case investigations, the volume of cases, and financial capacity. These mechanisms foster accountability in healthcare delivery and promote justice for the victims of medical malpractice.

#### 6.6.2. Administrative liability

Government institutions, such as MINISANTE and public service commission, could also conduct an investigation into the healthcare professional or health-providing institution following a malpractice incident. Aimed at protecting the public and ensuring institutional integrity, efficiency, and accountability in healthcare service delivery, these institutions can also conduct audits of health providers to assess their functioning, which may result in sanctions.

Administrative or disciplinary liability is imposed after disciplinary proceedings, which are independent from court proceedings. However, a disciplinary fault may give rise to both administrative disciplinary proceedings and court proceedings for civil or criminal charges.<sup>719</sup> For public sector health professionals, administrative disciplinary proceedings and disciplinary sanctions are determined by the Presidential Order on Professional Ethics for Public Servants. For a private sector suspect practitioner, those proceedings follow the provisions of the Labour Code of Rwanda. However, the new healthcare law regime provides the ministerial order establishing a committee responsible for addressing disciplinary issues in healthcare facilities.<sup>720</sup>

A suspected medical malpractice by a medical practitioner committed during dual clinical practice is also subject to investigation and sanction by the RMDC.<sup>721</sup> This procedure follows the General Statute Governing Public Servants, and the Presidential Order on Professional Ethics for Public

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<sup>718</sup> Article 32 of the Law N° 46/2012 of 14/01/2013 Establishing the Rwanda Allied Health Professions Council and Determining Its Organisation, Functioning and Competence (2013).

<sup>719</sup> Article 67 of the Law No. 017/2020 of 07/10/2020 Establishing the General Statute Governing Public Servants (2024).

<sup>720</sup> Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services, Art. 106.

<sup>721</sup> Article 16 of the Ministerial Instructions N° 7016 of 30/11/2020 Governing Dual Clinical Practice (2020).

Servants, rather than the ordinary code of professional ethics.<sup>722</sup> To understand the dual clinical practice environment, it should be noted that “dual clinical practice” refers to clinical work undertaken within and outside public hospitals, or outside the provider’s contracted work hours under public sector employment.<sup>723</sup> This work is not counted as part of the employee’s actual salaried employment; rather, it is a public hospital’s contractually remunerated work.<sup>724</sup>

The accused public sector health practitioner may be found guilty or not guilty. If guilt is established, the Council may impose disciplinary sanctions commensurate with the gravity of the fault.<sup>725</sup> These sanctions are categorised into two categories: the first category is for less severe ones, including a warning and reprimand,<sup>726,727</sup> while the second category is for the most severe sanctions, entailing temporary suspension from duties for a period not exceeding three months and dismissal.<sup>728,729,730</sup>

Apart from the suspension as a disciplinary sanction, disciplinary proceedings for a fault may result in the suspension of a suspect public servant (public sector health professional) when that fault could lead to a sanction of the second category, provided other conditions are met to justify this suspension.<sup>731</sup> The first condition is when it is the only way to prevent the suspect from disposing of evidence or exerting pressure on witnesses. The second condition is when the non-suspension of the suspect may undermine the image of an employing public institution, depending on the seriousness of the disciplinary fault, the circumstances of its commission, or the level of harm caused. This suspension could also be imposed when a public servant has been provisionally detained for a period not exceeding six (6) months.<sup>732</sup> Additionally, it is worth noting that the dismissal of a healthcare professional working in the public sector could result in blacklisting by the Ministry responsible for public service, which prevents them from being recruited or appointed to public service until they have undergone a rehabilitation process.<sup>733</sup>

Although this discussion does not intend to delve into faults and their respective sanctions, the following are some severe faults that constitute medical negligence or malpractice and are punishable by dismissal. For example, the list includes disclosing confidential information, committing any form of violence, abuse of power, harassment, and assaults on other persons as serious faults. A public sector medical professional may commit this fault against a healthcare service user. Another fault that could be linked to medical negligence and malpractice is the

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<sup>722</sup> Id.

<sup>723</sup> Ministry of Health of Rwanda, “Dual Clinical Practice Policy” (Kigali, Rwanda, 2020), p. 2.

<sup>724</sup> Ministry of Health of Rwanda, “Dual Clinical Practice Policy” (Kigali, Rwanda, 2020), p. 2.

<sup>725</sup> Article 26 of the Presidential Order No. 21/2021 of 24/02/2021 Determining Professional Ethics for Public Servants (2021).

<sup>726</sup> Ibid., Article 27.

<sup>727</sup> Ibid., Article 28.

<sup>728</sup> Ibid., Article 29.

<sup>729</sup> Law No. 017/2020 of 07/10/2020 Establishing the General Statute Governing Public Servants, Art. 40.

<sup>730</sup> Presidential Order No. 21/2021 of 24/02/2021 determining Professional Ethics for Public Servants, Art. 30.

<sup>731</sup> Law No. 017/2020 of 07/10/2020 establishing the General Statute governing Public Servants, Art. 40.

<sup>732</sup> Id.

<sup>733</sup> Ibid., Article 43.

practitioner's failure to perform duties, improper performance, or delay in performing those duties, resulting in serious consequences for the institution or the country.

Although investigations and disciplinary actions typically focus on the suspected misconduct committed during work hours and at the workplace of the accused practitioner, they may also extend to the public sector practitioner's conduct beyond that scope. This is supported by the General Statute for Public Servants, which provides that good professional conduct for a public servant should be exhibited at and away from work.<sup>734</sup> The reason for such an extension is to preserve public trust in the healthcare system.

Administrative proceedings for disciplinary faults against a public sector health professional, like any other public servant, have a 30-day time limit if they are subject to first-category sanctions. These days are counted from the date a suspected public servant was requested to provide explanations. If the disciplinary fault is subject to punishment of the second category, the timeframe is extended to three months, counted in the same way as mentioned above.<sup>735</sup> The competent authority to conduct disciplinary proceedings for faults punishable by sanctions of the first category against a health professional as a public servant is the immediate supervisor. Upon conviction, the head of the public institution in which the employee works, or the delegate, is the authority to impose sanctions of the first category.<sup>736</sup> The latter is also responsible for conducting disciplinary proceedings for faults punishable by sanctions of the second category, while the appointing authority or a delegated person imposes the sanctions, except for servants holding job positions of level 1.IV and above, whose disciplinary proceedings are conducted by their appointing authority or delegated person.<sup>737</sup>

Medical practitioners or interns working in the private sector (i.e., clinics, hospitals, and other private health facilities) or in the public sector under contract are bound by the Rwandan Labour Code in all labour-related matters.<sup>738</sup> For administrative proceedings against those practitioners, follow the Code's provisions to address their disciplinary faults. These proceedings are also independent from disciplinary proceedings conducted by the respective professional councils and court proceedings for civil and criminal matters. If a private-sector medical professional contravenes the professional medical code of ethics, like any other medical practitioner in the public sector, the council intervenes through the process mentioned earlier.

Private health institutions, like other private institutions, have disciplinary mechanisms for addressing disciplinary faults. Under this mechanism, an employee at fault may face one of the following sanctions depending on the gravity of the fault: oral warning, written reprimand,

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<sup>734</sup> Article 66 of the Law No. 017/2020 of 07/10/2020 establishing the General Statute governing Public Servants.

<sup>735</sup> Presidential Order No. 21/2021 of 24/02/2021 Determining Professional Ethics for Public Servants, Art. 39.

<sup>736</sup> *Ibid.*, Article 40.

<sup>737</sup> *Ibid.*, Article 40, para 3.

<sup>738</sup> Article 2 of the Law N° 66/2018 of 30/08/2018 Regulating Labour in Rwanda, Official Gazette No. Special of 06/09/2018 (2018).

temporary suspension not exceeding eight (8) working days, or dismissal.<sup>739</sup> Apart from the violation of obligations of an employee set by the Labour Code,<sup>740</sup> the internal rules and regulations of those institutions may list the faults and their categories based on their severity. Those rules and regulations are essential for the administrative liability of medical professionals operating in the private sector.

Furthermore, private health facilities are bound by their governing Ministerial Instructions, which prohibit certain practices that may benefit their clients' healthcare service users.<sup>741</sup> These instructions outline various faults that are punishable, such as practicing a health profession without a license or on unauthorized premises.<sup>742</sup> Additionally, the Ministry of Health may impose administrative sanctions not only on individual practitioners but also on healthcare institutions. After investigation, it may close a private healthcare provider to safeguard the public if it finds that the provider is putting healthcare service users at risk. For example, after an incident that led to the case of *Prosecutor v. Dr. MUGEMANSHURO Alfred and Another*, Baho International Hospital was shut down for investigation. Although the accused was acquitted, the Ministry of Health found, following an assessment, that the Hospital delivered poor health services.<sup>743</sup> This administrative sanction (a temporary shutdown) does not prevent civil and/or criminal proceedings in Rwanda.

Administrative liability for medical practitioners may be coupled with other proceedings, depending on the nature of the fault committed. If a suspected fault is both administrative and professional, both the suspect practitioner's employing health provider and the professional council may, independently of each other, conduct disciplinary proceedings and impose sanctions. For example, a doctor who delays providing medical intervention on an emergent incident after being informed by the nurse. In case the delay aggravates the patient's condition and results in an unexpected outcome, the doctor may be subject to investigation and sanctions through two disciplinary proceedings: the hospital's disciplinary proceedings and RMDC's disciplinary proceedings. These independent proceedings can also sanction the negligent practitioner. If such a delay results in death, the doctor could also be subject to court proceedings for the criminal offense of involuntary manslaughter.

The above scenario showcases how a medical practitioner may face three distinct legal and disciplinary tracks for a single fault. One can view it as a tripartite framework for punishing health professionals in Rwanda, reflecting the operationalization of both legal and ethical accountability in the healthcare system. However, this mode of punishment does not contradict the principle of

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<sup>739</sup> Ibid., Article 42.

<sup>740</sup> Ibid., Article 41.

<sup>741</sup> Article 12 of the Ministerial Instructions No. 20/003 of 23/09/ 2020 Governing Private Health Facilities in Rwanda, 2020.

<sup>742</sup> Ibid., Articles 13 and 15.

<sup>743</sup> Jean de la Croix Tabaro, "Second Hospital Closed in Kigali Over Poor Service," *KT PRESS*, October 3, 2021, <https://www.ktpress.rw/2021/10/second-hospital-closed-in-kigali-over-poor-service/>.

*non bis in idem* (prohibition of double jeopardy), as each proceeding and corresponding sanctions arise from separate legal regimes with distinct purposes, foundations, and authorities.

### 6.6.3. Civil liability

#### 6.6.3.1. Vicarious liability

Vicarious liability, which is also known as “imputed liability,” is a legal situation in which a party could be held liable for the torts of another. Under vicarious liability, natural or juridical persons are not only liable for their acts but also for the unlawful acts or omissions committed by others if they exercise control over the latter. Such control establishes subordination between the two parties and the existence of a legal relationship, such as employment or guardianship.

In the context of medical liability, health care institutions will be liable under the doctrine of “*Respondeat Superior*” for medical malpractice and negligence committed by their employees or ostensible agents in the course of their functions and for a related purpose within the scope of their relationships. Such liability arises from a presumption that the work was in the employer's interest, and thus any related error should be remedied by the employer. Jean Penneau explains the situation with the following French passage.

*Le dommage est le resultat de la seule faute personnelle du medecin, aucune faute de service n'a, par ailleurs, été commise, mais parcequ'elle a été commise à l'occasion du fonctionnement du service, cette faute, bien que detachable au point de devenir personnelle au medecin, n'est pas depourvue de tout lien du service, il en resulte que la responsabilite du service n'est pas écartée, du moins dans ses rapports avec le patient, à l'égard de qui celui-ci reste debiteurs de l'obligation de reparer le dommage.<sup>744</sup>*

Complainants of medical malpractice have more options for taking legal action to recover damages. Among others, they can choose to petition against the employer alone. In this regard, the claimant doesn't have to identify the negligent employee whose fault caused the damage for the employer to be convicted, when the latter's direct liability can be established.<sup>745</sup> This is known as liability resulting from the “employer-employee relationship”. With this logic, a health-providing corporation will be liable for its employees and ostensible agents whose acts fall in medical malpractice. The rationale for offering offended victims the possibility of seeking reparations from the employer, even though the employer's subordinate caused the harm, is traditionally based on a solvency guarantee.<sup>746</sup> For the employer to be liable for an employee's wrongful act or omission, three conditions must be met: a subordination relationship, the employee's personal fault, and the

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<sup>744</sup> Jean Penneau, *La Responsabilité Du Medecin*, ed. Dalloz, 2nd ed. (Paris, 1996).

<sup>745</sup> RPR M. CRESPIEN, Court of Cassation, Civil Chamber 2, of March 11, 1971, 70-10.366 (1971).

<sup>746</sup> “La Responsabilité Des Commettants (Employeurs) Du Fait de Leurs Préposés (Salariés),” *Www.Documentissime.Fr*, 2013, <https://www.documentissime.fr/dossiers-droit-pratique/dossier-157-la-responsabilite-des-commettants-employeurs-du-fait-de-leurs-preposes-salaries.html>.

absence of the employee's abuse of function or exceeding assigned duties.<sup>747</sup> The following cases exemplify the vicarious liability context in the Rwanda medical liability.

In *King Faisal Hospital Rwanda Ltd v. M.A and Others*, the Rwandan Intermediate Court of Gasabo, at first instance, found King Faisal Hospital and Rwanda Military Hospital guilty of medical malpractice.<sup>748</sup> King Faisal Hospital was held liable based on the medical report of its employee, Prof. Dr. Kyonkunda Lynnette, who was serving as the hospital's medical consultant. The appellate court underscored that King Faisal Hospital should be liable for its employee, whose medical malpractice (wrong diagnosis) resulted in M.A.'s harm.<sup>749</sup> Applying the "but for" test, the court stated that if King Faisal Hospital had not diagnosed breast cancer, the patient, M.A., should not have lost her breast, as Rwanda Military Hospital could not perform a mastectomy. For that reason, King Faisal Hospital was held liable for the malpractice of its employee, who administered a wrong diagnosis while performing her assigned medical duty.

Besides, the insurance of a medical professional whose acts resulted in a patient's injury or death does not nullify the usual vicarious liability principle.<sup>750</sup> The medical liability case is different from a traffic accident case, where the victim will be compensated by the insurer of the wrongdoer whose vehicle has injured or killed a third party. In the *N.A v. Kibungo Medical Center*, both Kibungo Medical Center and Prime Insurance Company Plc contributed to the damages as per the decision of the Court of Appeal.<sup>751</sup> In that case, the Kibungo Medical Center was vicariously liable for its employee, whose negligence while performing a circumcision on a child dubbed I.A led to the mutilation of an organ.

Unlike the previous context, where the health practitioner may harm a patient while fulfilling the assigned task, and in the interest of the healthcare provider (employer), the practitioner will be solely responsible for malpractice outside their duty without authorisation. However, if the physician exceeded the limits of the assigned mission without abusing the office, the employed physician and his employer will be held liable in *solidum*.<sup>752</sup> As outlined below, if a medical practitioner intentionally causes overwhelming harm to a patient, criminal liability will not be entirely placed on the practitioner's shoulders. Besides, the employer will be held liable for failing to exercise effective control over the employee.

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<sup>747</sup> Valérie LEMERLE, "Liability for Employees: The Conditions of the Liability of Employers in Respect of Their Employees," HÉMÉRA Lawyers, 2021, <https://www.hemera-avocats.fr/responsabilite-de-l-employeur-du-fait-des-salaries/>.

<sup>748</sup> *King Faisal Hospital Rwanda Ltd v. M.A and Others*, RC 00118/2019/TGI/Gsbo (2021).

<sup>749</sup> *King Faisal Hospital Rwanda Ltd v. M.A and others*, RCA 00125/2021/HC/KIG.

<sup>750</sup> McCague Borlack, "Collaborative Care and Vicarious Liability" (Toronto, January 2018), <https://mccagueborlack.com/emails/articles/vicarious-liability.html>.

<sup>751</sup> *N.A v. Kibungo Medical Center*, RCAA 00008/2020/CA (2021).

<sup>752</sup> LEMERLE, "Liability for Employees: The Conditions of the Liability of Employers in Respect of Their Employees."

#### 6.6.4. Criminal liability

Apart from the civil liabilities, medical malpractices might result in criminal liability. A medical malpractice or negligence claim could be criminal in case the harm was linked to a suspect practitioner's gross negligence. When negligent medical practitioners commit an act that causes significant damage or death to the healthcare users, such as assault and battery, manslaughter, or failing to assist someone in danger, they may be prosecuted and found guilty of committing an offence without intending to cause harm. Such malpractice is known as “gross negligence” or unacceptable negligence.<sup>753</sup>

When an incident qualifies as gross negligence, RIB can intervene either if the victim files a ‘citation direct’ individually, if RIB initiates an investigation into the matter, or if the MoH or the respective council cooperates with it. However, RIB can intervene on its initiative. At this stage, RIB can arrest the suspect and detain them for investigation. If the charge is found to be sound, RIB refers it to the National Public Prosecution Authority (NPPA) for review. The NPPA may, in turn, decide to prosecute by filing the charge with the competent court or enter a *nolle prosequi* or discontinue charges due to insufficient evidence. The duration of this process may vary, depending on their workload. However, the Integrated Electronic Case Management System (IECMS) simplifies these transfers and reduces delays. Either way, a private prosecution, known as “citation direct” or the prosecutor’s case referral, upon receiving the case, the court schedules a pre-trial hearing. During this hearing, the court can order pre-trial detention or release the suspect.

The Rwandan Criminal Code includes, among others, offences that may constitute medical malpractice resulting from overwhelming negligence. These offences may include assault and battery, manslaughter, or failing to assist someone in danger. Additionally, other medical malpractices falling within this scope, although their qualifications may vary from one jurisdiction to another, include unauthorised disclosure of patients’ recordings, false imprisonment, over-prescription of medications, drug misuse and diversion, breach of medical recording confidentiality, unnecessary surgical procedures, aiding patients in committing suicide, and performing unlawful abortions.

Let’s take manslaughter as an example in the Rwandan context. A healthcare practitioner who kills a healthcare user as a result of clumsiness, carelessness, inattention, negligence, failure to observe rules, or any other lack of precaution and foresight, but without intent to kill that patient, commits manslaughter.<sup>754</sup> The latter act is considered a crime and results from “deliberate negligence” or “gross negligence.”<sup>755</sup>

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<sup>753</sup> “Irradiated from Epinal: Two Doctors and a Physicist Sentenced to 18 Months in Prison,” 2013, <https://www.20minutes.fr/societe/1090199-20130130-irradies-epinal-deux-medecins-physicien-condamnes-a-18-mois-prison-ferme>.

<sup>754</sup> Law N°68/2018 of 30/08/2018 Determining Offences and Penalties in General. Art. 111.

<sup>755</sup> Janine Collier, “When Medical Negligence Becomes Criminal,” 2021, <https://www.teeslaw.com/insights/when-medical-negligence-becomes-criminal/>.

A practitioner may commit manslaughter through positive or negative acts during a medical procedure or treatment. Although there is no recorded Rwandan case of medical malpractice in which a suspect was convicted of gross negligence, either through positive or negative action, it may occur in a manner similar to those in other jurisdictions.

An example of positive action can be when a doctor unwillingly kills a patient through their acts, either by administering medicine or committing an error in a surgical operation, resulting in the latter's death. In *the Dr. Conrad Murray case*, Dr. Murray, a personal doctor of famous singer Michael Jackson, was convicted of involuntary manslaughter in 2011 and sentenced to four years of imprisonment. In this case, the U.S. court decided that Dr. Murray committed acts that posed a foreseeable danger to his patient's life, including recklessly administering a fatal dose of the anesthetic propofol, delaying seeking emergency interventions, a lack of sufficient informed consent, inappropriate treatment of insomnia, and failing to use practical resuscitation means.

A medical offence could also be committed by omission, as exemplified in *R v. Adomako*. This is a 1994 case under which the UK House of Lords convicted an anaesthetist, Dr Adomako, for manslaughter that resulted from gross negligence that occurred when a patient died of a cardiac arrest after a disconnection of an oxygen tube during surgery. The gross negligence was that the anaesthetist failed to notice or respond to apparent signs of the problem, which resulted in the patient's demise. This case established a legal test for a suspect to be convicted of manslaughter under gross negligence that encompasses four (4), of which three are similar to those applied in tort. Those elements include the following:<sup>756</sup>

- existence of the duty of care between the defendant and the victim;
- breach of that duty of care by gross negligent act or omission;
- contribution of that gross negligence to the victim's death (causal link);
- whether such a breach is under the ordinary principles of gross negligence amounting to an offence.

Other gross negligence offences may occur through scenarios such as a doctor who fails to help a labouring mother while bleeding and later dies of exsanguination after lacking the doctor's intervention. Or a nurse who carelessly receives a patient in critical condition and forgets to inform the doctor about the patient's state, resulting in the patient's death. In both cases, the result of the patient's death is a "*condicio sine qua non*," i.e., a condition for the health care practitioner to be liable for this offence. The two scenarios of criminal fault are based on four aspects: negligence, imprudence, lack of precaution, and non-compliance with rules.

Rwandan courts tried a small number of criminal cases involving medical malpractice, which presented various challenges, leading to the defendants' acquittals. For example, in *Prosecution v. Dr MUGEMANSHURO Alfred and others*, two medical practitioners at Baho International Hospital, Dr MUGEMANSHURO Alfred and Dr. NTAHONKIRIYE Gaspard, were accused of

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<sup>756</sup> "R v Adomako [1994]," UOLLB, July 6, 2024, <https://uollb.com/blogs/uol/r-v-adomako-1994>.

manslaughter under the Rwandan penal code, but they were later acquitted due to a lack of sufficient evidence.<sup>757</sup> This case was rooted in the incident of September 8, 2021, in which KAMANZI NGWINONDEBE Chantal died when the two practitioners were performing a hysteroscopy to remove a birth control device known as an intrauterine device (*sterilet*) from her uterus. The Autopsy demonstrated that Chantal's death was caused by cardiorespiratory failure due to hypoxia. It also mentioned that there was a fracture of the ribs resulting from the attempts to recover the patient from hypoxia. Despite the death of the patient and those pieces of evidence, the Primary Court of Gasabo dismissed the case, and the Intermediate Court of Nyarugenge upheld the same decision on appeal.<sup>758</sup>

When trying medical crimes, courts can apply *the Wednesbury principle and the res ipsa loquitur principle*. The former principle originates from *Associated Provincial Picture Houses Ltd v. Wednesbury Corporation (1948)*. This case established the possibility of judicial review of a public authority's decision if it is "so unreasonable that no reasonable authority could have rationally reached such a decision". This is known as the "irrationality standard" or Wednesbury unreasonableness. It is common in administrative law, where it can serve as the basis for the authority's accountability for those unlawful decisions. In the context of medical liability, the Wednesbury principle holds that the decision taken was not merely unreasonable but also outrageously defiant of accepted moral standards. Although this irrationality standard is not the primary test in medical malpractice claims like the *Bolam test*, its features, such as "irrationality" or "unreasonableness," is crucial at the threshold of liability. The principle can be found in the Bolitho addendum, which redefined the Bolam test through the UK case *Bolitho v City and Hackney Health Authority*, by adding a requirement of "logical defensibility" to expert opinion rather than merely "widely accepted".<sup>759</sup> The court can review and dismiss the medical expert testimony for being "illogically defensible" or lacking a rational basis, even if a body of peers may support it.<sup>760</sup> This is in line with the provisions of the law regulating evidence in Rwanda, where expert reports do not bind the court; instead, these reports may carry evidentiary weight depending on the context of the case.<sup>761</sup> Thus, to establish medical negligence under the rationality standard, the court must assess whether the medical option chosen was generally acceptable by the responsible body of medical opinion and whether the medical decision was logically defensible, even if the outcome was unfavorable.<sup>762</sup>

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<sup>757</sup> Law N°68/2018 of 30/08/2018 determining offences and penalties in general, Ibid.

<sup>758</sup> Prosecution v. Dr. Mugemanshuri and Another, RPA 00023/2023/TGI/NYGE (2024).

<sup>759</sup> Bolitho v City and Hackney Health Authority, AC 232 (1997).

<sup>760</sup> "How The Bolitho Test Changed the Understanding of Medical Negligence," *The UK Centre for Medico-Legal Studies*, accessed November 20, 2025, <https://www.ukcmls.co.uk/articles/tony-elliott/how-the-bolitho-test-changed-the-understanding-of-medical-negligence>.

<sup>761</sup> Article 78 of the Law No 062/2024 of 20/06/2024 Governing Evidence, Official Gazette N° Special of 27/06/2024 (2024).

<sup>762</sup> Maria Adams, "The Bolam Test Revisited: The Legal Standard for Medical Negligence Claims," *Lacey Solicitors*, June 30, 2025, <https://laceysolicitors.com/the-bolam-test-revisited-the-legal-standard-for-medical-negligence-claims/#:~:text=This is known as the, and Bolitho principles and found:>

Besides, the principle of *res ipsa loquitur*, i.e., “the thing speaks for itself,” is not new in tort law. It is commonly used in product liability and other medical malpractice cases where proving the direct cause of harm is hard. This principle establishes an inference of negligence by presuming the outcome that would not ordinarily occur without negligence, despite the defendant’s control.<sup>763</sup> This presumption shifts the onus of proof to the defendant to explain how the incident occurred without negligence. This principle does not apply to causation. The proof of risk may be considered proof of cause. If the defendant’s explanations are as plausible as the claimant’s, the claimant loses the case, as the legal burden of proof traditionally rests with him or her. However, if the defendant’s explanations are as plausible as the claimant’s but not more convincing, the defendant will lose the case.<sup>764</sup>

Although this principle is not frequently applied in Rwandan medical hearings, as courts often rely on circumstantial evidence to draw inferences, it may be relevant in some instances. Those may encompass cases in which the patient was unconscious, where the injury is not inherent to the procedure, where the practitioners have exclusive control over the situation, and when there is no direct evidence of what went wrong. Cases related to retained surgical instruments are a good example. This is because such incidents could not have occurred without negligence, the practitioners had exclusive control over the procedure, and the patient’s condition during the procedure led to unawareness of what happened. So, the burden of proof should be shifted to the defendant practitioner, who should explain how the standard of care was met.

In the context of medical malpractice, criminal liability applies to medical practitioners when their actions or omissions constitute willful or wanton misconduct, manslaughter, and health care fraud or abuse. These cases are beyond the realm of malpractice in civil law.

Criminality is generally based on two elements of an offence, “*mens rea*” (moral element) and “*actus reus*” (material act). Similar to other offences, the moral element should be proven beyond a reasonable doubt in medical crimes. The standards for producing evidence and proving guilt may vary across jurisdictions, but they must be higher than those in civil cases. However, malpractice that constitutes a medical offence often lacks the crucial element of *mens rea* as it results from gross misconduct or reckless behavior in medical settings that are traditionally unintentional. Thus, for a practitioner’s misconduct to constitute criminal behaviour, it must be egregious, and the resulting harm must be a foreseeable consequence of such behaviour. Besides, similar to civil case pursuit in negligence litigations, the link between *actus reus* and the suspect medical practitioner’s wrongdoing (i.e., breach of their duty to act competently and ethically) must be established to constitute a medical offence. The actions can be either direct or indirect, but the causal link must be specific, not merely probable. In addition, the judge must assess the condition without which

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<sup>763</sup> A Principle and A Doctrine, “Res Ipsa Loquitur – A Rule, A Principle, A Maxim, A Doctrine, A Myth or A Convenient,” *Irish Judicial Studies Journal* 8, no. 2 (2024): 67–77.

<sup>764</sup> Principle and Doctrine, p. 76.

the results would not have occurred. This is based on the general principle of law “*in dubio pro reo*” for which the judge must establish the fault beyond a reasonable doubt.

The primary purpose of criminal liability is to promote accountability and deter gross misconduct, reckless behavior, or intentional harm in medical settings. However, it has led to a profound ethical dilemma underpinned by the complexity of reconciling justice for the victims with fairness toward practitioners. While criminal liability remains necessary for holding medical practitioners accountable, its effectiveness in improving healthcare outcomes remains a topic of ongoing interdisciplinary debate among legal scholars, ethicists, and medical professionals. In response to these concerns, alternative models for delivering justice to victims have been proposed to address medical malpractice without compromising the legitimacy of practitioners by criminalising them. These frameworks include restorative justice and no-fault compensation systems.

#### 6.6.5. Assessment of damages in civil action arising from medical crimes

In Rwanda, a criminal act can result in personal injury, entitling the victim to seek damages from the offender. Beyond criminal liability, a medical practitioner who is prosecuted for offenses such as manslaughter, assault and battery, failing to assist someone in danger, healthcare fraud or abuse, stemming from deliberate negligence, may also incur civil liability. Civil action in criminal matters is defined as the “right for any person victim of an offence to seek compensation for damages caused by the offence in a (criminal) court seized with a criminal case.”<sup>765</sup> A civil action for damages can be instituted against the offender, co-offender, accomplice, the person liable to pay damages, or their heirs.<sup>766</sup> As discussed earlier in the section on civil liability, the Rwandan courts can award pecuniary and non-pecuniary damages.<sup>767</sup>

Damages resulting from a criminal act can be claimed jointly with the criminal case or separately.<sup>768</sup> Such action could be exercised in a criminal court by joining it with a criminal action initiated through public prosecution or private prosecution (*citation directe*). If the accused is convicted of an offence, the criminal court can order the defendant to compensate the victim with civil damages. However, the claim for civil damages could also be sued directly in civil court, seeking damages for an injury arising from an offence. In this case, the damages are likely to be awarded as the basis is the criminal judgment, which serves as evidence. It is also simple to determine the causal link between the criminal act against the victim and the harm suffered. It should be noted that the prescription period for a civil claim arising from a criminal act is five years from the time the offence was committed.<sup>769</sup>

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<sup>765</sup> “Article 10 of the Law N° 027/2019 of 19/09/2019 Relating to the Criminal Procedure” (2019).

<sup>766</sup> *Ibid.*, Article 11.

<sup>767</sup> Travis Peeler and Jose Rivera, “Defenses to Civil Battery Tort,” *Legal Match*, June 18, 2025, <https://www.legalmatch.com/law-library/article/civil-battery-defenses.html>.

<sup>768</sup> Article 112, para. 1, Law no. 027/2019 of 19/09/2019 relating to criminal procedure, OG. No. Special of 08/11/2019.

<sup>769</sup> *Ibid.*, Article 12.

In general, the courts can award civil damages arising from a medical offence in compensatory damages and punitive (exemplary) damages, depending on the jurisdiction. Nevertheless, damages to be granted in a criminal case should aim to bring the victim's "status quo ante" or restore the victim to the position they would have been in if the criminal act had not been committed.<sup>770</sup>

As in civil liability, damages arising from an offence should be granted on condition that there is a causal link between the harm suffered by the victim and the offence.<sup>771</sup> Thus, the victim (or the prosecutor, if applicable) must prove that the damage sustained is the consequence of the offender's criminal act (or omission), which should be the proximate cause of the harm.<sup>772</sup> However, if the accused (or defendant where applicable) wants to offset the restitution, the onus of proof is placed on their shoulders, such as having the victim received the damages through civil action for the same loss that would form the basis for the restitution claim in criminal court.<sup>773</sup>

Besides, the loss sustained must be quantifiable and precise. Thus, loss must be ascertainable, documented, and not speculative, as required in some jurisdictions. If losses are not straightforward, complex, or disputed, the courts may refuse to award damages and refer the victim to civil courts.<sup>774</sup>

Awarding damages in criminal proceedings has a basis in the victim's rights to reparation and participation. In this light, the court must inform the victims of their right to reparation and participation.<sup>775</sup> Besides, the process of awarding damages must be timely and procedurally fair. Thus, damages should be awarded without undue delay, and victims should not face unnecessary difficulties in the court's process. The procedure must also be transparent and respect the rights of both victims and the accused, particularly the accused's right to defense.<sup>776</sup>

#### 6.6.5.1. Rwanda

In the present context, assessing damages involves a comprehensive evaluation of both pecuniary and non-pecuniary losses incurred by an individual due to a medical offence. This may include actual losses, such as medical bills and transportation expenses, as well as prospective losses, including the cost of ongoing treatment. In Rwanda, these damages could also include litigation fees and property damage. The calculation of these damages is objective and requires the production of evidence, such as receipts and pay stubs.

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<sup>770</sup> African Court on Human and Peoples' Rights, *Comparative Study on the Law and Practice of Reparations for Human Rights Violations* (The Registry of the African Court on Human and Peoples' Rights, 2019), p. ix.

<sup>771</sup> Catharine M. Goodwin, "Federal Criminal Restitution: Basic Steps and Recent Issues" (USSC, New Orleans, USA: Thomson Reuters, 2015), p. 8.

<sup>772</sup> Goodwin.

<sup>773</sup> Catharine M. Goodwin, "Looking at the Law," *Federal Probation Journal* 62, no. 2 (1998): 98–100, [https://www.uscourts.gov/probation-journal-author/Catharine M. Goodwin?order=field\\_mydate&sort=asc](https://www.uscourts.gov/probation-journal-author/Catharine%20M.%20Goodwin?order=field_mydate&sort=asc).

<sup>774</sup> Peter Dostal, Restitution, 2020, Available at [https://criminalnotebook.ca/index.php/Restitution?utm\\_source=chatgpt.com](https://criminalnotebook.ca/index.php/Restitution?utm_source=chatgpt.com), Last visited on 25 November 2025.

<sup>775</sup> "Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power, General Assembly Resolution 40/34 of 29 November 1985" (1985), p. 1-3.

<sup>776</sup> Ibid.

The prosecution can invite the victim and assist them in negotiating with the defendant regarding the amount of damages to be awarded. In the event of disagreement, the victim will proceed with the claim in court.<sup>777</sup> The procedure is that if the prosecution invites the accused to negotiate with the victim on the amount of damages and the negotiation fails, the victim (or the prosecutor, where applicable) may decide to file a claim for damages jointly with the criminal case. In that case, the court will assess evidence of both criminal liability and damages and issue a judgment that encompasses both the determination of guilt and the damages awarded. However, if the victim chooses to claim damages separately from the criminal case, civil procedure will apply. In this case, the competent civil court will determine damages based on the value of the claimed damages.<sup>778</sup> The damages that the victim can claim comprise material or economic damages and moral or non-pecuniary damages.

#### 6.6.5.2. France

In France, like in Rwanda, the victim of a criminal act can institute a civil claim for damages arising from the criminal act during criminal proceedings as a civil party (*partie civile*) or separately in civil proceedings.<sup>779</sup> Compensation may cover both pecuniary and non-pecuniary damages. Sometimes, the compensation could be supplemented by the state-funded schemes. If attached to criminal proceedings, the same criminal court also rules on civil action for damages.<sup>780,781</sup> When the civil action is attached to the criminal proceedings, the court simultaneously assesses the extent of the harm and orders the offender to pay for damages after the criminal proceedings are complete. For the court to award damages, the compensable damages should be directly related to the harm suffered. The victim must prove the following:<sup>782</sup>

- the direct link between the harm suffered and the perpetrator's offence;
- the defendant is the one responsible for the loss;
- the damage is real and undeniable; and
- the damage concerns the victim personally.

When the victim lodges a claim in civil court, there is no appeal for the same complaint in criminal court, unless the prosecutor has initiated criminal proceedings before the civil court ruling on the merits.<sup>783</sup> The time limit for the victim's right to a civil claim arising from the criminal act is set for 5 years if the victim lodges a claim separately from the criminal proceedings.<sup>784</sup>

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<sup>777</sup> Article 24 (4), Law no. 027/2019 of 19/09/2019.

<sup>778</sup> Article 122.

<sup>779</sup> "Claiming Damages from the Offender," European e-Justice, 2019, [https://webgate.ec.europa.eu/e-justice/494/EN/claiming\\_damages\\_from\\_the\\_offender?FRANCE&member=1](https://webgate.ec.europa.eu/e-justice/494/EN/claiming_damages_from_the_offender?FRANCE&member=1).

<sup>780</sup> Article 3 of the French Code of Criminal Procedure of 1958 as Amended on August 13, 2025 by Law No. 2025-797.

<sup>781</sup> "Understanding Civil and Criminal Remedies in France for Financial Crimes," *Charles Russell Speechlys*, January 17, 2025, <https://www.charlesrussellspeechlys.com/en/insights/expert-insights/dispute-resolution/2025/understanding-civil-and-criminal-remedies-in-france-for-financial-crimes/>.

<sup>782</sup> "Claiming Damages from the Offender," 2019.

<sup>783</sup> "Claiming Damages from the Offender."

<sup>784</sup> Jeannin, French Code of Criminal Procedure as amended on August 13, 2025 by Law No. 2025-797.

If the perpetrator could not be identified or has failed to pay the compensation, the victim may apply for state-guaranteed compensation. This is possible only in cases where the criminal proceedings have been initiated, and the individual seeking compensation has obtained official status as a victim in those proceedings.<sup>785</sup> The criminal court grants the civil status after ascertaining that the victim's harm is a result of an offence. In this regard, the victim files a claim with the Commission for Compensation to Victims of Offences or CIVI (Commission d'indemnisation des victimes d'infraction), along with all supporting documents, which is then forwarded to the Victims' Guarantee Fund or FGVI (Fonds de garantie des victimes).<sup>786</sup> If CIVI is unable to pay the compensation, the victim could file with the Offence Victims Recovery Assistance Service or SARVI (Service d'aide au recouvrement des victimes d'infractions), which may pay in part or in whole and recover the amount from the perpetrator. The involvement of the state in the compensation process is to ensure respect for the victim's right to an effective remedy, as the offender might be bankrupt and hinders this right from being exercised.<sup>787</sup>

Like any other perpetrator in France, a medical practitioner prosecuted for a medical offence may be compelled to pay compensation to the healthcare service user who sustained harm as a result of such an offence. However, such a civil claim for damages may be handled by the same criminal court or a separate civil court, depending on whether it is filed as part of different court proceedings.

#### *6.6.5.3. Hungary*

In Hungary, victims of medical practitioners' criminal acts within the scope of medical malpractice can seek compensation for both pecuniary and non-pecuniary damages resulting from the harm suffered. The Hungarian courts can admit claims for civil damages arising from a criminal act under the Code of Criminal Procedure (Act XC of 2017). Awarding these damages based on the civil code regulating damages and restitution.

The victim may seek compensation either directly against the offender through criminal proceedings or through state-supported mechanisms in cases where the perpetrator fails to pay, similar to France. Additionally, Hungary incorporates EU directives on victims' rights, establishing its obligations to ensure the minimum standards of protection for victims.

The victims of a criminal act can file a civil claim (polgári jogi igény) in parallel to, or in conjunction with, criminal proceedings, similar to those in Rwanda and France. If the civil claim is filed in conjunction with a criminal action, it should be submitted to the court of first instance at the earliest procedural step before appearing in court. The court communicates these steps to the victim, and if the victim fails to do so, late submissions are inadmissible.<sup>788</sup> However, the general

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<sup>785</sup> "Claiming Damages from the Offender," 2019.

<sup>786</sup> "Claiming Damages from the Offender."

<sup>787</sup> "Claiming Damages from the Offender."

<sup>788</sup> "Claiming Damages from the Offender," European e-justice, January 21, 2019, [http://e-justice.europa.eu/topics/your-rights/victims-crime/compensation/claiming-damages-offender/hu\\_en](http://e-justice.europa.eu/topics/your-rights/victims-crime/compensation/claiming-damages-offender/hu_en).

statute of limitations for civil claims in Hungary is 5 years.<sup>789</sup> If the criminal court finds the offender guilty, it can order the payment of compensation or refer the case to a civil court if it determines that the claim is too complex.

Another point of consideration on the Hungarian medical liability system is that it incorporates foreign claimants, which may raise cross-border liability issues. Besides, in compliance with European human rights standards, the Hungarian compensation system has recently introduced a state compensation mechanism for excessively lengthy proceedings.<sup>790</sup> In this regard, the reasonable time for the proceeding is assessed on a case-by-case basis.

The framework for medical liability in civil courts in Hungary is established by the Civil Code (Act V of 2013). If claims are civil, they are governed by the Code of Civil Procedure (Act CXXX of 2016), which outlines the procedures for bringing claims before civil courts.<sup>791</sup> This is similar to the civil claims lodged in conjunction with a criminal act. Civil damages apply only when the medical offence, arising from deliberate or gross negligence, resulted in the patient's harm. In the context of medical liability, the Hungarian court can award restitution in kind as corrective medical treatment. If not practicable, courts can award financial compensation.

#### *6.6.5.4. South Africa*

In South Africa, Section 300 of the South African Criminal Procedure Act 51 of 1977 outlines the procedure for applying for and awarding damages in criminal proceedings. The court, upon application by the injured person or the prosecutor, is allowed to award compensation if the criminal act has resulted in damage or loss of property.<sup>792</sup> Civil claims arising from medical malpractice resulting in an offence are subject to a statutory limitation of three years. Failure to lodge the case within this time limit extinguishes the right to claim. However, for minors or people with disability, this prescription period is suspended until their majority age, or they regain capacity, respectively.<sup>793</sup>

If there is a person convicted of an offence that has caused damage, the court may, upon application of the injured person or of the prosecutor acting on the instructions of the injured person, award compensation to the injured person. The court cannot decide to award compensation if it has not been applied for by the injured person or by the prosecutor acting under the instructions of the victim of the criminal act. When the prosecutor acts on their own initiative, the sentence given by the court, which includes an award of damages, can be set aside. As discussed earlier, these

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<sup>789</sup> "Claims and Statutes of Limitations in Hungary," Specht & Partner, accessed January 12, 2025, <https://www.specht-partner.com/statutes-of-limitations-hu/>.

<sup>790</sup> Peter Gritta and Richard Schmidt, "New Monetary Compensation for Lengthy Litigations in Hungary From 2022," Smart Legal, 2021, <https://smartlegal.hu/publication/new-monetary-compensation-for-lengthy-litigations-in-hungary-from-2022>.

<sup>791</sup> "Act CXXX of 2016 on the Code of Civil Procedure. This Act came into force in 2023.

<sup>792</sup> Criminal Procedure Act 51 of 1977, s. 300

<sup>793</sup> "Time Limits on Medical Negligence Claims in South Africa," DSC Attorneys, accessed December 1, 2025, <https://www.dsclaw.co.za/articles/time-limits-on-medical-negligence-claims-in-south-africa/>.

damages can be awarded in both pecuniary and non-pecuniary forms and may be awarded in cash or in kind.

The medical liability system in South Africa is a rights-based approach that intersects constitutional guarantees with common law principles. It ensures both restorative and deterrent functions. The primary compensation is awarded in cash, although it could also be awarded in kind by exception. However, they aim to cover both financial and emotional harm.

#### 6.6.5.5. Canada

According to the Criminal Code of Canada, damages for a victim of a criminal act are assessed and awarded through restitution orders and a victim surcharge. The restitution orders require the offender to compensate the victim for all financial losses resulting from the criminal acts they committed. The restitution order is part of the sentence and can be a stand-alone order or part of a probation or conditional sentence.<sup>794</sup> It is the victim's right to have a court consider issuing a restitution order to the offender when deciding the sentence. If the offender fails to pay the amount ordered by the court, the victim has the right to register the restitution order with a civil court.

Prosecutors and courts have an obligation to assist victims in exercising their right to request restitution. The Crown Counsel has the responsibility to allow the victim to request restitution.<sup>795</sup> In the event that it has not been granted, the court may, upon the prosecutor's application or on its own motion, postpone sentencing to allow the victim to make an application for restitution.

Under Canadian law, both pecuniary and non-pecuniary damages are awarded for direct losses and prospective losses, as determined by expert testimony.<sup>796</sup> A restitution order covers, among other things, bodily injury or psychological harm caused by the criminal act and loss of income. The victim must prove the financial losses suffered due to the criminal act through documents such as receipts, invoices, pay slips, and absence forms from work to prove lost wages, bills for medical treatment costs, and any other loss that can help prove financial loss caused by the crime.<sup>797</sup> The amount of financial damages claimed must be ascertainable, and the victim's application for damages cannot be denied if there are disputes over such amount between the victim and the offender. However, in cases where there is incomplete information, varying information, complicated calculations, or a clear dispute over fundamental issues, these may constitute grounds for the court to reduce the amount or deny the restitution order.<sup>798</sup>

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<sup>794</sup> See *Criminal Code*, s 738(1).

<sup>795</sup> See *Criminal Code*, s 737.1(1) and (2).

<sup>796</sup> Samin Mortazavi, "Understanding Damages in Canadian Civil Litigation," *Pax Law*, January 6, 2025, <https://www.paxlaw.ca/understanding-damages-in-canadian-civil-litigation/>.

<sup>797</sup> Victim's Rights in Canada, Available at [https://www.justice.gc.ca/eng/cj-jp/victims-victimes/factsheets-fiches/restitution-dedommage.html?utm\\_source=chatgpt.com](https://www.justice.gc.ca/eng/cj-jp/victims-victimes/factsheets-fiches/restitution-dedommage.html?utm_source=chatgpt.com), consulted on 25 November 2025.

<sup>798</sup> As decided in *R v Ghislieri*, 25 AR 465 (ABCA); *R v Bullen*, 2001 YKTC 504, and *R v Semeniuk*, 2004 BCCA 233, *R v Dunlop* 2006 NSSC 311 (NSCA) cited by Public Prosecution of Canada, Restitution, available at <https://www.ppsc-sppc.gc.ca/eng/pub/fpsd-sfpg/fps-sfp/tpd/p6/ch07.html>, Last visited on 26 November 2025.

In addition, non-pecuniary damages are also awarded in Canada, subject to limitations. The Canadian Supreme Court capped non-pecuniary damages at CAD \$100,000 in its judgment *Andrews v. Grand & Toy Alberta Ltd.* (1978). This cap was later adjusted to CAD \$400,000 due to inflation.<sup>799</sup>

There are specific considerations that the Crown Council must take into account when deciding on an application for restitution. They include the severity of the offence, the degree of responsibility of the offender in causing the loss or damage, connection between the criminal act and the loss suffered by the victim, the financial ability of the offender to pay now or at a reasonably ascertainable future date, if the amount of the restitution is entirely or partially ascertainable, the impact of the restitution order on the offender's rehabilitation, etc.<sup>800</sup>

In all 4 countries compared above, victims of criminal acts are entitled to damages awards. They all have a dual-track mechanism to ensure efficiency and protect the victim's right to effective reparation. However, civil claims are subject to strict adherence to procedural deadlines, which vary from one jurisdiction to another. Either criminal courts or civil courts can award damages to the victims of medical crime. However, there are some differences.

In Rwanda, the law permits a full civil claim to be joined to the criminal case, encompassing both material and non-material or moral damages. The prosecutor has to invite the injured person to file a claim for damages. If the claim has not been joined to the criminal proceeding, the victim can initiate a civil action in the civil courts. This is also the case for Hungary, although the state can compensate the victim of medical crime if the proceedings have become too lengthy. Additionally, the Hungarian court can also pay the victim in kind for corrective medical treatment, although this form of compensation is replaced with financial damages if it is not viable. Additionally, South Africa permits the prosecutor to apply for damages on behalf of the victim of the offence, and the damages award forms part of the sentence. Canada uses restitution orders that are integrated into the sentencing process within the criminal courts. However, restitution orders mainly relate to easily provable material losses, while non-material losses are mostly left to civil courts. Like Rwanda, France has a compensation system that enables victims to seek compensation for damages arising from a criminal act through both criminal and civil proceedings. However, in France, state intervention in the compensation process is necessary to ensure the victim's right to effective reparation.

#### 6.6.6. Corporate liability

Corporate or enterprise liability, as applied within the context of tort law, is aligned with institutional liability, both of which underscore organisational accountability for systemic failures. In the context of medical liability, healthcare institutions owe a duty to their patients to provide

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<sup>799</sup> Diana L. Dorey and Brent L. Rentiers, "The Calculation of Damages for Bodily Injury Claims," *Dolden*, 2014, <https://dolden.com/the-calculation-of-damages-for-bodily-injury-claims/>.

<sup>800</sup> "As decided in *R v Ghislieri*, 25 AR 465 (ABCA); *R v Bullen*, 2001 YKTC 504, and *R v Semeniuk*, 2004 BCCA 233, *R v Dunlop* 2006 NSSC 311 (NSCA)," cited in *Restitution* by Public Prosecution of Canada, <https://www.ppsc-sppc.gc.ca/eng/pub/fpsd-sfpg/fps-sfp/tpd/p6/ch07.html>.

high-quality care.<sup>801</sup> Corporate liability arises when these institutions fail to fulfill their corporate responsibilities in that spectrum, such as maintaining accurate patient records, possessing proper medical equipment, recruiting capable staff, instituting effective supervisory and control mechanisms, and providing ongoing training and professional development for their personnel.<sup>802</sup>

Before the introduction of corporate liability theory to hospitals, they enjoyed absolute immunity from liability.<sup>803,804,805,806</sup> Some factors shielded hospitals from liability in the early days. Hospitals were in a hospital-independent contractor relationship with physicians, who could utilise them to practice their art of healing rather than employing them. Physicians could use the hospital as a facility for their patients when needed. The courts reasoned that the medical profession requires high-level skills and specialisation that a hospital's administrator cannot control.<sup>807</sup> Additionally, there was a perception that they function like charitable organisations in many countries, whose trust fund could not be used for compensating medical malpractice.<sup>808</sup> In the context of hospital liability, the doctrine of "respondeat superior" was not applicable, as there was no direct relationship between an employer and employee in medical institutions. Other liability mechanisms seemed impractical, as hospitals were separate businesses that did not have a direct relationship with the patients.

Nevertheless, hospitals and medical clinics are sophisticated profit-making entities in modern medical practice, which positions them in a liability standpoint through various mechanisms. Apart from individual physicians, healthcare providing corporations, hospitals, and medical clinics owe patients certain duties. Those corporations with legal personality can be held liable for their medical negligence and malpractice under the corporate negligence theory. Under the U.K. Corporate Manslaughter and Corporate Homicide Act 2007, an organisation can be criminally convicted of corporate manslaughter in the U.K. following its operations that are managed or organised in a way that causes a person's death and amounts to a gross breach of a relevant duty of care it owes to the deceased.<sup>809</sup> This is mostly related to the organisation's shortage of

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<sup>801</sup> Arthur F Southwick and Arthur F Southwick, "The Hospital's New Responsibility," *Cleveland State Law Review* 17, no. 1 (1968): 146–47, <https://engagedscholarship.csuohio.edu/clevstlrev/vol17/iss1>.

<sup>802</sup> David H Rutchik, "The Emerging Trend of Corporate Liability: Courts' Uneven Treatment of Hospital Standards Leaves Hospitals Uncertain and Exposed," *Vanderbilt Law Review* 47, no. 2 (1997): 540-548.

<sup>803</sup> Bradley C. Canon and Dean Jaros, "The Impact of Changes in Judicial Doctrine: The Abrogation of Charitable," *Law & Society Review* 13, no. 4 (1979): 969–86, <https://www.jstor.org/stable/3053152>.

<sup>804</sup> Rutchik, "The Emerging Trend of Corporate Liability: Courts' Uneven Treatment of Hospital Standards Leaves Hospitals Uncertain and Exposed," p. 536-571.

<sup>805</sup> William Mitchell, "Theories for Imposing Liability Upon Hospitals for Medical Malpractice: Ostensible Agency and Corporate Liability," *William Mitchell Law Review* 11, no. 2 (1985): 576–583.

<sup>806</sup> "Abolition of Charitable Immunity for Nonprofit Hospitals in Michigan," *Casemine*, September 16, 1960, <https://www.casemine.com/commentary/us/abolition-of-charitable-immunity-for-nonprofit-hospitals-in-michigan/view>.

<sup>807</sup> Mitchell, "Theories for Imposing Liability Upon Hospitals for Medical Malpractice: Ostensible Agency and Corporate Liability," p. 561-572."

<sup>808</sup> Court of Appeals of Kentucky, *Forrest v. Red Cross Hospital, Inc.* (1954).

<sup>809</sup> Corporate Manslaughter and Corporate Homicide Act (Section 1)" (2007), [https://www.ilo.org/dyn/natlex/natlex4.detail?p\\_isn=94983&p\\_lang=en](https://www.ilo.org/dyn/natlex/natlex4.detail?p_isn=94983&p_lang=en).

occupational safety and health measures. The establishment of a causal link between the results and the acts is always necessary. Although those acts can be either direct or indirect, the causal linkage should be specific.

There has been a blurred line between institutional accountability and the traditional protection of corporate personhood. The corporate hospital liability aims to hold healthcare institutions accountable for institutional negligence that has led to medical malpractice and harmed healthcare service users.<sup>810</sup> However, the doctrine of “piercing/lifting the corporate veil” remains an exceptional remedy that allows courts to disregard the corporate formality and its separation from its shareholders, thereby preventing the misuse of the corporate structure.<sup>811</sup> In the context of medical liability, the court can lift the corporate veil in cases where healthcare entities are used to shield their owners or stakeholders from liability resulting from malpractice claims.

Under the doctrines of corporate liability and institutional liability, corporations are held liable for their failures. This might be based on healthcare service users' malpractice claims or on the healthcare entity's setting conditions that pose health risks to healthcare service users. This liability may be attached to the institution itself, although the health practitioner, as an employee, may be involved. In the latter case, the entity is liable for failing to maintain safety standards, recruiting inappropriate staff, or failing to exercise effective control over its employees. However, in some cases, the court may hold the corporation's minds, such as corporate stakeholders or executives, personally liable by lifting the corporate veil. The court may apply this doctrine in cases involving fraudulent concealment of malpractice, misuse of corporate structures to avoid patient compensation, or bankruptcy maneuvers.<sup>812,813</sup>

In the Rwandan context, healthcare providers, hospitals, clinics, or any other healthcare entities have a “non-delegable duty” to provide a safe care environment to patients. Under the theory of corporate negligence, failure to fulfill this duty may invoke corporate liability even if there was no medical practitioner's negligence.<sup>814</sup> Furthermore, the managers or minds of these entities could also be personally held liable under the doctrine of lifting the corporate veil if they misuse their powers and commit offenses for their own personal interests.

Institutional liability compels hospitals to fulfill their obligation to implement risk assessment systems that reduce the incidence of medical malpractice. Those systems include the development of standardised protocols, adherence to evidence-based practices, and instituting mechanisms for

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<sup>810</sup> James B. Cohoon, “Piercing the Doctrine of Corporate Hospital Liability,” *San Diego Law Review* 17, no. 2 (1980): 383–401, <http://id.loc.gov/authorities/names/n79122466>.

<sup>811</sup> Cohoon.

<sup>812</sup> Davy Aaron Karkason, “Corporate Veil Piercing: Understanding the Dynamics,” *transnationalmatters.com*, March 3, 2025, <https://www.transnationalmatters.com/corporate-veil-piercing-understanding-the-dynamics/>.

<sup>813</sup> LegalClarity Team, “What Is Piercing the Corporate Veil and When Does It Apply?,” *LegalClarity*, February 5, 2025, <https://legalclarity.org/what-is-piercing-the-corporate-veil-and-when-does-it-apply/>.

<sup>814</sup> Erika L. Amarante, “Corporate Liability for Hospitals,” *Medical Liability and Healthcare Law*, February 2016, <https://www.wiggin.com/publication/corporate-liability-for-hospitals/>.

oversight, enabling the identification and addressing of risks before they culminate in harm. Healthcare institutions must embed these safeguards into their institutional structures.

Following the human error theory, which underpins the present research, corporate liability ensures that healthcare delivery is inherently collaborative and dependent on institutional infrastructure. This could not be separated from the Normal Accident Theory (NAT) introduced by Charles Perrow in 1972.<sup>815</sup> This theory posits that in complex, tightly coupled systems, such as hospitals, failures are inevitable because they are inherent in the system's design. Such failures result from the interaction of multiple interdependent components, where even a minor fault can trigger an unpredictable adverse outcome. In this light, any organisational failure creates room for adverse patient outcomes. Therefore, liability should not be confined to the individual practitioners' negligence but extended to the systemic deficiencies that open the door to malpractice.<sup>816</sup> According to William M. Sage, the basis of corporate liability emerges from the traditional growing dependence of clinical practice on institutional resources and expertise.<sup>817</sup> Outstandingly, the distribution of liability compels both healthcare providers and practitioners to prioritise patient safety, and corporate governance should adopt a patient-centric approach.<sup>818</sup> Both corporate and institutional liability are punitive and preventive mechanisms that aim to compel healthcare providers to uphold high standards of care by adopting proactive strategies that safeguard healthcare users, mitigate risks, and enhance integrity in clinical practice.

#### 6.6.7. Medical liability from a human rights context

An effective remedy for injury is a right grounded in principles such as restitution, compensation, rehabilitation, satisfaction, and guarantees of non-repetition, which are outlined in various international and regional treaties. These include the International Covenant on Civil and Political Rights (ICCPR), the African Charter on Human and Peoples' Rights (Banjul Charter), the European Convention on Human Rights (ECHR), and the American Convention on Human Rights (ACHR). Different courts have acknowledged these rights from various perspectives of international law.

The Constitution of Rwanda and the legal system indicate the country's commitment to international human rights. Rwanda has ratified most of the core international human rights treaties, and its legal framework reflects these obligations. Regarding medical care, the Constitution of Rwanda guarantees fundamental rights such as the right to life and physical and

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<sup>815</sup> Michelle M Mello et al., "Who Pays for Medical Errors? An Analysis of Adverse Event Costs, the Medical Liability System, and Incentives for Patient Safety Improvement," *Journal Of Empirical Legal Studies* 4, no. 4 (2007): 835–60, <https://doi.org/10.1111/j.1740-1461.2007.00108.x>.

<sup>816</sup> Sri Setiawati and Pratiwi Ayu Sri Daulat, "Hospital Liability as a Corporation in Medical Malpractice," in *Proceedings of the International Conference On Law, Economics, and Health (ICLEH 2022)* (Atlantis Press, 2023), 85–86, <https://doi.org/10.2991/978-2-38476-024-4>.

<sup>817</sup> Rutchik, "The Emerging Trend of Corporate Liability: Courts' Uneven Treatment of Hospital Standards Leaves Hospitals Uncertain and Exposed," p. 159.

<sup>818</sup> Ashwani Bhatia, "Physician-Led Governance: A Blueprint for Sustainable, Patient-Centered Healthcare," *Becker's Hospital Review*, June 2025, <https://www.beckershospitalreview.com/hospital-management-administration/physician-led-governance-a-blueprint-for-sustainable-patient-centered-healthcare/>.

mental integrity.<sup>819</sup> As a result, Rwandan courts are generally expected to consider and apply international human rights law by interpreting the national law on medical liability in a way consistent with international human rights standards.

From a human rights perspective, both procedural and substantive remedies are recognized under international law and regional legal frameworks. The International Covenant on Civil and Political Rights (ICCPR) guarantees the right to an effective remedy, obligating states to ensure that individuals whose rights have been violated can access redress. These remedies must be determined by competent authorities and enforced once granted.<sup>820</sup>

The African Charter on Human and Peoples' Rights (Banjul Charter) similarly affirms this right, stating: "Every individual shall have the right to have his cause heard." This encompasses the right to appeal to competent national bodies against violations of fundamental rights, the right to be tried within a reasonable time by an impartial court, and the right to a defense, including legal representation.<sup>821</sup>

The ECHR further articulates the right to an effective remedy, requiring that domestic redress mechanisms be accessible, capable of addressing alleged violations, and empower national authorities to investigate complaints, adjudicate their merits, and provide appropriate relief. Additionally, the Convention provides for "just satisfaction" as a form of reparation, which may include monetary compensation for both material and non-material harm.<sup>822</sup>

Within the framework of international human rights law, the American Convention on Human Rights (ACHR) articulates a comprehensive approach to reparations, extending beyond pecuniary compensation when the Inter-American Court of Human Rights (IACtHR) determines a violation has occurred. These reparations encompass restitution, aimed at restoring victims to their original condition prior to the violation; compensation, which includes financial redress for both material and moral damages; rehabilitation, involving medical, psychological, and legal assistance; satisfaction, delivered through symbolic measures such as official apologies, commemorative monuments, or the dedication of public spaces; and guarantees of non-repetition, which entail structural reforms, legislative amendments, and capacity-building initiatives for state actors to prevent future violations.<sup>823</sup> This multifaceted remedial framework reflects the normative commitment to effective redress, as similarly enshrined in the ECHR. In this regard, Rwanda's domestic legal system may be interpreted as embodying the principle of effective remedy, insofar

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<sup>819</sup> Office of the United Nations High Commissioner for Human Rights, "Human Rights Committee Reviews the Report of Rwanda," 2016, <https://www.ohchr.org/en/press-releases/2016/03/human-rights-committee-reviews-report-rwanda#:~:text=The Constitution specifically provided for,children%2C persons with disabilities and.>

<sup>820</sup> Article 2 of the International Covenant on Civil and Political Rights (1966).

<sup>821</sup> Article 7 of the African Charter on Human and Peoples' Rights (Banjul Charter) (1981).

<sup>822</sup> Article 41 of the "European Convention on Human Rights" (1950), [https://www.echr.coe.int/documents/d/echr/convention\\_ENG](https://www.echr.coe.int/documents/d/echr/convention_ENG).

<sup>823</sup> Article 63 of the American Convention on Human Rights (Pact of San José) (1969).

as it aligns with the substantive and procedural standards articulated in both the Banjour Charter, ECHR, and ACHR.

It is important to underscore that medical liability, when construed as a civil wrong, is primarily addressed within the domain of civil law rather than under the rubric of human rights violations. The principal objective in such cases is to provide compensation for harm suffered by the victim, rather than to establish state accountability for breaching human rights obligations. However, medical negligence may attain the threshold of a human rights violation in circumstances where it reflects a systemic failure by the state to safeguard the right to health, or where the conduct—whether through action or omission—is sufficiently grave to infringe upon the right to life or physical integrity. In this context, the absence of an effective domestic remedy for medical malpractice, or a demonstrable form of substandard health care in state-operated health facilities resulting in serious harm, may substantiate claims of human rights violations under international legal standards.

In case it becomes a human rights issue, the victim of medical malpractice could, in theory, petition a regional human rights court, such as the African Court on Human and Peoples' Rights (AfCHPR), to order reparations on the condition that they have exhausted all domestic remedies and believe that the outcome was insufficient or the process was ineffective.

In instances where medical malpractice transcends the boundaries of civil liability and constitutes a human rights violation—particularly through systemic state failures or egregious neglect—the affected individual may, in principle, seek recourse through regional human rights mechanisms. Specifically, the victim could petition the AfCHPR to adjudicate the matter and, if so ordered, to order reparations. Such a petition, however, is contingent upon the exhaustion of all available domestic remedies, in accordance with the principle of subsidiarity, and a demonstrable claim that the national legal process was either ineffective or yielded an inadequate outcome. This pathway underscores the intersection of civil accountability and human rights protection, particularly in contexts where state obligations to uphold the rights to life, health, or physical integrity have been fundamentally compromised.

#### 6.6.8. Liability from the contractual relationship

Contracts in the healthcare sector encompass agreements between healthcare professionals and healthcare providers. These contracts often extend to social insurance providers, creating a chain of relationships with healthcare providers and ultimately with healthcare service users. The specific characteristics of the services provided under these agreements profoundly influence the duties binding on the parties involved.<sup>824</sup> Specifically, a medical practitioner's delivery of treatment, being inherently a process of healing, is generally construed not as a contract for a specific result, but rather as a contract for the undertaking of services.

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<sup>824</sup> De Gruyter, *Medical Liability in Europe: Tort and Insurance Law*, ed. Bernhard A Koch (Berlin/Boston, 2011), p. 21-23.

Among various contractual agreements in medical settings, those involving medical practitioners impose “a duty to exercise reasonable and comprehensive professional care and skill.”<sup>825</sup> As a learned profession, medical practice requires physicians to adhere to generally accepted standards, demonstrating the prudence and expertise expected of specialists within their respective fields. These contracts have far-reaching implications, as third parties—such as beneficiaries affected by medical treatment—may invoke claims for breach of contractual obligations owed to the primary patient, including a parent, spouse, or child.<sup>826</sup>

In addition to contracts with individual medical practitioners, healthcare institutions also may engage in contractual agreements vis-à-vis healthcare users. These agreements follow the same legal principles that hold healthcare providers accountable for medical liability. In cases where an employed or ostensible practitioner causes an adverse event, the healthcare organisation is vicariously liable. However, in jurisdictions such as Austria, patients may have the option to select a specific physician to provide care, rather than having one assigned by the healthcare institution. When a physician voluntarily consents to treat the patient, liability shifts from the healthcare organisation to the individual practitioner. This is contrary to situations in Rwanda, where the institution designates a doctor for patient care.

Furthermore, hospital visitors and the patient's family members may also fall within the protective scope of the patient's contractual rights. As such, they may pursue claims for breaches of contractual duties, including obligations to maintain safety and mitigate risks, should they suffer harm, in instances such as a hospital visit.<sup>827</sup>

#### *6.6.8.1. Nature of medical contractual relationship and pertaining liability*

According to Abugu, the legal sense of the word “patient” explains the legal status of a person in a special relationship with a doctor, a team of doctors, or a hospital.<sup>828</sup> This raises enquiry about the nature of this relationship. The terms “doctor-patient relationship” and “professional-patient relationship” are commonly understood to refer to the contractual relationship between healthcare practitioners and patients in healthcare settings.

This contractual relationship establishes a basis for holding liable those responsible for medical malpractice. The aggrieved patients may sue for damages resulting from a breach of contract between themselves and their healthcare givers. The professional-patient relationship is considered contractual in nature, particularly in private healthcare settings. The common nature of this contract is implied as it is founded on the doctor's acceptance to treat a patient. This acceptance positions the medical practitioner in an obligation to provide care with reasonable skill and knowledge, diligence, and compliance with medical standards.<sup>829</sup> However, in some cases, an

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<sup>825</sup> Gruyter.

<sup>826</sup> Gruyter.

<sup>827</sup> Gruyter.

<sup>828</sup> Uwakwe Abugu, “Understanding the Basics of Doctor - Patient Relationship,” *University of Abuja*, 2013, 2.

<sup>829</sup> Marina Losevich, Aigars Laizāns, and Inga Kudeikina, “Aspects of Contractual Relations in Healthcare,” *Socrates: RSU Elektroniskais Juridisko Zinātnisko Rakstu Žurnāls* 3, no. 3 (2022): 91–105, <https://doi.org/https://doi.org/10.25143/socr.24.2022.3.091-105>.

explicit contract exists for a specific treatment agreement or specialised healthcare services.<sup>830</sup> Either an implicit or an explicit contract imposes a binding duty of care on a healthcare practitioner towards the patient.

The objective of the contract is to provide medical care aimed at restoring the patient's state of health or for medical needs.<sup>831</sup> For capacity, medical practitioners have special legal capacity arising from their license to practice medicine and the registration process. In contrast, the patient's capacity (both decisional and executive) should be assessed before, during, and at the termination of the professional-patient relationship.<sup>832</sup> Unless in an emergency, the patient will only be allowed to be an active participant in the treatment process when competent; if not, participation will be facilitated through the patient's qualified representative. Additionally, practitioners should ensure the legality of the healthcare service to be delivered.<sup>833</sup>

In addition to the duty of care they owe their patients, practitioners have the duty to maintain confidentiality, continue treatment until it is properly terminated, and seek informed consent before any medical treatment. Practitioners must also be honest and truthful about the services they provide during their professional-patient relationship with healthcare users. This is known as the "duty of candour," which obliges the practitioners and providers to tell the truth to their patients by revealing all information regarding their treatment options, potential risks, offering an apology, and supporting them through any adverse outcome.<sup>834</sup> These duties have been discussed in the section on the legal and regulatory framework for medical malpractice in Rwanda.

Within that contract, each party has obligations to fulfill so that the contract can be effective. However, in all circumstances, a medical practitioner must maintain a high level of professionalism, even in the face of challenging or confrontational behavior from the patient.<sup>835</sup> The British Medical Association (BMA) Ethics Toolkit states that doctors cannot only opt to end the professional relationship with troublesome patients after carefully considering other possibilities. They must also be fair and non-discriminatory against the patients. However, practitioners could immediately remove such patients from the list if their behaviour constitutes a threat to other people's safety.<sup>836</sup>

Following the above responsibilities, if a practitioner fails to meet their contractual obligation, such failure constitutes medical malpractice or negligence, which is a ground for the victim patient to sue for damages under the contractual liability layer. The contractual breach is based on the failure to provide the agreed-upon services or the non-compliance with the agreed-upon terms and

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<sup>830</sup> Losevich, Laizāns, and Kudeikina, p. 97.

<sup>831</sup> Losevich, Laizāns, and Kudeikina, p. 93-97.

<sup>832</sup> Losevich, Laizāns, and Kudeikina, p. 93.

<sup>833</sup> Ibid.

<sup>834</sup> Giles Emmanuel, Michelle Cabot, and Beverley Lacey, "The Duty of Candour - What Is It?," VIBERTS, July 24, 2024, <https://www.viberts.com/news-insights/the-duty-of-candour-what-is-it/>.

<sup>835</sup> B M A Medical, *Ethics Toolkit: The Doctor-Patient Relationship* (BMA, 2025), p. 42-43.

<sup>836</sup> Ibid.

conditions. This differs from a negligence claim, which must be based on the negligent behavior in the provision or non-provision of healthcare services.<sup>837</sup>

In the Rwandan context, courts have exercised one layer of liability for medical malpractice, which is the “tort liability system”. However, other approaches, such as contractual liability and liability arising from the violation of consumer protection laws, could also be effective. The victim of medical malpractice can use those layers of liability when seeking compensation for the harm suffered. In the Rwandan context, contractual medical liability can be exercised by victims of medical malpractice, provided that the healthcare practitioner or healthcare provider has failed to provide the agreed-upon or promised healthcare services. Additionally, this could be applied when the treatment was performed below accepted medical standards, when there has been a breach of confidentiality, and in cases where the practitioner has abandoned the patient without providing care after assuming responsibility for the treatment. Although the current research did not identify any malpractice cases handled under a contractual liability basis, such cases may occur in the future. For example, when a hospital fails to deliver services that are included within the package of his insurance policy, or when the private clinics fail to provide post-operative care. However, if the claimants use a contractual liability layer to pursue damages, they cannot circumvent its limits by invoking tort liability under Rwandan Law. This is known as the “principle of non-cumul”.<sup>838</sup>

Nevertheless, one can consider many factors when approaching contractual liability, such as whether there will be an improvement in healthcare services and patient safety if the law treats the professional-patient relationship as a contract. Shan’t it change the nature of medical practice from means-based obligation to result-based obligation? If so, it could only apply to specific healthcare services, particularly those whose purpose is not medically necessary. Another aspect to consider is whether breaches of express contracts and breaches of implied contracts should be treated alike. Generally, the doctor-patient relationship is regarded as an implied contract based on the doctor’s commitment to undertake the patient’s treatment using all necessary skills, knowledge, and equipment at their disposal. However, we have observed that express contracts are also feasible for specific healthcare services. Thus, the express commitment of a practitioner includes a sense of healing possibility or forecasting the result with certainty, which is different from the traditional nature of medicine or the art of healing. Therefore, the breach of an express contract would result in heavier damages compared to the breach of an implied contract.

Additionally, Almas Shaikh emphasises that certain aspects of measuring damages may undermine some elements of harm, including physical pain and mental suffering.<sup>839</sup> These are measuring damages based on the fact that the plaintiff should be placed in as good a position as they would have been had the defendant fulfilled the contractual obligation, including the reasonable foreseeability of the consequences within the contemplation of the parties at the time of concluding

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<sup>837</sup> Almas Shaikh, “Doctor-Patient Relationships: The Distinction Between Contractual and Tortious Liability,” *Academike*, February 2015, <https://www.lawctopus.com/academike/doctor-patient-relationships-the-distinction-between-contractual-and-tortious-liability/>.

<sup>838</sup> Roobesh S. Ramanjooloo and Pritesh Ramsaha, “Mooradally B. N. v Gunessee R. & Ors (2025 SCJ 62): Le Principe de Non-Cumul,” *DLA Piper Africa*, March 2025, <https://www.dlapiperafrica.com/en/rwanda/view.html?item=fbfa4b4c-089c-11f0-aa24-069fd42faff7>.

<sup>839</sup> Shaikh, “Doctor-Patient Relationships: The Distinction Between Contractual and Tortious Liability.”

their contract.<sup>840</sup> Therefore, it is essential for lawmakers in Rwanda to carefully consider the contractual nature of the doctor-patient relationship, as it differs significantly from ordinary commercial contracts.

#### 6.6.9. Medical liability under the Consumer Protection Act

The provision of healthcare services has increasingly become a business where healthcare services may be treated like consumer transactions, which are regulated to prohibit unfair or deceptive practices. In this consumer marketplace, healthcare is a business that sells services and sometimes products, including medical devices and medications. This highlights a potential need for assurance of consumer protection rights in the context of patient safety.<sup>841</sup> In India, for example, healthcare services have been included among the services covered under the Consumer Protection Acts.<sup>842,843</sup> In this light, medical practitioners and providers are considered suppliers who supply (healthcare) services and goods (pharmaceuticals and medical devices) to some extent.<sup>844</sup> Additionally, as in India, a consumer may be a patient, their representative, relatives, or any person who pays for the patient to receive services from a medical practitioner or provider;<sup>845</sup> Rwanda could also adopt this concept. Besides, consumers of healthcare services are individuals who seek or obtain medical care from providers who have a duty to deliver safe and effective treatment that will not cause iatrogenic injury or exacerbate diseases.

Healthcare service delivery, as an economic activity, falls within the scope of the Rwandan Competition and Consumer Protection Law (Rwandan Consumer Protection Act). This Act is set to apply “to any economic activity carried out or having an effect within Rwanda.”<sup>846</sup> It guarantees consumer protection rights with a primary focus on promoting good consumption.<sup>847</sup> Under this Act and the related laws and regulations, as well as the consumer protection policy, nine (9) consumer rights were reiterated, including the right to information, the right to access, the right to quality of service, the right to fairness, the right to complain, the right to safety and security, consumer education, privacy, and accurate bills.<sup>848</sup> Despite this framework, the work of entities with a mandate for consumer protection, such as RURA and RICA, and that of nongovernmental bodies, including ADECOR, continued to be unfocused in the respect of healthcare services.

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<sup>840</sup> Shaikh.

<sup>841</sup> Nishant Bhimraj Barapatre and Vishnu Prabhakar Joglekar, “The Rights of Patients as Consumers: An Ancient View,” *AYU, An International Quarterly Journal of Research in Ayurveda* 37, no. 3–4 (2018): 153, [https://doi.org/10.4103/ayu.AYU\\_216\\_15](https://doi.org/10.4103/ayu.AYU_216_15).

<sup>842</sup> Jyoti Dharm, “Medical Negligence Liability Under the Consumer Protection Act: A Judicial Approach,” *Bharati Law Review*, 2014, 12–15.

<sup>843</sup> Oishani Deb, “Medical Negligence and Consumer Protection Act,” *International Journal of Advanced Research* 12, no. 09 (2024): 1464–71, <https://doi.org/10.21474/IJAR01/19583>.

<sup>844</sup> Slabbert and Pepper, “The Consumer Protection Act : No-Fault Liability of Health Care Providers F Orum.”

<sup>845</sup> Pankaj Kukreja, Suhas S Godhi, and Patthi Basavaraj, “Consumer Protection Act and Medical Negligence-A Brief Insight,” *Journal of Indian Association of Public Health Dentistry* 2011, no. 17 (2011): 522–27, <http://www.jiaphd.org>.

<sup>846</sup> Article 3 of the Law N° 36/2012 of 21/09/2012 Relating to Competition and Consumer Protection (2012).

<sup>847</sup> *Ibid.*, Article 42.

<sup>848</sup> RURA, “Consumer Rights and Responsibilities” (Kigali, Rwanda), accessed October 24, 2022, [https://rura.rw/fileadmin/Documents/docs/Brochure\\_on\\_Consumer\\_s\\_right\\_and\\_responsibilities.pdf](https://rura.rw/fileadmin/Documents/docs/Brochure_on_Consumer_s_right_and_responsibilities.pdf).

Patients who believe a healthcare practitioner has harmed them may take action for damages resulting from a deficiency of services,<sup>849</sup> such as an unfair or misleading business practice, under consumer protection laws, rather than pursuing a claim for professional negligence. As in other business domains, failure to comply with consumer safety standards in healthcare invokes penalties for those healthcare-providing corporations.<sup>850</sup> According to Sahoo, “Consumer Protection Laws offer broader remedies than traditional malpractice claims, including treble damages, class actions, and injunctive relief”.<sup>851</sup> In the United States, a court can award damages, including treble damages, punitive damages, and an attorney’s fee under consumer protection laws.<sup>852</sup>

As discussed earlier, traditional medical malpractice cases involve several key elements, including the practitioner’s duty of care, breach of that duty, consequential harm, and causation. On the contrary, medical malpractice cases, in the context of consumer protection laws, are concerned with deceptive representations about services and unfair practices, such as misleading advertisements, billing, and unconscionable actions that exploit healthcare service users’ lack of knowledge to a grossly unfair degree.<sup>853</sup>

Unlike malpractice claims, which require the claimant to prove causation and actual damages, claims by aggrieved patients or their representatives under the layer of consumer protection laws may not require doing so.<sup>854</sup> In Rwanda, the present research has not identified any case law addressing unsafe or unfair healthcare practices or the delivery of substandard or falsified medicine or medical devices through the lens of consumer protection laws.

The current Rwandan healthcare law shifted the terminology from “patient” to “healthcare service user,” which at least places the latter in the scope of a definition of a consumer under the Rwandan Consumer Protection Act. A consumer is defined as “a person who purchases or acquires a commodity or a service for personal or family use for non-commercial purposes”.<sup>855</sup> Indeed, a healthcare service user is considered a person who acquires healthcare services for personal use, not for commercial purposes. As ascertained by Bhartiya and Sisodia, free medical services would

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<sup>849</sup> Kukreja, Godhi, and Basavaraj, “Consumer Protection Act and Medical Negligence-A Brief Insight.”

<sup>850</sup> Henny Saida Flora, “Legal Protection on Victim of Medical Malpractice,” *International Journal of Business, Economics and Law* 13, no. 4 (2017): 6–8.

<sup>851</sup> Sahoo, “Medical Negligence and Liability and under the Consumer Protection Act.”

<sup>852</sup> Eric J. Neiman, Eric Werner, and Epstein Becker, “Distinguishing Deceptive Trade Practices From Negligent Care: Exploring the Boundaries Between Consumer Protection and Medical Malpractice Claims,” *National Law Review* XV, no. 338 (2025): 1–3, <https://natlawreview.com/article/distinguishing-deceptive-trade-practices-negligent-care-exploring-boundaries>.

<sup>853</sup> Neiman, Werner, and Becker.

<sup>854</sup> Eric J. Neiman and Eric Werner, “Navigating the Legal Risks of Consumer Protection Claims in Healthcare,” *Health Law Advisor*, June 12, 2025, <https://www.healthlawadvisor.com/navigating-the-legal-risks-of-consumer-protection-claims-in-healthcare>.

<sup>855</sup> Article 2 para 11 of the Law N° 36/2012 of 21/09/2012 Relating to Competition and Consumer Protection (2012).

not fall into this realm.<sup>856</sup> All these aspects remain unclear, which necessitates legal clarity on this matter, either through regulations or a judicial decision.

On one hand, one may wonder whether bringing the case to the court under the layer of the Consumer Protection Act will not be considered a “frivolous case” in Rwanda because judges are not familiar with this approach, which may raise the reluctance or narrow their interpretation on the basic terminologies such as “consumer” and “market” due to lack of guidance and required knowledge in the matter. However, this may be an opportunity to include healthcare services and pharmaceuticals within the scope of goods and services under consumer protection laws, on the other hand. Nevertheless, the mere fact that healthcare services are increasingly becoming businesses like any other commercial services is not enough without the underpinning legal framework. If fair competition and consumer protection is the prerequisite to sustain economic growth of Rwanda as articulated by Usanase,<sup>857</sup> healthcare services should be included among the protected components of the Rwanda’s consumer protection laws and policy. This will contribute to the enhancement of patient rights and safety and thereby reduce medical malpractice incidents.

#### *6.6.9.1. Strict liability for failure to warn and failure to counsel*

In the context of drug-related liability issues, the layman’s understanding may lead to a belief that a pharmacist is the one to bear the consequences. However, they are not strictly liable for dispensing pharmaceuticals unless they dispense the wrong medication or fail to identify clear prescription errors. Nevertheless, they could be liable for mass drug injuries or off-label marketing practices in some jurisdictions. Furthermore, the failure to warn about known or foreseeable risks can be a reasonable ground for liability for pharmaceutical manufacturers, even if the drug was manufactured correctly and appropriately prescribed.<sup>858,859</sup>

Product liability for healthcare providers could be based on harm caused by the products they offered under three dimensions: manufacturing defects, design defects, and inadequate warning or instruction defects. Under this spectrum, a consumer who is harmed by the product seeks damages from the manufacturer, distributor, seller, or importer of the product.<sup>860</sup> For example, in *Tukakira et al. v. Hôpital La Croix du Sud et. al.*, the High Court of Rwanda stated that in the event of defective imported medicine, the legal liability rests with the licensed pharmacy importer.<sup>861</sup>

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<sup>856</sup> Vaibhav Goel Bhartiya and Ana Sisodia, “Medical Professionals Under Consumer Protection Act, 2019 - An Analysis,” *Journal of Anatomical Sciences* 28, no. 2 (2021): 119–25, <https://doi.org/https://doi.org/10.46351/jas.v28i2pp119-125>.

<sup>857</sup> Usanase Aimée, “Institutional Framework of Consumer Protection in Rwanda” (University of Rwanda, 2014), p. 65.

<sup>858</sup> Adrienne M. Grover, “CACI No. 1205. Strict Liability - Failure to Warn - Essential Factual Elements,” in *Judicial Council of California Civil Jury Instructions*, Series 100 (California: LexisNexis Matthew Bender, 2024), 750–56, Judicial Council of California Civil Jury Instructions.

<sup>859</sup> Precedentix Team, “Understanding Liability for Failure to Warn Clients in Legal Practice,” Precedentix, November 2024, <https://precedentix.com/liability-for-failure-to-warn-clients/>.

<sup>860</sup> Deb, “Medical Negligence and Consumer Protection Act.”

<sup>861</sup> *Tukakira et al. v. Hôpital La Croix du Sud et. al.*, RCA00321/2016/HC/KIG, RCA00320/2016/HC/KIG, RCA00322/2016/HC/KIG, RCA00336/2016/HC/KIG.

Davis J. Mary asserts that the drug-related adverse events or pharmaceutical injuries are not mainly resulting from the practitioners' medical administration, but rather the use of the pharmaceutical products. Consequently, she advocates for strict liability for pharmacists, similar to other scholars, such as Tanya, who advocate for recognising the patient-pharmacist relationship, which imposes a duty to warn and counsel pharmacists.<sup>862</sup> For the sake of the victims' remedy, Davis adds on that injuries arising from the inherent risks of an FDA-approved pharmaceutical must be compensable, regardless of the FDA's finding that the product is safe and effective if used as prescribed.<sup>863</sup>

While pharmaceutical manufacturers may be held liable for drug defects in design, manufacturing, or labeling, this liability may also extend to a medical practitioner who fails to prescribe an appropriate medication or who does so without informing the healthcare service user of the associated risk information.<sup>864</sup> Davis puts it in these words "Physicians are expected to prescribe the proper medicine for a patient's needs given knowledge about the patient and knowledge about the risk profile of the alternative pharmaceutical choices for treatment."<sup>865</sup> This liability is based on the "learned intermediary doctrine," which considers a medical practitioner a "learned intermediary" who has specialised knowledge and is in a position to understand the risks of a drug or device, balance the benefits with the dangers for individual patients, and warn the patient.<sup>866,867</sup>

Exploring liability under the layer of consumer protection law promotes safety in healthcare service delivery, particularly in light of growing consumer expectations and technological advancements in healthcare settings. Nolte et al. emphasise that this trend is against the backdrop of increasing financial constraints. This also highlights an increasing need for the efficient use of economic resources.<sup>868</sup>

## 6.7.Recoverable damages in medical malpractice cases

### 6.7.1. Pecuniary damages

In medical malpractice, pecuniary liabilities (economic damages) refer to tangible, quantifiable financial losses incurred by a healthcare user due to medical malpractice. The court can grant damages for both *damnum emergens* (direct loss) and *lucrum cessans* (prospective loss) if the plaintiff provides supporting documents and expert testimony.

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<sup>862</sup> Tanya E Karwaki, This Article, and This Article, "Establishing A Patient-Pharmacist Relationship: Clarifying Duties and Improving Patient Care," *Baylor Law Review* 72, no. 3 (2021): 509–63, [https://law.baylor.edu/sites/g/files/ecbvkj1546/files/2023-11/8\\_Karwaki.pdf](https://law.baylor.edu/sites/g/files/ecbvkj1546/files/2023-11/8_Karwaki.pdf).

<sup>863</sup> Davis, "Time for a Fresh Look at Strict Liability for Pharmaceuticals," p. 442-443.

<sup>864</sup> Davis, "Time for a Fresh Look at Strict Liability for Pharmaceuticals," p. 432-433.

<sup>865</sup> Davis, "Time for a Fresh Look at Strict Liability for Pharmaceuticals,," p. 431.

<sup>866</sup> Keri L Arnold and Sarah C Duncan, "The Learned Intermediary Doctrine: A Historical Review," *Product Liability Law360* (New York, October 16, 2014), <https://www.law360.com/articles/587180/the-learned-intermediary-doctrine-a-historical-review>.

<sup>867</sup> Jennefer Girod, "The Learned Intermediary Doctrine: An Efficient Protection for Patients, Past and Present," *Indiana Law Review* 40, no. 2 (2007): 397–422.

<sup>868</sup> Ellen Nolte, Sherry Mercur, and Andrew Anell, eds., *Achieving Person-Centred Health Systems: Evidence, Strategies and Challenges* (UK: Cambridge University Press, 2020), <https://doi.org/http://doi.org/10.1017/9781108855464>.

The damages for *damnum emergens* are a concept originating from Roman Law, meaning actual or direct loss suffered. The concept remained influential in modern civil law jurisdictions such as Italy, France, and Rwanda. In the common law tradition, they are categorised into special damages and consequential damages, which refer to direct loss and lost profits, respectively. *Damnum emergens* encompasses lost income, such as wages lost during the recovery period, as well as lost earnings due to partial or total incapacity, and out-of-pocket expenses, including transportation and medical bills. These damages could also include litigation fees and property damage. The calculation of these damages is objective and requires the production of evidence, such as receipts and pay stubs.

Besides, other losses could be determined based on the actual situation of the victim. These may include both the loss of future benefits and future expenses that would not have been incurred had the medical malpractice not occurred. These are known as *lucrum cessans* and may include future costs for medical treatment, surgery, rehabilitation, medication, and assistive medical devices. Unlike the determination of damages for *danum emergens*, establishing and computing *lucrum cessans* is a complex process that requires actuarial projections, contracts, market data, and expert testimony.

#### 6.7.2. Non-pecuniary damages

Some medical treatments and procedures can cause various physical and psychological harm to patients, also known as “biological or psychological prejudices”. These physical or emotional harms reduce the human capacity to fully enjoy the right to life as they jeopardise human integrity and dignity. For instance, phantom limb pain—traumatic postamputation pain—occurs after unnecessary amputation of a leg or because of clinical error. If not well rehabilitated, this harm can interfere with the victim’s psychosocial life.<sup>869</sup> If this bodily or mental pain and anguish were avoidable, an injured party could take action against the health provider seeking non-pecuniary damages.

Non-pecuniary or emotional damages encompass intangible harm, including pain and emotional suffering. They relate to subjective, non-monetary harm that cannot be precisely measured, although it has a significant impact on the victim’s quality of life. These damages include pain and suffering from both physical discomfort and emotional distress resulting from malpractice. They also entail loss of enjoyment of life, such as the inability to participate in hobbies, social activities, or daily routines.

Additionally, emotional distress resulting from the injury and loss of consortium also falls in this category. For example, in *Nyirabatesi Laurence v. King Faisal Hospital*, the Court of Appeal granted both pecuniary and non-pecuniary or emotional damages in 2019. The Court granted emotional damages for non-monetary harm after finding that Ms. Nyirabatesi suffered permanent

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<sup>869</sup> W T Oosthuizen and P A Carstens, “Medical Malpractice: The Extent, Consequences and Causes of the Problem,” *Tydskrif Vir Hedendaagse Romeins-Hollandse Reg* 2013, no. 103 (2015): 271–72, <http://ssrn.com/abstract=2693960>.

reproductive damage, social dispossession, and breakdown of her marriage and marital relationship. These health conditions followed a vesico-vaginal fistula (VVF) and other serious health complications associated with King Faisal Hospital’s negligence while performing a C-section.

While pecuniary damages aim to restore financial stability and could be calculated objectively, non-pecuniary damages acknowledge the human cost of medical harm. They are subjectively calculated based on expert testimony, psychological evaluations, and the severity of injury. Both types of damage are central to the delivery of justice to the victim of medical malpractice and ensure accountability in medical practice. To fully compensate the victim, the courts usually award both types of damages.

## 6.8. Comparative approaches on civil damages

Despite the above considerations on pecuniary and non-pecuniary damages, courts may vary in their awarding of them across different jurisdictions. Like in Rwanda, courts in all jurisdictions of France, Hungary, South Africa, and Canada recognise both pecuniary damages and non-pecuniary damages. However, their extent of application, level of inclusivity, and standards of evidence present notable differences. While damages for medical malpractice in Rwanda have been discussed in previous discussions, this section delves into those jurisdictions.

### 6.8.1. France

In France, there is a liberal approach that allows courts to compensate any harm suffered without limitation, known as “tout préjudice doit être réparé” in French.<sup>870</sup> This compensation was initially based on Article 1382 of the 1804 French Civil Code, which was later revised to Article 1240 in 2016. Pecuniary damages, whether based on contractual liability or tort liability, are determined based on the monetary and quantifiable loss suffered and profits deprived as a result of a wrongful event. In the context of medical liability, pecuniary damages encompass direct financial losses, including hospital bills and the loss of income or profits, such as salary and earnings.<sup>871,872</sup> They also encompass future economic losses (*lucrum cessans*), such as long-term care costs, and consequential harm. In personal injury cases such as medical malpractice, the court can award pecuniary damages for both the past and future losses.

The consequential loss is a “second degree” injury and considered an indirect economic loss resulting from a harmful event. Although the word “consequential” is not originally French,

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<sup>870</sup> Jean-Sebastien Borghetti, “Non-Pecuniary Damages in France,” *The Chinese Journal of Comparative Law* 3, no. 2 (2015): 268–88, <https://doi.org/10.1093/cjcl/cxv012>.

<sup>871</sup> Louise Sura, “Damages in Arbitration – A Perspective from France,” *Daily Jus*, June 20, 2025, <https://dailyjus.com/world/2025/06/damages-in-arbitration-series-a-perspective-from-france>.

<sup>872</sup> Aurore-Emmanuelle Rubio, “CMS Guide to Consequential Loss in France,” CMS, September 1, 2025, <https://cms.law/en/int/expert-guides/cms-guide-to-consequential-loss-clauses-in-the-energy-sector/france#:~:text=First%2C a purely legal definition,the damage — direct or indirect>.

“consequential loss” is applied in energy contracts to denote a distinct meaning from direct loss, which is the loss that arises from the actual course of events. Consequential loss is a direct consequence of the harmful event, although not immediately linked to the first causal event.<sup>873</sup> Thus, it represents intangible harm, a necessary consequence of the initial, immediate harm. An example of consequential loss might be a loss of profit resulting from the supplier’s failure to deliver items, or a faulty machine in a factory, which led to lost sales. Unless this is explicitly defined as recoverable damage in the contract, the court may consider it consequential. On a contractual basis, French courts can award consequential damages, including lost profits (*lucrum cessans*), under Article 1231-2 of the Civil Code. These consequential damages also extend to loss of business opportunity, reputational harm, and loss of use.

Non-pecuniary damage reveals a wide range of harms, including pain and suffering (*pretium doloris*) or loss of life enjoyment, and the stand-alone harm (*préjudice moral pur*) such as infringement of personality rights, honor, dignity, or emotional integrity. Additionally, the French Civil Code enables compensation for grief and suffering resulting from the loss of a relative or an animal, loss of enjoyment of nature, reputational damage, violation of personal dignity and privacy, anxiety or fear for exposure to a risk,<sup>874</sup> and wrongful birth and wrongful life.<sup>875</sup> This framework extends to harm related to non-pecuniary interests of juridical persons, such as goodwill and intellectual property.<sup>876</sup> The latter originates from the framework of the European Court of Human Rights (ECHR) and the Court of Justice of the European Union (CJEU).<sup>877</sup>

Non-pecuniary damages could be compensated either in damages or in kind, depending on the judge’s discretion. However, the practicability of “in kind” compensation kept being a subject for debate due to various issues. For example, since compensation in kind involves allocating a substitute, one can consider what could constitute a suitable substitute in the event of a loss, such as the death of a relative or wrongful birth. Another issue is whether the substitute could be morally acceptable or legally recoverable from the tortfeasor.<sup>878</sup>

In France, the claimant can seek damages for stand-alone harm (*préjudice moral pur*), which are “pure” non-pecuniary damages without accompanying pecuniary loss. Although the claimants do not prove pecuniary damages associated with the harm suffered, courts can award damages for emotional distress, loss of enjoyment of life, reputational harm, and violation of dignity.<sup>879</sup> In the context of medical liability, the French medical liability system allows courts to compensate

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<sup>873</sup> Rubio.

<sup>874</sup> Stéphanie Porchy-simon, “Revue Générale de Droit L ’ Indemnisation Des Préjudices d ’ Angoisse En Droit Français,” *General Law Review* 50, no. 2 (2025): 407–22.

<sup>875</sup> *Ibid.*, p. 278

<sup>876</sup> *Ibid.*

<sup>877</sup> Researcher Ondřej Pavelek, “Compensation for Non-Material Damage Caused to Legal Entities in the Decision-Making Practice of the CJEU and the ECHR,” *Juridical Tribune* 13, no. 3 (2023): 331–45, <https://doi.org/10.24818/TBJ/2023/13/3.01>.

<sup>878</sup> *Ibid.*, p. 281.

<sup>879</sup> Borghetti, *Non-Pecuniary Damages in France*, p. 275-76.

healthcare users and relatives for emotional and dignity harms. These may include patients suffering from non-pecuniary harm, without requiring proof of financial loss, and can compensate them as standalone damages.<sup>880</sup> These could entail the violation of patient dignity and privacy, anxiety harm (préjudice d'anxiété),<sup>881,882</sup> loss of enjoyment of life (préjudice d'agrément), and moral harm to relatives (préjudice moral des proches). For example, in the *Perruche Case*, the Court of Cassation recognized the right to claim moral damages for being born with disabilities resulting from the medical negligence in prenatal diagnosis in 2000.<sup>883</sup> The Court awarded moral damages for moral suffering and loss of life opportunities, standing alone from financial harm.

French Law recognizes moral damages (préjudice moral) known as “préjudice d'impréparation” resulting from the lack of preparation in clinical practice. This type of remedy aims to compensate for the moral distress related to the victims' suffering, acknowledging that they were not given a chance to prepare for the risks that occurred while they were not informed.<sup>884</sup> This presumption of damage recalls the patients' fundamental rights to patient autonomy, protection, and dignity, as well as the obligation of healthcare practitioners to provide accurate and timely information to their patients. This form of remedy, however, raises some challenges in its assessment and place vis-à-vis other existing damages such as loss of opportunity.<sup>885</sup>

It is worth noting that the French court system is divided into two branches, all of which are capable of handling medical malpractice claims. The first branch is composed of judicial courts, which deal with civil jurisdictions that involve independent practitioners, private hospitals, and other healthcare institutions, as well as their insurers.<sup>886</sup> Additionally, judicial courts can also handle criminal cases involving medical accidents. The second one is the administrative branch, which entails administrative jurisdictions that address the state or its bodies in the event of a medical accident or malpractice occurring in a public hospital or healthcare institution. Each of these courts has its highest court: Cour de cassation for judicial courts and *Conseil d'État* for administrative courts. This structure may contribute to pluralism in the interpretation of laws.<sup>887</sup>

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<sup>880</sup> Vincent Rivollier, “Medical Compensation under French Law : Fault , No-Fault , and the Point of Liability,” *Otago Law Review* 16, no. 1 (2017): 179–98, <https://www.austlii.edu.au/nz/journals/OtaLawRw/2019/10.pdf>.

<sup>881</sup> Olivia Dufresnes, “Compensation for Anxiety-Related Harm: Legal Developments and Perspectives,” *Juridique Actualité*, July 10, 2025, <https://www.debeugny-cortier-avocats.fr/lindemnisation-du-prejudice-danxiete-evolutions-juridiques-et-perspectives/>.

<sup>882</sup> Porchy-simon, “Revue Générale de Droit L ’ Indemnisation Des Préjudices d ’ Angoisse En Droit Français.”

<sup>883</sup> Brigitte Feuillet-Le Mintier, “The Perruche Case and French Medical Liability,” *Drexel Law Review* 4, no. 1 (2011): 139–49, <http://shs.hal.science/halshs-00668141v1>.

<sup>884</sup> Olivier Gout, “Le Préjudice d ’ Impréparation En Matière Médicale,” *Revue Générale de Droit* 50, no. 2 (2020): 363–71, <https://doi.org/https://doi.org/10.7202/1074599ar>.

<sup>885</sup> *Ibid.*

<sup>886</sup> Rivollier, “Medical Compensation under French Law : Fault , No-Fault , and the Point of Liability,” p. 181.

<sup>887</sup> *Ibid.*

### 6.8.2. Hungary

In Hungary, compensation for personal injury and other harms is fault-based, with strict liability in some circumstances, and is founded on tort law, as governed by the Hungarian Civil Code (Act V of 2013). In this regard, the medical liability system is primarily fault-based. Similar to other jurisdictions, such as Rwanda, the Hungarian tort liability system considers four key elements to determine liability: unlawful conduct, fault, a causal link between the unlawful conduct and the fault, and the resulting harm.<sup>888</sup> Apart from tort liability, courts can also apply contractual liability based on the doctor–patient relationship.<sup>889</sup>

The Hungarian civil liability system recognises both pecuniary and non-pecuniary damages, known as “*vagyoni kár*” and “*nemvagyoni kár*” in Hungarian, which the Hungarian courts can award under the general rules of civil law.<sup>890</sup> Like France and Rwanda, pecuniary damages under the Hungarian liability system include actual monetary losses suffered by the aggrieved party due to negligence or medical malpractice. As highlighted earlier, these damages include financial losses such as medical bills and lost income.

Before the new era introduced by the 2013 Civil Code, some Hungarian courts used to award compensation for non-pecuniary losses, such as violations of the right to privacy, without necessarily proving actual harm or losses, and at the judge’s discretion. This led to a lack of harmonization among courts regarding the extent of compensable non-pecuniary losses.<sup>891</sup> With the new Code, non-pecuniary damages have been replaced by restitution, which allows any person whose rights relating to personality have been infringed to claim damages resulting from the non-material violation suffered.<sup>892</sup> The subsequent provision permits the harmed party to sue for non-pecuniary damages under the provisions of liability for damages resulting from unlawful actions.<sup>893</sup>

The Szeged and Pécs Regional Court of Appeal has developed an approach that considers awarding non-pecuniary damages for the loss of the chance of recovery to the patient resulting from the practitioner’s violation of the patient’s personal autonomy, as well as for pain and suffering (*solatium doloris*).<sup>894</sup> Additionally, in case of the death of the patient due to medical malpractice, the dependents of the *decujus* can petition for loss of maintenance. However, according to the Hungarian Civil Code,<sup>895</sup> the fault or involvement of the victim or aggrieved

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<sup>888</sup> Barzó, “Medical Liability in the Light of New Hungarian Civil Code,” p. 210-212.

<sup>889</sup> Barzó.

<sup>890</sup> Flóra Krisztina Józán, “Considerations about Medical Malpractice,” *JURA* 2 (2017): 327–30, <https://szakcikkadatbazis.hu/doc/2634080>.

<sup>891</sup> *Ibid.*, p. 113.

<sup>892</sup> “Section 2:52 of the Act No V of 2013 on the Civil Code of the Hungarian Republic” (2013).

<sup>893</sup> *Ibid.*, Section 2:53.

<sup>894</sup> Ádám Fuglinszky, “Risks and Side Effects: Five Questions on the ‘New’ Hungarian Tort Law,” *ELTE Law Journal*, no. 2 (2014): 213-214.

<sup>895</sup> “Sections 6:529, paragraph 1 and 6:525 paragraph 1 of the Act No V of 2013 on the Civil Code of the Hungarian Republic” (2013).

party in the causal chain is considered if it can be assessed, and damages will be granted in proportion to the degree of that fault. If it cannot be evaluated, the tortfeasor and the victim will equally bear the damage. The determination of non-pecuniary damages depends on the discretion of the judge.

The ascertainment of personal injury heavily relies on reports from medical and forensic experts with specialised training.<sup>896</sup> This expert-led methodology enables courts to evaluate the nature of the injury, its severity, its temporary and permanent consequences, and causation, informing the quantification of damages in practice.<sup>897</sup> However, the literature indicates that the ambiguity in clinical injury reports' terminologies may complicate those assessments.<sup>898</sup>

In Hungary, the liability system is strictly restorative and does not recognise symbolic awards such as punitive, restitutionary, and nominal damages.<sup>899</sup> In medical malpractice cases, the courts award pecuniary and non-pecuniary damages for harm suffered based predominantly on vicarious liability. These include measurable financial harm, encompassing both direct and prospective losses, rather than damages in kind.<sup>900</sup> However, it is worth noting that settlement of medical malpractice claims does not always require court litigation.

### 6.8.3. South Africa

In South Africa, courts apply the fault-based liability under common law principles. Additionally, various Acts underpin the liability system. For individuals such as medical practitioners or private healthcare providers, the 1957 State Liability Act (Section 1) applies, as it enables the aggrieved party to claim damages caused by another party, regardless of whether a contract exists between them.<sup>901</sup> For public entities and the State, common law principles, supported by legal precedents, establish vicarious liability for public institutions in cases where the loss or harm suffered by the victim arises from the misconduct of a public sector official, and when a claim is made against the state. Additionally, the 1999 Public Finance Management Act (Section 76(1)(h)) requires the National Treasury to formulate regulations or issue instructions for departments regarding the settlement of claims by or against the state. Apart from the legislation, South Africa has no particular legislation to address medical claims.<sup>902</sup>

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<sup>896</sup> Eva Keller et al., "Methods of Ascertainment of Personal Damage in Hungary," in *Personal Injury and Damage Ascertainment under Civil Law*, ed. Santo Davide Ferrara, Rafael Boscolo-Berto, and Guido Viel (Springer, 2016), 209–36, [https://doi.org/https://doi.org/10.1007/978-3-319-29812-2\\_13](https://doi.org/https://doi.org/10.1007/978-3-319-29812-2_13).

<sup>897</sup> Keller et al.

<sup>898</sup> Katalin Fogarasi et al., "Terminological Ambiguities in Clinical Injury Reports and Their Impact on Forensic Assessment: A Multidisciplinary, Retrospective, Corpus-Based Study in Hungary," *Forensic Sciences* 5, no. 3 (2025): 1–16, <https://doi.org/10.3390/forensicsci5030046>.

<sup>899</sup> Attila Menyhárd, "Punitive Damages in Hungary," in *Punitive Damages: Common Law and Civil Law Perspectives* (Vienna: Springer, 2009), 87–102, [https://doi.org/10.1007/978-3-211-92211-8\\_5](https://doi.org/10.1007/978-3-211-92211-8_5).

<sup>900</sup> Barzó, "Medical Liability in the Light of New Hungarian Civil Code."

<sup>901</sup> Gregory Whittaker, "Medical Malpractice in the South African Public Sector Medical," *Actuarial Society of South Africa* (Cape Town, April 30, 2021), p. 9.

<sup>902</sup> Ibid.

Courts can award both pecuniary and non-pecuniary damages based on fault (*culpa*) under tort law. Similar to other jurisdictions discussed above, the plaintiff must prove negligence (*culpa*), causation, and the harm suffered.<sup>903</sup> The practitioner's negligence or malpractice is assessed in reference to the "reasonable expert in the same circumstances." Thus, negligence could be determined if the defendant failed to foresee the likelihood of an injury in situations where a reasonable person (*diligens pater familias*) in the same circumstances would have foreseen it and would have taken measures to prevent its occurrence. Holmes JA established this negligence test in the 1966 case of *Kruger v Coetzee*. In medical malpractice cases, the test adapts to the standard of care of a reasonable medical practitioner in comparable situations to the defendant.<sup>904</sup>

The South African Courts can also grant other damages, such as those resulting from infringements of the constitutional rights of others and psychiatric injury or emotional shock.<sup>905</sup> Although there is no precedent regarding compensation for the infringement of others' constitutional rights in medical litigations, this type of damages has been awarded on several occasions by the South African Constitutional Court and the Supreme Court of Appeal for the infringement of the right to access courts and the right to social assistance, respectively. Furthermore, the Supreme Court of Appeal has recognised the principle of awarding damages for psychiatric injury since 1972, as seen in *Bester v Commercial Union Versekeringsmaatskappy van SA Bpk*. The court can grant these damages based on the suffering resulting from harm caused to another person. Although the assessments of negligence in cases related to psychiatric shock vary court by court, they have, in most cases, recognised and granted damages in cases involving death or a serious negligent act against their relatives or children.<sup>906</sup>

The South African Court can also award compensation in kind, in the form of delivering healthcare services in a public health institution, to a plaintiff whose claim against negligence against a provincial Department of Health (DOH) is successful.<sup>907</sup>

It should be noted that the South African liability system applies a common law principle of "once and for all" in awarding damages for medical malpractice.<sup>908</sup> That means the aggrieved party must seek complete and satisfactory compensation for both the actual loss suffered and the prospective loss in a single claim. For prospective losses, the court applies contingency deductions to account for uncertainties in the plaintiff's future circumstances. In all medical malpractice litigations, courts award compensation considering proportionality and fairness.

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<sup>903</sup> South African Law Reform Commission, "South African Legal Landscape," in *Discussion Paper 154 – Project 141: Medico-Legal Claims* (South African Law Reform Commission (SALRC), 2021), 34–35, <https://www.justice.gov.za/salrc/dpapers/dp154-prj141-Medico-Legal-Claims.pdf>.

<sup>904</sup> *Ibid.*

<sup>905</sup> *Ibid.*, p. 58-59.

<sup>906</sup> *Ibid.*, p. 59-64.

<sup>907</sup> *Ibid.*, p. 64.

<sup>908</sup> *Ibid.*, p. 38.

Hence, an injured person who has been awarded damages may, within 60 days after the date on which the award was made, renounce the award in writing. If not, the person will not be allowed to file any further claim for damages against the accused in respect of the injury for which the award was made.<sup>909</sup>

#### 6.8.4. Canada

The Canadian liability system is fault-based and underpinned by tort law. Medical malpractice claims are governed by procedural rules and regulations in every province. Apart from the criminal process, these cases are primarily addressed under the civil liability system through tort or contractual baseline. Additionally, healthcare institutions are held liable for the actions of their employed practitioners that resulted in tort cases, under the doctrine of vicarious liability.<sup>910</sup> The prescription period for a medical malpractice claim in Canada is two years running from the time the plaintiff knew or ought to have known of the occurrence of fault.

If the victim of medical malpractice proves a breach of the standard of care, causation, and harm, the court can award pecuniary damages and non-pecuniary damages. To successfully prove the deviation from the standard of care, expert reports are mandatory. The standard of care in Canada is based on the Supreme Court decision in the 1956 case of *Crits v. Sylveste*, which outlined the reasonable standard of care owed by a medical practitioner. The courts have consistently reiterated the importance of ensuring the reasonableness of healthcare practitioners in applying their knowledge and skills when delivering healthcare services.<sup>911</sup>

Nevertheless, the Canadian medical liability system poses significant challenges for victims of medical malpractice incidents. They must find lawyers for legal representation who are, in most cases, unaffordable to many, while physicians are defended by the Canadian Medical Protective Association (MPA).<sup>912</sup> The burden of proving the practitioner's failure to meet the standards of care and that such a failure caused the harm suffered is placed on the claimant. To understand the situation, it is estimated that the number of injured patients who receive compensation is below 0.3 percent.<sup>913</sup>

In every province and territory, there are Colleges of Physicians and Surgeons that require all practicing physicians to possess insurance for medical malpractice liability coverage.<sup>914</sup> This approach aims to ensure equitable compensation for injured patients and to protect practitioners.

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<sup>909</sup> See Criminal Procedure Act 51 of 1977, s. 300(5)(a) and (b)).

<sup>910</sup> Whittaker, "Medical Malpractice in the South African Public Sector Medical," p. 89.

<sup>911</sup> Jennifer Lamb and Urvil Thakor, "Medical Malpractice Law in Canada," Carscallen, 2021, <https://carscallen.com/blog/insurance-and-tort-liability/medical-malpractice-law-in-canada/>.

<sup>912</sup> Shoo K. Lee et al., "Canada's System of Liability Coverage in the Event of Medical Harm: Is It Time for No-Fault Reform?," *Healthcare Policy* 17, no. 1 (2021): 30–41, <https://doi.org/10.12927/hcpol.2021.26580> Discussion and Debate.

<sup>913</sup> Lee et al.

<sup>914</sup> Whittaker, "Medical Malpractice in the South African Public Sector Medical," p. 89.

Under the Canadian medical liability system, courts can award damages for both pecuniary and non-pecuniary losses. Symbolic damages, such as punitive damages, could be awarded in exceptional cases. Damages can be awarded for both actual losses and prospective losses. For future losses, courts base their determinations on actuarial evidence for life-care plans and discount rates.

## 6.9. Remedial recourses and forums for healthcare users in Rwanda

The recognition of healthcare service users to take legal action against healthcare providers serves as a cornerstone of accountability within healthcare systems.<sup>915</sup> This legal mechanism empowers individuals to seek redress when they suffer harm resulting from medical services within a five-year time limit, particularly where healthcare providers have breached their duty of care.<sup>916</sup> The Rwandan healthcare law upholds the rights of healthcare users by providing two distinct mechanisms for seeking redress: the responsible bodies in the healthcare professional council, which deal with disciplinary faults by healthcare professionals, and the Committees responsible for dealing with disciplinary faults in healthcare facilities.<sup>917</sup> Those Committees, despite their prescribed function within the framework of professional medical liability, have not been operational until now. In their absence, the medical councils, the Ministry of Health, and judicial courts could fulfill this function.

The realisation of this mechanism involves a systematic evaluation of multiple interrelated factors. These include the legal foundation for the claim, the applicable standard of care, the existence and scope of the duty of care, the breach of that duty, the harm incurred by the healthcare service user, and the direct causal link between the breach and the harm.<sup>918</sup> Additionally, critical procedural elements such as statutory time limits for filing claims (prescription periods), potential compensation caps, and the availability of appropriate remedial forums are central to the enforcement of this right.<sup>919</sup>

### 6.9.1. Role of regulatory and professional bodies

In Rwanda, there are four professional health councils, including the RMDC, NCM, NPC, and RAHPC, which serve as regulatory bodies for the mandated categories of professions in the medical realm. They also serve as remedial recourses for healthcare service users in Rwanda, as they are forums for patients to formally report malpractice or the practitioners' misconduct through established complaint mechanisms. The councils can also suspend, revoke licenses, or impose disciplinary sanctions to ensure accountability in healthcare practice.

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<sup>915</sup> Watson and Kottenhagen, "Patients' Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe."

<sup>916</sup> Article 107 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>917</sup> Ibid., Article 106.

<sup>918</sup> Legal Clarity Team, "Can You Sue a Doctor for Malpractice? Here's What to Know - LegalClarity," 2025, <https://legalclarity.org/can-you-sue-a-doctor-for-malpractice-heres-what-to-know/?form=MG0AV3>.

<sup>919</sup> Watson and Kottenhagen, "Patients' Rights, Medical Error and Harmonisation of Compensation Mechanisms in Europe."

Additionally, although professional councils do not award damages to victims, they indirectly contribute to the compensation process by providing findings from malpractice investigations to strengthen both civil and criminal litigation. Additionally, these councils establish systemic safeguards by enhancing standards that reduce the recurrence of malpractice and improve patient safety. Thus, although these medical councils do not replace civil or criminal litigation mechanisms, they contribute to these proceedings.

### 6.9.2. Alternative compensation system

Many jurisdictions use various means to provide medical malpractice victims with justice through their legal systems. Some have established no-fault and alternative dispute resolution (ADR) procedures as alternatives, while others have implemented a no-fault system for compensating medical damages.<sup>920</sup> Alternative dispute resolution (ADR) has been developed to deal with administrative, civil, and commercial issues in many jurisdictions,<sup>921</sup> including Rwanda, by delivering restorative justice to the disputants. However, Rwanda's ADR system is not fully operational in matters of medical negligence and malpractice.

Contrary to the courts, ADR is a mechanism for resolving disputes involving parties' civil rights and obligations, which is recognised for being flexible, equitable, and efficient in terms of both time and money. The voluntariness of the disputants is, however, the foundation of this procedure. The applicability of ADR techniques may vary from one jurisdiction to another. The most well-known ADR techniques include arbitration, conciliation, mediation, and negotiation. The ADR paradigm may also include the ombudsman process and other complaint and dispute procedures. The Rwanda ADR mechanism is court-annexed mediation and can be used to resolve medical malpractice lawsuits. However, not all of the ADR model's techniques apply to cases of medical misconduct.

The ADR concept is rooted in the national history of community-based dispute resolution tactics in the Rwandan context. It explores Rwandan societal ideals introspectively. The ADR mechanism has recently been given priority in dispute resolution to reduce the backlog of court cases. The new ADR Policy suggests using arbitration (Ubukemurampaka), conciliation (Ubwunzi), or mediation (Ubuhuza) to substitute courts to resolve civil, commercial, and administrative matters.<sup>922</sup> The Judiciary of Rwanda indicated that the cases handled through mediation in 2022 amounted to Rwf 11 billion.<sup>923</sup> Several cases can be settled through court mediation. The latter is applied in two mechanisms: pretrial conference and judge-facilitated mediation.<sup>924</sup>

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<sup>920</sup> Daniel P. Kessler, Nicholas Summerton, and John R. Graham, "Effects of the Medical Liability System in Australia, the UK, and the USA," *Lancet* 368, no. 9531 (2006): 242–45, [https://doi.org/10.1016/S0140-6736\(06\)69045-4](https://doi.org/10.1016/S0140-6736(06)69045-4).

<sup>921</sup> Choctaw, *Avoiding Medical Malpractice: A Physician's Guide to the Law*, p. 30.

<sup>922</sup> "Alternative Dispute Resolution Policy" (Kigali, Rwanda, 2022), [www.minijust.gov.rw](http://www.minijust.gov.rw).

<sup>923</sup> Christine Nyiranshimiyimana, "Rwanda Launches Policy Boosting ADR Use," *International Institute for Conflict Prevention & Resolution (CPR)*, 2023, <https://www.cpradr.org/news/rwanda-launches-policy-boosting-adr-use#%23>.

<sup>924</sup> Supreme Court of Rwanda, "Performance of the Judiciary during the Year 2021-2022," 2022.

### 6.9.3. Courts

Courts have been the most judicial forums to deliver justice to the disputants. However, private dispute settlement mechanisms have been developed and enhanced in many jurisdictions to adjudicate civil matters in a timely and cost-effective manner. The court is an autopoietic entity.<sup>925</sup> The court applies the law with recognised principles depending on the judicial system. It can independently interpret the law and create precedents to which it will refer in future. However, it could identify the relevance of the works of eminent legal scholars. Ordinary civil courts can adjudicate medical negligence and malpractice cases with various approaches. Courts can try medical malpractice cases by applying tort law, contract law, or criminal law. In Rwanda, victims of medical negligence and malpractice still rely on civil law courts when filing their claims for medical liability.

Although courts are believed to deliver procedural justice, the proceedings take a long time. This raises concerns about dissatisfaction with the administration of justice, which is aptly framed in the famous phrase, “justice delayed is justice denied.”<sup>926</sup> However, courts are not the sole forum for handling medical negligence and malpractice cases.

### 6.10. Role of physician apology in the reparation process

In the context of medical liability, a physician's apology is a statement acknowledging and expressing regret for a medical error, its impact on the patient, and the harm it caused.<sup>927</sup> Physician apologies play a nuanced role in medical liability, especially in the context of apology laws.<sup>928</sup> They influence malpractice risk, patient relationships, and legal outcomes.<sup>929</sup> According to Ross and Newman, an apology is considered to have therapeutic potential for both the patient and the healthcare provider, and its absence is one of the reasons for pursuing a malpractice suit.<sup>930</sup>

When a hospital is required to take action against its personnel for negligence that resulted in malpractice, there may be a dilemma in the compensation process. This comes in two forms: attempts to cover up the malpractice that has occurred to avoid liability and shield its reputation. Indeed, acceptance could be an issue, particularly when health liability insurers are involved. Thus, once the hospital admits its role in the malpractice, the insurer is provided with a report and could pay in proportion to the existing agreements. However, there is always the assumption that such

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<sup>925</sup> Anthony Beck, “Is Law an Autopoietic System?,” *Oxford Journal of Legal Studies* 14, no. 3 (1994): 406–8, <https://doi.org/10.1093/ojls/14.3.401>.

<sup>926</sup> Editorial Advisory Board, “Justice Shouldn’t Be Delayed or Denied,” *The Daily Record* (Maryland, July 2025), <https://thedailyrecord.com/2025/07/29/justice-shouldnt-be-delayed-or-denied/#:~:text=delayed or denied-,Editorial Advisory Board/July 29%2C 2025//,to criminal and civil matters>.

<sup>927</sup> Jennifer K. Robbennolt, “Apologies and Medical Error,” *Clinical Orthopaedics and Related Research* 467, no. 2 (2009): 376–79, <https://doi.org/10.1007/s11999-008-0580-1>.

<sup>928</sup> Nina E. Ross and William J. Newman, “The Role of Apology Laws in Medical Malpractice,” *Journal of the American Academy of Psychiatry and the Law* 49, no. 3 (2021): 1–7, <https://doi.org/10.29158/JAAPL.200107-20>.

<sup>929</sup> Ian C. Fischer and Richard M. Frankel, “‘If Your Feelings Were Hurt, I’m Sorry...’: How Third-Year Medical Students Observe, Learn From, and Engage in Apologies,” *Journal of General Internal Medicine* 36, no. 5 (2021): 1352–58, <https://doi.org/10.1007/s11606-020-06263-6>.

<sup>930</sup> Ross and Newman, “The Role of Apology Laws in Medical Malpractice.”

acceptance could affect the hospital's reputation and finances, as the compensation amount could exceed the insurer's maximum payment limit.

On the one hand, the healthcare provider's acknowledgment and apology constitute another essential step in the victim's reparative process. On the other hand, healthcare providers fear that such recognition could be used as evidence in court, potentially preventing them from reaching an amicable agreement with the victim. To avoid those risks associated with litigation and payment, they choose to ignore and divert the absolute truth. This has a significant effect on the compensation process. Hiding the truth and attempting to shield medical personnel whose actions or behaviors led to an adverse outcome have far-reaching consequences. It victimizes the affected patients' families and undermines accountability in medical practice.

So, the dilemma is whether the healthcare provider admits fault or negligence and pays compensation, risking reputation damage, or denies responsibility by hiding the truth and shielding their staff, potentially avoiding payment or paying less at the cost of accountability and ethical practice.

## 6.11. Consequences of medical litigation

Medical malpractice has far-reaching consequences when it becomes the basis for litigation. Such a situation may have a series of effects whose victims may be either the patient, the medical practitioner, or a third party, such as the community and the healthcare system. The following part briefly discusses those effects.

### 6.11.1. Medical malpractice stress syndrome (MMSS)

Medical malpractice has resulted in a phenomenon known as the Medical Malpractice Stress Syndrome (MMSS).<sup>931</sup> This Syndrome refers to the mental anguish suffered by health care practitioners who have to deal with some form of legal liability.<sup>932</sup> MMSS will take the form of anxiety, depression, and a lack of professional confidence that can adversely affect medical judgment and patient care. MMSS has caused many healthcare practitioners to commit suicide in many jurisdictions, such as the United States, India, and the UK.<sup>933,934</sup> The MMSS exemplifies the stakes arising from medical liability and the need for equitable legal protections for medical practitioners, due process, and institutional support to minimize its effects on healthcare practitioners while ensuring accountability in healthcare systems.

Additionally, the adversarial litigation process has been noted to have effects on both litigants. In this regard, the psychological and emotional impacts of medical litigation not only affect medical

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<sup>931</sup> S. Sandy Sanbar, *The Medical Malpractice Survival* (Philadelphia: Elsevier, 2007), p. 9-16.

<sup>932</sup> Robert T. Muller, "Litigation Culture Causing Burnout in American Physicians," *Psychology Today*, December 2021, <https://www.psychologytoday.com/us/blog/talking-about-trauma/202112/litigation-culture-causing-burnout-in-american-physicians?form=MG0AV3&form=MG0AV3>.

<sup>933</sup> Muller.

<sup>934</sup> R Madan et al., "Consequences of Medical Negligence and Litigations on Health Care Providers – A Narrative Review," *Indian Journal of Psychiatry* 66, no. 4 (2024): 317–25, [https://doi.org/10.4103/indianjpsychiatry.indianjpsychiatry\\_799\\_23](https://doi.org/10.4103/indianjpsychiatry.indianjpsychiatry_799_23).

practitioners but also extend to the patient plaintiffs and their family members, as asserted by Tumelty.<sup>935</sup>

### 6.11.2. Defensive medicine

Besides, balancing the interests of patients and healthcare practitioners remains a critical concern in modern medical practice. This conflict is evident in defensive medicine (DM),<sup>936</sup> where physicians engage in care not primarily for patients' benefit but as a safeguard against potential legal liability.<sup>937,938</sup> Practitioners' concerns about medical litigation can lead to defensive medicine. Defensive medicine is the practice of healthcare professionals to minimise the risk of legal liability.<sup>939</sup> It manifests in two forms: negative defensive medicine, in which physicians refrain from offering high-risk treatments to avoid potential litigation, and positive defensive medicine, in which unnecessary medical interventions or diagnostic procedures are performed to protect against patients' or other health care users' legal claims.<sup>940</sup> Although no studies specifically address defensive medicine (DM) in Rwanda, the growing influence of medical liability and related factors encourages its practice. The literature indicates that DM is prevalent even in countries renowned for their advanced healthcare systems, such as the United States, the Netherlands, and Japan. It occurs at high rates across various medical specialities, reflecting the widespread influence of legal concerns on clinical decision-making.<sup>941</sup>

Defensive medicine helps protect healthcare providers from legal risks but can lead to inefficiencies in service delivery and ethical concerns in patient care.<sup>942</sup> Consequently, medically unnecessary interventions or omissions do not improve patient well-being, may undermine healthcare quality, and damage the healthcare reputation.<sup>943</sup> Indeed, unnecessary medical tests and procedures can waste human and financial resources.<sup>944</sup>

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<sup>935</sup> Mary Elizabeth Tumelty, "Exploring the Emotional Burdens and Impact of Medical Negligence Litigation on the Plaintiff and Medical Practitioner: Insights from Ireland," *Legal Studies* 41, no. 4 (2021): 633–56, <https://doi.org/10.1017/lst.2021.20>.

<sup>936</sup> Ivan Dieb Miziara and Carmen Silvia Molleis Galego Miziara, "Medical Errors, Medical Negligence and Defensive Medicine: A Narrative Review," *Clinics* 77, no. March (2022): 100053, <https://doi.org/10.1016/j.clinsp.2022.100053>.

<sup>937</sup> Johan Christiaan Bester, "Defensive Practice Is Indefensible: How Defensive Medicine Runs Counter to the Ethical and Professional Obligations of Clinicians," *Medicine, Health Care and Philosophy* 23, no. 3 (2020): 413–19, <https://doi.org/10.1007/s11019-020-09950-7>.

<sup>938</sup> Hanming Fang, Ming Li, and Jia Xiang, "Fear and Risk Perception: Understanding Physicians' Dynamic Responses to Malpractice Lawsuits" (Cambridge, 2025), p. 1-31.

<sup>939</sup> Raposo, "Defensive Medicine and the Imposition of a More Demanding Standard."

<sup>940</sup> Angelo Antoci, Alessandro Fiori Maccioni, and Paolo Russu, "The Ecology of Defensive Medicine and Malpractice Litigation," *PLoS ONE* 11, no. 3 (2016): 1–3, 11–13, <https://doi.org/10.1371/journal.pone.0150523>.

<sup>941</sup> Edris Kakemam et al., "The Occurrence, Types, Reasons, and Mitigation Strategies of Defensive Medicine among Physicians: A Scoping Review," *BMC Health Services Research* 22, no. 1 (2022): 1–11, <https://doi.org/10.1186/s12913-022-08194-w>.

<sup>942</sup> Eftekhari et al., "Exploring Defensive Medicine: Examples, Underlying and Contextual Factors, and Potential Strategies - a Qualitative Study."

<sup>943</sup> Eftekhari et al.

<sup>944</sup> Bester, "Defensive Practice Is Indefensible: How Defensive Medicine Runs Counter to the Ethical and Professional Obligations of Clinicians."

Defensive medicine arises from various factors, including patient expectations, physician concerns, organisational pressures, and broader societal influences.<sup>945</sup> To address these drivers, standard solutions may include structured training programs, strengthened physician-patient relationships, healthcare system reforms, and improvements to liability regulations.<sup>946,947</sup> In the Rwandan context, establishing a well-structured medical liability system within a comprehensive and inclusive legal and policy framework is essential for balancing accountability and ethical medical practices.

### 6.11.3. Malpractice-induced exit, career transition, and change in practice

Medical malpractice litigation has further consequences, including stress resulting from the financial costs of legal defense, settlements, or increased malpractice insurance premiums,<sup>948</sup> as well as uncertainty associated with potential future lawsuits.<sup>949</sup> Psychologically, the fear or pressure of medical malpractice litigation leads both medical providers and practitioners to likely reconsider their professional trajectories or opt for other career paths.

Medical litigation doesn't always terminate a professional's career, but it reshapes it. Some physicians may exit clinical practice, while others transition into new administrative, research roles, or change their approach to clinical practice to reduce risk.<sup>950,951</sup> Indeed, while not every lawsuit results in revocation of license, the reputational, financial, and psychological consequences of litigation often prompt physicians to reevaluate their priorities, leading to thoughtful changes in their careers and practices.

## 6.12. Conclusion

The analysis of Rwanda's medical liability system reflects a dynamic interplay between colonial legacies, contemporary legal reforms, and global best practices. It reveals that it is firmly anchored in a fault-based approach. While this liability model is known to promote accountability and deterrence, its reliance on adversarial litigation poses challenges of procedural complexity, high litigation costs, and limited accessibility for victims of medical malpractice. This necessitates the need for complementary mechanisms such as ADR and patient-centered approaches. In addition to the need for a robust structure of the newly introduced ADR mechanism, a hybrid model of compensation that encompasses both a fault-based system and a patient-centered approach, such

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<sup>945</sup> Kakemam et al., "The Occurrence, Types, Reasons, and Mitigation Strategies of Defensive Medicine among Physicians: A Scoping Review."

<sup>946</sup> Kakemam et al.

<sup>947</sup> Hazem Abbas, "Defensive Medicine: What It Is, Why It Happens, and How It Affects You as a Patient?," January 2025, <https://medevel.com/defensive-medicine-what-it-is/?form=MG0AV3>.

<sup>948</sup> Madan et al., "Consequences of Medical Negligence and Litigations on Health Care Providers – A Narrative Review."

<sup>949</sup> David A. Hyman et al., "Association of Past and Future Paid Medical Malpractice Claims," *JAMA Health Forum* 4, no. 2 (2023): E225436, <https://doi.org/10.1001/jamahealthforum.2022.5436>.

<sup>950</sup> Susan Fink Childs, "Handling Litigation — How to Live (Well) with a Lawsuit," *Physician Leadership Journal* 11, no. 6 (2024): 23–26, <https://doi.org/https://doi.org/10.55834/plj.3669960390>.

<sup>951</sup> D. M. Studdert et al., "Changes in Practice among Physicians with Malpractice Claims," *The New England Journal of Medicine* 380, no. 13 (2019): 1247–55, <https://doi.org/10.1056/NEJMSa1809981>.

as a no-fault system, would be essential to ensure fairness and efficiency in the compensation process.

Liability enforcement is multi-layered through a tripartite structure comprising professional councils, administrative bodies, and courts. However, harmonising these processes to ensure timely and equitable remedies for the victims has been a persistent challenge. The analysis indicates that adopting innovative strategies into healthcare regulations, such as well-structured compensation approaches, enhanced risk management, and integration of consumer protection principles, is essential to strike a balance between professional accountability and ethical healthcare service delivery. Furthermore, it is crucial to embed liability within a broader framework of corporate responsibility and human rights obligations, thereby reinforcing the constitutional guarantees of life, health, and dignity.

Therefore, in line with Rwanda's efforts to achieve universal healthcare coverage, quality care, and shift to medical tourism, reforms are necessary in the adjudication structure of medical claims, enhancement of institutional capacity, and promotion of proactive risk management, to strengthen its liability system. This will not only curb malpractice incidents but also reinforce public trust, transparency, and adherence to ethical and legal standards in healthcare delivery.

## CHAPTER SEVEN

### INFORMED CONSENT AND RELATED LEGAL ACCOUNTABILITY

This chapter provides a comprehensive overview of informed consent in medical practice and its associated legal accountability, emphasizing patient autonomy and the responsibilities of healthcare providers. It also addresses the validity of verbal and written consent, highlighting that while documentation is common, true informed consent relies on the quality and clarity of information given and the absence of undue pressure, rather than merely a signature. The chapter delves into the historical evolution of informed consent, its fundamental principles, and the legal consequences of its violation. It discusses how it is applied within Rwanda's health sector, noting that despite legal recognition, its practical implementation often falls short, with a tendency to rely on signatures rather than comprehensive discussions. The discussion covers various aspects of informed consent, from its fundamental role in medical practice to its application in specific contexts and the legal tests used to determine liability.

#### 7.1. Essence and evolution of informed consent in medical practice

Informed consent is not a modern doctrine. It was cited to be traced back to the eighteenth century in the 1767 case of *Slater v. Baker and Stapleton*.<sup>952</sup> Under this precedent, it was essential to obtain a patient's consent before exercising the profession of a surgeon. Ignorance of that was considered unskillfulness and thus contrary to the rule of the profession. In this regard, a physician who failed to respect this standard of care was subject to liability.<sup>953</sup>

The *Canterbury v. Spence* is another landmark case in medical malpractice and informed consent, which is argued to have highlighted the nature of informed consent in modern medical practice.<sup>954</sup> The case involved Jerry W. Canterbury, a 19-year-old who underwent a laminectomy by Dr. William Thornton Spence for the relief of severe back pain. Canterbury was not, however, informed of the risk of paralysis from the procedure. He fell from his hospital bed after surgery and subsequently developed paralysis from the waist down, with long-term complications.

On March 7, 1963, Canterbury brought suit in U.S. District Court against Dr. Spence and Washington Hospital Centre for negligence, both in failing to inform of surgical risks and in post-operative care. The trial court ruled in the defendants' favour, finding that Canterbury failed to provide medical testimony of negligence. This ruling affirmed that physicians had discretion in determining the extent of information to disclose before a medical procedure. Similarly, the case of *Sidaway v Board of Governors of the Bethlem Royal Hospital* (1985) rejected strict informed consent, applying the Bolam test to assess the adequacy of such a disclosure. In later cases, patients' right to information was weighed against acting in their best interests. Contrary to the U.S. District Court's ruling in *Canterbury v. Spence*, the U.S. Court of Appeals for the District of

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<sup>952</sup> John Petrila, *Informed Consent: Legal Theory and Clinical Practice, Second Edition, Psychiatric Services*, vol. 53, 2002, <https://doi.org/10.1176/appi.ps.53.4.492>.

<sup>953</sup> Petrila, Op. Cit. p. 42.

<sup>954</sup> *Canterbury v. Spence*, No. 22099 (D.C. Cir. 1972).

Columbia Circuit reversed the ruling in favour of the appellant, establishing a legal precedent for patient rights to information.

The *Canterbury v. Spence* case played a pivotal role in shaping the doctrine of informed consent, significantly expanding patients' rights by granting them greater autonomy in health-related decision-making. It also provided patients with broader legal avenues to sue for lack of informed consent, holding physicians more accountable for their disclosures. Before this case, doctors adhered to the professional standard that they disclosed only risks that were deemed necessary by their peers under the Bolam test. However, this ruling shifted the standard to a reasonable person standard, mandating medical practitioners to inform patients of any risks that a rational individual would want to know before consenting to a procedure. This has also been emphasised in *Montgomery v. Lanarkshire Health Board* (2015), which shifted the standard toward a more patient-centred approach, emphasising doctors' fundamental duty to inform patients of the material risks entailed in medical interventions. This change reduced physician immunity, challenging the long-standing notion of medical discretion and ensuring that doctors could no longer withhold critical information under the professional guise.

The initial logic of informed consent has changed nowadays. For example, in surgery cases, physicians had to tell the patients what should be done to them to prepare their minds to perceive that situation, and then cooperate with physicians in the operation without anaesthesia.<sup>955</sup> On the contrary, informed consent's essence today is to respect the patient's autonomy and dignity as a human. This autonomy enables a patient to decide on and control what would or would not be performed on his body.<sup>956</sup> Under the standards of care, a physician has an obligation to disclose material risks to the patient to allow him to balance the degree of risk probability and its gravity.<sup>957</sup> The necessary information to be given varies depending on the jurisdiction. The failure to obtain the patient's consent would preclude the physician from administering any medical procedure to that patient. Consequently, any physician's act without that will be considered a violation of the patient's dignity and therefore impose liability on him.

In most cases, physicians need informed consent to administer a medical procedure or decide not to do anything for the patient.<sup>958</sup> Those cases may include, but are not limited to, ordinary medical treatment, disclosing patient data, vaccines, surgery, blood transfusion, radiation therapy, and anaesthesia. In the case of the healthcare giver's inaction, it raises a debate as everyone has a right to life, but having the right to die is questionable. This right seems to be acceptable in some

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<sup>955</sup> Ibid.

<sup>956</sup> Jennifer Ilo van Nuil et al., "Informed Consent, Community Engagement, and Study Participation at a Research Site in Kigali, Rwanda," *Developing World Bioethics* 18, no. 4 (2018): 350, <https://doi.org/10.1111/dewb.12149>.

<sup>957</sup> Paul McGivern and Natalia Ivolgina, "Legal Liability in Informed Consent Cases: What Are the Rules of the Game?," *McGill Journal of Law and Health*, 2013, 131–32, <https://canlii.ca/t/7gq>.

<sup>958</sup> Nikšić, "Understanding Medical Liability."

jurisdictions where euthanasia is legalised, in cases of incurable, degenerative, or agonising diseases or conditions.<sup>959</sup>

Nevertheless, in all cases, there is a need for rationality for a patient to give consent. This concept brings another important foundation of informed consent on the patient's side. That is 'reasoning', without which a patient cannot be autonomous and cannot take an autonomous decision of their free will.<sup>960</sup> In this context, the physician has to ensure that the patient comprehensively understands the given information and has the mental capacity to make a rational decision.<sup>961</sup> The *Macy v. Blatchford* case highlights the vital role of communication in the informed consent process. With this ruling, the court emphasised that informed consent involves more than signing forms; it requires that the patient understands and knows the relevant issues and material information in order to make an informed decision.<sup>962</sup> In addition, the decision reached in *McQuitty v. Spangler* significantly elaborated the legal meaning of informed consent by affirming the physician's duty to obtain a patient's informed consent for any and all forms of treatment, whether surgical or some other invasive procedure. The Maryland Court of Appeals decided that informed consent requires the physician's responsibility to advise about material risks of proposed interventions, whether they be decisions to postpone an intervention or the intervention itself.

In this case, the court found that Dr. Spangler did not inform Peggy McQuitty about the risks associated with delayed delivery or choosing an earlier Cesarean section. The facts show that as a result of the complete placental abruption, her only son, Dylan McQuitty, suffered severe neurological injuries. The court describes the failure to warn about the risk to the mother's physical autonomy during delivery as a failure of the physician's duty to advise of the material risks of the treatment, effectively holding the physician responsible for the intervening disaster that this patient experienced.<sup>963</sup>

Informed consent implies the principle of '*volenti non fit iniuria*', a Latin legal term that means 'to a willing person, it is not wrong'. A patient's consent must be fully voluntary, free from coercion or undue influence, ensuring informed and autonomous decision-making.<sup>964</sup> In this context, any risky medical act performed on a patient under the latter's voluntariness will not constitute harm, and therefore, no claim for damages would be invoked.<sup>965</sup> However, there are some cases in which

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<sup>959</sup> Suresh Bada Math and Santosh K. Chaturvedi, "Euthanasia: Right to Life vs Right to Die," *Indian J Med Res* 136, 136, no. 6 (2012): 899–902, [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3612319/#:~:text=Caregivers burden%3A %27Right-to,such as severe mental illness](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3612319/#:~:text=Caregivers%20burden%3A%20Right-to,such%20as%20severe%20mental%20illness).

<sup>960</sup> Alasdair Maclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge*, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (New York: Cambridge University Press, 2009), <https://doi.org/10.1017/CBO9780511576119>.

<sup>961</sup> Kelvin Quan and Jessica Lynch, "The High Costs of Language Barriers in Medical Malpractice," ed. Sarah Lichtman Spector and Mara Youdelman (Washington, D.C.: National Health Law Program, 2010), <https://healthlaw.org/resource/the-high-costs-of-language-barriers-in-medical-malpractice/>.

<sup>962</sup> *Macy v. Blatchford*, 8 P.3d 204 (2000).

<sup>963</sup> *McQuitty v. Spangler*, 410 Md. 1, 976 A.2d 1020 (2009).

<sup>964</sup> Robert Young, "Informed Consent and Patient Autonomy," in *A Companion to Bioethics*, ed. Peter Singer Helga Kuhse, 2nd ed., 2009, 531–40, <https://doi.org/10.1002/9781444307818.ch44>.

<sup>965</sup> Nikšić, "Understanding Medical Liability."

medical practitioners decide to act without informed consent, including the following: (1) in life-threatening emergencies; (2) when the patient is incapacitated, and (3) when there is voluntary waived consent.<sup>966</sup>

Although informed consent is a prerequisite for physicians to undertake any medical procedure, it does not preclude their compliance with the law and medical ethics and standards while applying their knowledge and skills to improve the patient's condition. Failure to uphold informed consent can result in legal liability and significantly erode trust in healthcare providers, ultimately undermining patient confidence in medical care. In other words, informed consent does not secure the physician in all circumstances. It was introduced in the medical profession to legalise doctors' activities by reflecting the lawfulness of health assistance and the principle of patient autonomy.

The duty of health care practitioners' disclosure extends beyond obtaining informed consent; it remains a fundamental obligation for medical practitioners even after a patient safety incident occurs. A widely accepted approach is open disclosure, a structured process that fosters honest, empathetic, and timely communication between healthcare professionals and the patient or their representative following such an incident.<sup>967</sup> Recognised as a humanistic response to the impact of medical errors on patients, open disclosure aims at building trust and promoting ethical medical practice. Its practice is, however, limited, as doctors' responses to errors can generate feelings of fear and anger, thus complicating the disclosure process.<sup>968</sup> However, open disclosure presents a viable method for improving doctor-patient trust, promoting excellence in the practice of medicine, and maintaining disclosure and apology laws.

## **7.2. Validity of verbal and written consent**

Patient consent is often obtained through verbal communication rather than formal documentation, with medical practitioners maintaining records throughout the process. While routine procedures are documented, high-risk or life-threatening situations require structured consent forms for consent or refusal. In many cases, obtaining a signature authorises further interventions but may inadvertently limit comprehensive discussions, where vital information should be conveyed to the patient or their representative. Consequently, a signed form can falsely imply informed consent, even when essential details have not been disclosed. However, valid consent is not guaranteed solely by a signature, particularly if key information is absent. As Ann Sommerville emphasises, "... what counts is the quality and clarity of the information provided and the lack of any undue pressure on the patient."<sup>969</sup> Therefore, effective healthcare communication demands transparency, accuracy, and accessibility to empower patients in medical decision-making.

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<sup>966</sup> Parth Shah et al., "Informed Consent," in *StatPearls [Internet]. Treasure Island (FL)*, vol. 16 (Kigali, Rwanda: StatPearls Publishing, 2022), 253, <https://www.ncbi.nlm.nih.gov/books/NBK430827/?report=reader>.

<sup>967</sup> Ivan Dieb Miziara and Carmen Silvia Molleis Galego Miziara, "Recognition of Medical Error: It Is Not Too Late for an Open Disclosure – a Narrative Review," *Clinics* 80 (2025): 1–4, <https://doi.org/10.1016/j.clinsp.2025.100622>.

<sup>968</sup> Faguet, "From the Patient's Perspective."

<sup>969</sup> Ann Sommerville, *Everyday Medical Ethics and Law*, ed. Sophie Brannan et al., *Everyday Medical Ethics and Law* (London: Blackwell Publishing, 2013), p. 82.

### 7.2.1. Capacity in informed consent procedure

As highlighted above, the validity of consent relies on the patient's voluntary decision-making, ensuring autonomy in healthcare choices.<sup>970</sup> However, the mental capacity plays a crucial role in this process. It enables patients to comprehend the implications of proposed interventions, assess their relevance to personal health, and rationally weigh benefits against risks. The ability to communicate decisions freely further guarantees informed and independent consent.

In adults, capacity is presumed unless there is a reason to suspect impairment due to cognitive disorders, mental illness, or temporary factors such as medication effects or distress.<sup>971</sup> Medical practitioners must conduct thorough evaluations, ensuring patients receive information in a clear and accessible format to support informed decision-making.

Contrary to adults, the literature on the minors' decision-making has been documented to be controversial based on conventional stage theories of child development. Some authors like Steinberg have highlighted the reasons the adolescents' decisions could result in negative outcomes due to their vulnerability, including the gaps between emotion, cognition and behaviour.<sup>972</sup> Contrary to prevailing assumptions, Dr. T. Thirumoorthy and Dr. Peter Loke assert that patients may possess the capacity to make healthcare decisions even if they lack competence in other domains, such as financial decision-making.<sup>973</sup>

They further contend that a patient's decision-making ability is often contingent on factors such as the nature and severity of their medical condition or the complexity of the decision at hand. Thus, patients can have the capacity to consent to some types of treatment but not all. However, for those incapable persons who have fluctuating capacity, it should be considered that the fact that they can capture the information relevant to the decision, even though it is only for a moment, does not prevent them from being incapable of making the decision.<sup>974</sup> For example, the concept of "Gillick competence" in English law allows minors under 16 to consent to medical treatment if they demonstrate sufficient maturity and understanding.<sup>975</sup>

A child's capacity to provide an independent healthcare decision without the parent's consent is assessed by applying the Gillick clinical test of competence. The test is applied on a case-by-case basis, with an understanding that competency will differ in relation to the specific decision, since the majority age differs by jurisdiction, typically under 15, 16, or 18. Healthcare providers evaluate the minor's comprehension, reasoning ability, and awareness of the consequences of treatment.

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<sup>970</sup> Ann Sommerville, *Everyday Med. Ethics Law*. p. 82.

<sup>971</sup> British Medical Association, "Consent and Refusal by Adults with Decision-Making Capacity: A Toolkit for Doctors" 2024, no. January 2024 (2019): 6–9, <https://www.bma.org.uk/media/2481/bma-consent-toolkit-september-2019.pdf>.

<sup>972</sup> Tim Hawkins and Martin Curtice, "Consent in Minors: The Differential Treatment of Acceptance and Refusal. Part 2 Minors' Decision-Making and the Reach of Their Capacity," *BJPsych Advances* 30, no. 3 (2024): 179–82, <https://doi.org/10.1192/bja.2022.76>.

<sup>973</sup> Thirumoorthy and Loke, "Consent in Medical Practice 3 – Dealing with Persons Lacking Capacity."

<sup>974</sup> Thirumoorthy and Loke.

<sup>975</sup> Hawkins and Curtice, "Consent in Minors: The Differential Treatment of Acceptance and Refusal. Part 2 Minors' Decision-Making and the Reach of Their Capacity," p. 181-182

Thus, in ensuring standards of informed consent in the treatment of children, the process relies on both decision-making capacity and maturity assessment.<sup>976</sup> Those children who meet these criteria are considered Gillick-competent and able to give informed consent. Healthcare service eligibility often depends on jurisdictional regulations. For example, a recent healthcare law in Rwanda lowered the age of consent for healthcare services to 15.<sup>977</sup> However, depending on the jurisdiction, specific treatments, such as contraception, may be restricted even for individuals legally recognised as mature.

Thirumoorthy and Loke argue that the capacity to make decisions should be considered at the specific moment when consent is to be obtained. In this light, the consent would be legitimate if it were determined that the person's capacity was there at the time of the consent. In addition, those incapable persons could be aided by various factors such as the best time of day, location, and the use of decision-making tools like pictures and drawings.<sup>978</sup>

Minors and those deemed incapable of making decisions are frequently assumed to be legally incapable of giving informed consent in medical practice. Nevertheless, this presumption may change based on the jurisdiction and particular context. For example, in many states of the US, adolescents of 13 to 18 are eligible to consent to some health care services such as contraceptives, pregnancy, sexually transmitted diseases, and psychiatric problems.<sup>979</sup> However, the literature suggests that minors below the age of 11 do not have the intellectual ability and volition to give informed, voluntary, and rational consent. Those who may not be eligible to provide consent can provide "assent," which is the process of expressing their agreement to medical treatment. Although an assent does not carry the same legal weight as consent, it is an essential component for ethical practice that respects the developing autonomy of minors.<sup>980</sup>

#### 7.2.2. Key elements of an informed consent discussion

To obtain informed consent, the patient should be provided with enough information throughout the doctor-patient discussion, as was previously discussed. The discussion should contain adequate, understandable, and accurate information regarding the suggested medical procedure or treatment choice. Additionally, such a conversation should be customised with the patient's best interests in mind, taking into account the type and complexity of the recommended medical intervention, the level of risk involved, and the patient's personal concerns, desires, and beliefs. The following have been proposed to be the dimensions of coverage in the debate.

- The following have been put forth as the discussion's covered topics.
- The purpose of the examination or treatment;

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<sup>976</sup> Tim Hawkins and Martin Curtice, "Consent in Minors: The Differential Treatment of Acceptance and Refusal. Part 2 Minors' Decision-Making and the Reach of Their Capacity," *BJPsych Advances* 30, no. 3 (2024): 172–83, <https://doi.org/10.1192/bja.2022.76>.

<sup>977</sup> Article 2 (o) of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services (2025).

<sup>978</sup> Thirumoorthy and Loke, "Consent in Medical Practice 3 – Dealing with Persons Lacking Capacity."

<sup>979</sup> Tara Kuther, *Medical Decision-Making and Minors: Issues of Consent and Assent*, 2003, p. 345-55.

<sup>980</sup> Kuther, p. 352-5.

- The diagnosis uncertainties and details;
- The treatment alternatives available, including the refusal of treatment;
- The possible efficacy and success rate of each alternative;
- The risks and potential side effects, along with undesirable results, i.e., treatment failure;
- The name of the doctor who is ultimately responsible for the patient's care;
- A notice that the patient can withdraw from the treatment whenever he or she wants; and
- Any potential problems that may arise while the patient is unconscious, if relevant.

The British Medical Association advises medical doctors to consider several key aspects in obtaining patients' consent. They should, therefore, keep the following questions in mind.<sup>981</sup>

- Has the patient been adequately informed about the potential risks of the suggested treatment?
- Does the patient know about available alternative options, including their respective benefits and risks?
- Have all reasonable measures been taken to present information so that it is understandable by the patient?
- Does the patient know that he or she has a right to refuse the recommended treatment?

### **7.3. Beyond passive acquiescence: advancing patient-centred care**

In medical practice, patients or their health care users express their consent or refusal in different ways, often through actions or body language rather than words. This type of consent or refusal is considered “implied,” applying only to immediate medical procedures and not to any later examinations or treatments.<sup>982</sup> This differs from passive acquiescence, which does not reflect active patient autonomy. Such acquiescence does not constitute any form of consent unless the patient is well informed about the nature of the intervention and the option to refuse it.

However, the healthcare giver may unintentionally attribute a passive role to patients during goal-setting and action planning discussions.<sup>983</sup> Research has shown that patients may adopt a passive role in medical decision-making due to various factors, including inherent behavioural tendencies and the communication strategies employed by healthcare providers.<sup>984</sup> Evidence suggests that many patients lack the motivation, confidence, or preparedness to fully engage in collaborative discussions regarding their healthcare goals and the appropriate interventions,<sup>985</sup> highlighting the need for tailored strategies to promote active patient participation.

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<sup>981</sup> British Medical Association, “Consent and Refusal by Adults with Decision-Making Capacity: A Toolkit for Doctors.”

<sup>982</sup> Ann Sommerville, *Everyday Medical Ethics and Law*, ed. Sophie Brannan et al., *Everyday Medical Ethics and Law* (London: Blackwell Publishing, 2013), p. 81-82.

<sup>983</sup> Stephanie A. Lenzen et al., “Ascribing Patients a Passive Role: Conversation Analysis of Practice Nurses’ and Patients’ Goal Setting and Action Planning Talk,” *Research in Nursing and Health* 41, no. 4 (2018): 389–95, <https://doi.org/10.1002/nur.21883>.

<sup>984</sup> Lenzen et al.

<sup>985</sup> Lenzen et al., p.394.

The doctor-patient relationship is inherently asymmetric, as healthcare providers possess specialised expertise and extensive training that patients typically lack. This imbalance can lead patients to hesitate in proposing potential solutions or interventions, fearing that doing so might contradict their reasons for seeking medical care. In this context, a debilitated patient is particularly susceptible to passivity, which may be intensified by the informed consent process when communication from healthcare practitioners is unclear, intimidating, and predominantly unilateral.<sup>986</sup> Moreover, trust is a fundamental element of effective communication and plays a crucial role in shaping the doctor-patient relationship. It serves as the foundation for setting meaningful healthcare goals and selecting appropriate interventions. However, informed consent discussions are sometimes initiated by a physician who has no prior interaction with the patient.<sup>987</sup> This absence of established trust may hinder open dialogue, reinforcing the patient's passive role in decision-making.

The asymmetry in the doctor-patient relationship, compounded by patients' lack of confidence and trust, underscores the critical need for transparent, empathetic, and collaborative strategies that empower individuals and enhance medical decision-making. Therefore, healthcare professionals must actively foster patient engagement and encourage meaningful participation, particularly in the informed consent process.

#### **7.4. Ethical dilemmas in life-saving treatments requiring third-party consent**

Some cases could raise challenges in determining whether the patient has provided express or explicit consent for medical intervention, mostly in life-threatening situations. Such undue influence from a third party could manifest when the patient makes unexpected decisions conflicting with their known wishes or appear out of character. This could happen due to the discussed asymmetry between doctor and patient or the tendency to satisfy someone else. Before reading the example of this context, let's see another real-life example.

If a mother always expresses the wish for her daughter to be a nun from her childhood, it is most likely that the latter will join the consecrated life, if other requirements are met, not because it is her choice. Rather, because if she does not, it will be to compromise and betray her mother, who believes in her to be a nun. In other words, she is a sister on her mother's behalf or her mother in a nun through her daughter.

The above example indicates how a third party's influence could direct an individual to an undesired life. Another example is retrieved from the testimony of Dr Ngoga, an Obstetrician and Gynaecologist at Rwanda Military Hospital, of the last two decades at the CHUK.<sup>988</sup> The expectant mother was taken to the CHUK in a state of emergency, about to deliver with a seriously low haemoglobin level that would require an immediate blood transfusion. Despite the urgent medical need, her husband and family members refused consent for transfusion based on religious beliefs

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<sup>986</sup> B. N. Waller, "Patient Autonomy Naturalized," *Perspectives in Biology and Medicine*, p. 585

<sup>987</sup> Lenzen et al., "Ascribing Patients a Passive Role: Conversation Analysis of Practice Nurses' and Patients' Goal Setting and Action Planning Talk."

<sup>988</sup> Ntiringanya, "New Bill Proposes Treatment without Patient's Consent in Emergency Cases."

against blood transfusion. Unfortunately, both the expectant mother and the unborn baby passed away.<sup>989</sup> This case outlines legal and ethical dilemmas facing medical professionals when patient autonomy and religion compromise life-saving medical interventions.

To address the challenge, the new healthcare law provides the right to refuse treatment or withdraw consent.<sup>990</sup> Such refusal could be expressed in any form, either in writing, verbally or in sign language, and is subject to documentation in the healthcare service user's file by the attending healthcare professional.<sup>991</sup> This could be important in life-saving interventions, such as blood transfusions, where healthcare workers are prevented from acting against the patient's or guardian's refusal. In this regard, CHUK adopted a policy allowing doctors to provide such interventions to minors when their lives are in danger, despite the refusal of their parents, as asserted by Lisine Tuyisenge, a paediatrician at CHUK.<sup>992</sup>

### **7.5. Application of informed consent in Rwanda's health sector**

In Rwanda, informed consent is also recognised by the law as a right of patients or other healthcare users.<sup>993</sup> Informed consent is defined as “a process by which a fully informed patient participates in decision-making and provides permission to staff before an intervention is conducted”.<sup>994</sup> The Rwandan healthcare law defines a consent as follow:

*[M]eans a voluntary agreement by a healthcare service user or his or her representative to receive a healthcare service, after having been informed of, and clearly understood, the type of healthcare service he or she is about to receive, the process for receiving it, his or her rights and obligations and the potential risks and benefits of such a healthcare service he or she is about to receive.*<sup>995</sup>

The right to informed consent is related to the right to information, hence physicians have an obligation to properly inform patients on their state of health. This serves as the basis for rationally taking informed decisions about their health. Theoretically, some Rwandan hospitals publish the rights and obligations of patients on their websites.<sup>996</sup> Under the right to choose, a patient can participate in decision-making about their care, treatment, medication, and provision of informed consent to care.<sup>997</sup> In this regard, the patient has the right to admit or refuse any of those health care services and be informed about the associated consequences of making such a decision.

However, the informed consent doctrine is underdeveloped in Rwanda. As Bruce N. Waller asserted, “traditional informed consent often promotes passive acquiescence rather than active

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<sup>989</sup> Ntirenganya.

<sup>990</sup> Article 63 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>991</sup> Ibid., Article 63 (3).

<sup>992</sup> Ntirenganya, “New Bill Proposes Treatment without Patient's Consent in Emergency Cases.”

<sup>993</sup> Article 62 of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services (2025).

<sup>994</sup> Shah et al., “Informed Consent.”

<sup>995</sup> Ibid., Article 2 (s).

<sup>996</sup> Kibungo Referral Hospital, “Patients Rights and Responsibilities,” accessed November 18, 2022, <https://www.krh.gov.rw/patients-info/patient-rights>.

<sup>997</sup> Kibungo Referral Hospital.

exercise of autonomy.”<sup>998</sup> Despite that inclusive definition, the role of informed consent seems to be practically limited to surgical interventions. The way physicians obtain informed consent in Rwanda is questionable. In hospitals and clinics, physicians tend to bring papers and tell patients that there are documents to sign before undertaking surgical procedures. It is rare to find a doctor who takes the time to explain to the patient how the operation would benefit them and the associated risks, although they have this obligation under the healthcare law.<sup>999</sup> This is problematic as obtaining a signature from a patient, his representative, or guardian in the case of a minor would not justify the latter’s consent following the violation of the procedure to obtain valid consent.

### **7.6. Medical liability for informed consent violations**

As discussed earlier, informed consent is a cornerstone of ethical and compliant medical practice, and failure to uphold it can expose medical practitioners to legal liability beyond the loss of professional credibility. Although no violation of informed consent case has been reported by existing research in Rwanda, results from the current study show that issues like offensive language and poor communication between healthcare providers and patients continue to persist.<sup>1000</sup> These are issues that indicate that proper consent procedures are not always followed, thus affecting the validity of the consent. In this regard, landmark cases such as *Canterbury v. Spence* and *Montgomery v. Lanarkshire Health Board* underscore the transformative role of informed consent in advancing a patient-centred model of care. Apart from echoing the duty of medical practitioners to open disclosure, these rulings put a stress on the drastic consequences of disregarding this fundamental responsibility.

It would be understood that a physician who does not abide by the informed consent, either by performing less or in excess, will also be liable as if they acted without it. As it was well exemplified in the famous words of Justice Benjamin Cardozo in the *Schloendorff v. Society of New York Hospital* case, “Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who operates without his patient's consent, commits an assault, for which he is liable in damages.”<sup>1001</sup> By picking the phrase “what shall be done with his own body,” its interpretation is not deduced to what a physician will think to be right in his discretion. Instead, it brings back the question of the extent to which the information to be disclosed to the patient would be. Thus, what the physician does would have been materialised by his discussion with the respective patient. Otherwise, performing less or extra work, which results in the patient’s harm, will be considered battery and thus impose medical liability.<sup>1002</sup>

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<sup>998</sup> Lenzen et al., “Ascribing Patients a Passive Role: Conversation Analysis of Practice Nurses’ and Patients’ Goal Setting and Action Planning Talk.”

<sup>999</sup> Article 68 (c, d) of the Law N° 026/2025 of 17/09/2025 Regulating Healthcare Services.

<sup>1000</sup> Mukamana et al., “Dehumanizing Language, Motherhood in the Context of HIV, and Overcoming HIV Stigma - the Voices of Rwandan Women with HIV: A Focus Group Study.”

<sup>1001</sup> Court of Appeals of New York, *Schloendorff v. Society of New York Hospital*, - 211 N.Y. 125, 105 N.E. 92 (1914).

<sup>1002</sup> David H. Sohn, “Informed Consent: A ‘New’ Form of Medical Liability?,” *AAOS*, no. May (2013): 3, <https://www.aaos.org/aaosnow/2013/may/managing/managing4/>.

Medical liability for informed consent violations is governed by legal provisions and ethical standards that uphold patient autonomy and mandate physicians to obtain informed consent prior to treatment. Legal and ethical obligations impose medical liability for informed consent violations in Rwanda. In cases of misconduct where gross negligence or malicious intent is involved, patients are entitled to claim damages for injury sustained through authorised treatment, and such violations can lead to professional, civil, and criminal liability.

### **7.7. Informed consent and causation tests**

In exceptional cases, such as emergencies requiring immediate medical intervention where the patient cannot give consent, informed consent may not apply. In any case, legal standards still evaluate whether healthcare providers acted appropriately under these circumstances. To succeed in an informed consent claim, claimants must satisfy two key causation tests: the modified objective test and the “but for” test.

#### **7.7.1. Modified objective test**

The modified objective test evaluates if the medical practitioner’s intervention or inaction violates the standard of care, considering what a reasonable doctor would have done in similar circumstances.<sup>1003</sup> Another important point is that this causation considers the patient’s unique circumstances, such as medical history, pre-existing conditions, and individual risk factors. That is, would the patient have consented to the operation or treatment if he or she had been apprised of material risks?<sup>1004</sup> This has been elaborated in the *Reibl v. Hughes* (1980) case and elucidated in the *Arndt v. Smith* case (1997). In this case, the Supreme Court of Canada underscored the role of good communication between physicians and patients, which constitutes a routine clinical practice, as an important key to positive health outcomes. The Court highlighted that, despite its critical importance, securing informed consent would not be enough. Rather, there should be good communication entailing comprehensible conversations about any special needs, considering the patient’s particular case. The Court also recalled physicians to keep relevant records of all discussions as well as the responses to the patient’s questions.<sup>1005</sup>

#### **7.7.2. Factual Causation, ‘but for’ test**

This test is applied in tort law and criminal law to determine factual causation. It is much farther than the modified objective causation. P is the action of a person, followed by the consequence Q. In case of non-occurrence of the act of P, then result Q will not exist. But due to the existence of P act, Q would not exist. When applied to medical liability, this causation does not introduce the question of whether the information was not fully disclosed to the patient to consent to treatment. Instead, it reconciles the previous question to the latter: “But for” the given medical treatment, the injury would not have occurred? Or, ‘but for’ the treatment rendered, would the injury have been avoided? The logic behind this causation is to assess whether the lack of informed consent is a

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<sup>1003</sup> Supreme Court of Canada, *Reibl v. Hughes*, 2 SCR 880 (1980).

<sup>1004</sup> K. Capen, “Supreme Court Reaffirms Landmark Informed-Consent Ruling in Chickenpox Case,” *CMAJ. Canadian Medical Association Journal* 157, no. 5 (1997): 553–54.

<sup>1005</sup> Supreme Court of Canada, *Arndt v. Smith*, 213 N.R. 243 (1997).

proximate cause of the incurred injury. Otherwise, in the absence of this causation, the defendant will not be held liable.

However, the “but-for” causation has been criticised for its ambiguity. This is because it might be hard to assess all remote factors that can result in the victim’s injury.<sup>1006</sup> To solve this illusory, some courts have developed the “likelihood survival test,” whereby if, for example, the physician’s intervention or inaction has decreased the victim’s chance of survival, he should be held liable.<sup>1007</sup> In other words, it ignores the doctor’s obligation, the “obligation of means”, which does not always ensure positive results. Besides, the proximate cause doctrine and acceleration theory are useful to assess the causation in tort liability and criminal law, although they also have their pros and cons.

### **7.8. Conclusion**

This chapter examined the doctrine of informed consent, tracing its historical roots, ethical foundations, and legal significance. Far from a mere formality, informed consent is a core ethical and legal obligation that prioritises patient autonomy and meaningful dialogue. Evolving from cases like *Slater v. Baker* to *Canterbury v. Spence*, the doctrine requires that for consent to be valid, it must be voluntary, based on comprehensive and understandable information, moving away from passive acquiescence, and given by an individual with the capacity to make rational decisions, emphasising the quality of information over signatures. Despite challenges—such as inherent asymmetry in doctor-patient relationships and medical necessity—failure to obtain valid consent can result in professional, civil, or criminal liability, assessed through causation tests like the modified objective and 'but for' tests. Ultimately, informed consent demands transparent communication, respect for patient capacity, and a commitment to shared decision-making.

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<sup>1006</sup> McGivern and Ivolgina, “Legal Liability in Informed Consent Cases: What Are the Rules of the Game?”. P. 141.

<sup>1007</sup> LII, “But-for Test,” accessed November 24, 2022, [https://www.law.cornell.edu/wex/but-for\\_test](https://www.law.cornell.edu/wex/but-for_test).

## CHAPTER EIGHT

### TOWARDS A COMPREHENSIVE FRAMEWORK ENHANCING ACCOUNTABILITY AND PATIENT SAFETY IN THE HEALTHCARE SYSTEM OF RWANDA

#### 8.1. Introduction

Previous chapters have established the foundation for a liability framework for medical malpractice in Rwanda. This chapter addresses issues raised throughout the earlier chapters of this treatise. It aims to answer a primary question about mechanisms that could promote accountability, patients' rights, and safety in the Rwandan healthcare service delivery. The chapter develops an appropriate model for Rwanda healthcare system, grounded in human error theory, professional liability, and a deontological paradigm. It outlines pathways to broader patient protection without pre-empting the final recommendations.

Drawing on international best practices, the section advances mechanisms that cover governance, inspection and compliance, performance-based financing, independent facility certification, incident reporting, and “just culture,” as well as patient and family engagement, workforce capability, digital safety analytics, primary-care readiness standards, and transparent public reporting. These mechanisms align with the nation's current policy and digital trajectory, as drawn in the Health Sector Strategic Plan V (2024–2029), the national digital health architecture (which entails the Rwanda Health Information Exchange (RHIE) and e-Ubuzima), and the 2025 healthcare law. Collectively, they ensure the legal enforceability, operational feasibility, and evidential standards necessary for malpractice adjudication.

Throughout this dissertation, empirical data have been integrated with doctrinal insights from case laws and various reports. This enabled the researcher to evaluate the law “in action” versus law “on the book” to provide a foundational approach for addressing enforcement challenges.

#### 8.2. Existing remedial situation on medical malpractice

Various forms of medical malpractice have been documented, with a high rate in Obstetrics/Gynaecology, which accounted for 59.9% of the 101 cases received by RMDC over the seven years from 2016 to 2022, and 69.5% of the 59 malpractice complaints received by NCNM over the four years from 2021 to 2024. Those numbers represent far fewer medical injuries (either reported or unreported) incurred in various settings of Rwandan health facilities. This justifies the fact that the medical malpractice liability system does not accurately reflect the extent of injuries suffered by healthcare service users in those settings, thereby undermining its compensatory or remedial role for the victims. Besides, even the compensation awarded in this context of remedy is limited to those who institute claims, which is relatively low due to various reasons. A similar situation is described in the snippet below from Makuluma's thesis in South Africa.

[...] far fewer patients institute claims against the hospital or doctor for injuries incurred during their treatment. Clearly, only a fraction of eligible claims ever reaches the legal system. This implies that the medical malpractice litigation system is not reflective of the extent of patient injuries and therefore its

compensation function for injured patients is limited to those that institute claims.<sup>1008</sup>

Similar to South Africa, the number of claims against hospitals and medical practitioners in Rwanda is far lower than the number of injuries incurred by patients in those healthcare facilities. Thus, the number of medical injuries resulting from the conduct of unlawful or unethical practitioners in clinical practice is not always considered malpractice for various reasons. Many victims of unsafe healthcare services do not disclose what occurred to them or their families due to the uncertainty of the litigation's outcome, often resulting from a lack of sufficient evidence or other technicalities in malpractice adjudication proceedings. Meanwhile, others may be unaware of the available remedies, or even when they are aware of remedial forums, they may be limited by their existing relationship with their doctors. This creates another sense, which is beyond unacceptable behaviour, leading the victim to understand that they cannot sue their friends, claiming that even if they made an error, they did not intend to harm them.<sup>1009</sup> Victims may also fear what might happen to them if they complain against a wealthy professional or provider who might take revenge against them using their ability and networks.

Besides, every stage of court proceedings involves a financial loss, which may worsen the situation of a suffering patient or their family, who have incurred high costs of medical treatments due to iatrogenic injuries and rehabilitation. Consequently, they cannot afford or are not prepared to incur the litigation fee.

Culture and belief are two related factors that also hinder victims of wrongful clinical practice from litigating against medical providers or professionals. In Rwanda, medical authority is highly respected, and social trust in healthcare institutions is very high, which tends to deter patients who may want to challenge the provider or suspect that they have been injured through negligence. In addition, the religious beliefs, particularly those that offer care through church affiliated facilities, encourage forgiveness, tolerance of suffering, and reconciliation, as opposed to confrontation. Moreover, litigation is perceived as disruptive due to the cultural focus on social harmony and unity, as well as a lack of legal knowledge and the fear of being stigmatized, which further suppresses claims, especially in rural areas.

Yet, the legal and policy framework for medical liability in Rwanda indicates a progressive effort to foster accountability in healthcare. The number of medical professionals sanctioned annually ranges between 30 and 40. Sanctions vary from administrative to criminal liability, while remedial forums are mainly comprised of professional councils and courts. The role of professional insurance has been minimal in the compensation process for medical malpractice and negligence.

The existing medical liability system presents various limitations, primarily at the enforcement level, where issues such as incomplete operation of professional liability insurance, low litigation

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<sup>1008</sup> Hlombe Azukile Makuluma, "An Analysis of Medical Risk Inspections in the Context of the Office of Health Standards Compliance (OHSC)" (University of Pretoria, 2021), p. 21.

<sup>1009</sup> Bill Sandweg, "Why Medical Malpractice Victims Don't Sue," sandwegandager.net, April 2025, <https://www.sandwegandager.net/2025/04/why-medical-malpractice-victims-dont-sue/#:~:text=Causation,permanent%2C debilitating injury or death.>

rates due to cultural factors, evidentiary challenges, delays in the compensation process, and inadequate compensation are prevalent.

### 8.3. Proposed solutions to identified challenges

Throughout this study, as highlighted in the previous text, some challenges have been identified that have not received appropriate redressal. The journey towards a vigorous, accountable, and compliant healthcare system is hampered by multifaceted challenges, including insufficient accountability and a lack of law enforcement mechanisms that disadvantage healthcare service users, a lack of public awareness regarding patient rights, and operational deficiencies such as poor planning and vulnerabilities in patient confidentiality. While the existing legal and regulatory frameworks aim to promote public health and deliver justice, specific areas require further change, enhancement, and clarification. The following discussion is built on those challenges, aiming to find effective solutions.

Professional negligence and patient harm necessitate a re-examination of existing medical and legal frameworks to ensure patient safety and justice. However, a robust law enforcement framework is necessary, as suggested by the proposed model below, under this chapter. Several key points need to be considered, including establishing an enforcement mechanism that ensures transparent quantum criteria, providing apology protection, settling malpractice claims within a time-bound framework, and implementing a no-fault compensation system.

#### 8.3.1. Limited healthcare accountability and loopholes in the regulatory framework

Limited healthcare accountability and regulatory loopholes have been identified as a critical challenge in the journey towards patient safety and fair compensation for medical malpractices. The persistent challenge of accountability in healthcare persists and can erode public trust. In Rwanda, there is an increase in the commercialisation of healthcare services, presenting complex dynamics between profit motives and patient welfare. Despite this shift, the current legal framework remains incomplete, as it does not include corporate liability, making healthcare providers liable alongside individual medical practitioners. Additionally, the institutions mandated to protect consumers, such as RURA and RICA, as well as non-governmental bodies like ADECOR, have not prioritised oversight on healthcare service delivery. Their mandate is broader, covering utilities and consumer rights without mechanisms to address substandard healthcare delivery. Regulatory bodies of the medical profession, such as the RMDC and NCNM, could be complemented by the efforts of another public regulatory body in protecting healthcare service consumers. This lapse in institutional oversight, within the mandates of RURA and RICA, exposes patients to risks, with no special public regulatory authority to enforce adherence to the standards of quality and safety in healthcare delivery.

The lack of a legal and regulatory framework protecting healthcare service users as consumers of healthcare services and pharmaceutical products suggests a need for specific guidelines and enforcement mechanisms to ensure corporate responsibility in healthcare service delivery. This will bridge accountability and create a healthcare environment that prioritizes patient rights, upholds professional standards, and provides clear pathways for compensation in the event of harm. Furthermore, if liability is expanded to encompass a broader context of corporate

responsibility and human rights obligations, healthcare service users will benefit from enhanced constitutional guarantees of life, health, and dignity.

Furthermore, the healthcare law falls short in its use of certain terminologies that may lead to ambiguity in judicial interpretations, or it grants excessive discretion to healthcare professionals or providers in the exercise of their duties. For example, the law states terms such as “serious consequences” resulting from a fault or “public interest” consideration in the treatment, which requires clarification to avoid any potential jeopardy to the patient's rights and dignity. Furthermore, the lack of ministerial orders implementing the new Healthcare Law creates a gap in the current healthcare legal regime's implementation. For example, the lack of ministerial order regarding professional liability insurance undermines the compensation regime and proportional liability approach in cases involving multiple parties. The enactment of those ministerial orders implementing the healthcare law is essential to promote accountability and transparency in healthcare service delivery and to provide an adequate compensatory regime for malpractice victims.

Furthermore, regulators draw the most attention during system failures, yet their true worth lies in preventing those failures completely. For Mutheu, “true regulatory impact lies in preventing harm.”<sup>1010</sup> Indeed, the regulatory institutions’ mandate would be redesigning the healthcare system for safety, not for punishment. In this regard, SOPs could play a crucial role. Prioritising holding healthcare practitioners civilly and criminally liable compromises their legitimacy. It has also been found to accelerate defensive medicine, career transition, and other psychological consequences. Additionally, the fault-based system in medical litigation places a heavy burden of proof on plaintiffs to establish a guilty conviction against the defendant. This undermines the victims' access to adequate remedies due to the complexities and technicalities of medical negligence cases. Additionally, there are no defined standards of care, nor are there benchmarks for what constitutes malpractice or acceptable clinical practice, which creates variation in judicial interpretations of expert opinions and renders expert testimony more subjective.

To strike a balance between accountability and fairness in medical malpractice, alternative approaches for delivering justice in medical malpractice cases have been proposed to avoid compromising the legitimacy of practitioners through criminalization. These include restorative justice and no-fault compensation systems. Thus, there would be a prerequisite for an amicable settlement process for medical malpractice claims through a designated organ mandated to adjudicate malpractice claims before they reach the court. In this regard, Rwanda can learn from Romanian procedures for resolving medical malpractice complaints out of court and commissions for monitoring and professional competence in malpractice cases. These procedures and commissions are widely regarded as best practices. These mechanisms focus on ensuring ready, timely, and accessible resolution using mediation and negotiation, and lessen the use of expensive and prolonged litigation. Through dialogue and mutual understanding, they are able to resolve grievances in an effective manner without causing any strain to the system of justice and putting

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<sup>1010</sup> Esther Mutheu, “AMCOA 2025 Annual Capacity Building Workshop: Strategic Role of Health Regulators in Managing Medical Malpractice” (Nairobi, Kenya, 2025), <https://amcoa.org/wp-content/uploads/2025/04/Strategic-Role-of-Health-Regulators-in-Management-of-Medical-Malpractice-Adv.-Esther-Mutheu.pdf>.

pressure on the judicial system. To complement such activities, there are also special commissions that review the actions and clinical choices of practitioners, hold them accountable, and continue their professional growth. Their control improves patient safety, detects the spheres of improvement, and strengthens patient confidence in medical care. These two measures establish a comprehensive framework for balancing the rights of patients and professional integrity.<sup>1011</sup>

Moreover, medical malpractice litigations always require specialists' interventions who can help to assess medico-legal evidence to ensure that liability is determined based on contextually relevant information rather than solely on statutory language. However, many victims of adverse events could not afford those experts. To address this challenge, a consolidated effort between professional regulatory bodies and the government is required to establish a standardized process for vetting and accrediting medical experts for medical litigation, as well as clear guidelines outlining the admissibility criteria for expert opinion in medical malpractice cases, as suggested by Damian Capozzola and Jamie Terrence.<sup>1012</sup> Those guidelines should necessitate the testimony's reasonability and consistency with the facts of the case at hand.

Transparency and accountability constitute a big part of enablers in the healthcare system's accountability, although without a smooth reporting system, it would not be possible. By quoting late Dr. Lucian Leape, the famous doctor whose work contributed to patient safety in medical practice, "In medicine, silence in the face of error is complicity."<sup>1013</sup> Thus, underreporting of medical malpractice and negligence incident should be considered a silence in the face of wrongdoing and considered complicity. In this regard, there have been people who heroically echoed that silence in the face of wrongdoing is a form of complicity including Albert Einstein, Martin Luther King Jr., and Joan Didion.

A lack of adequate regulatory mechanisms that effectively enforce transparency and accountability has also been found to accelerate the underreporting of malpractice incidents, which underestimates the true scope of the problem. Indeed, in the absence of effective mechanisms to oversee, inspect, and punish malpractice, health practitioners might not be motivated to report on their errors or adverse incidents. Moreover, an absence of motivation or protection for whistleblowers accelerates a culture of silence and concealment, instilling fear among healthcare practitioners who may testify against their peers. What makes this matter even more complicated is the conflict of interest in the medical circles, where professional responsibility and professional fraternity collide with the ethical obligation to report misconduct. Practitioners are reluctant to testify against fellow professionals, fearing that they may destroy a professional relationship, tarnish their own reputation, or face retaliation. Such hesitation undermines accountability systems in which careless behaviour can remain unpunished. These issues can be resolved through a set of radical reforms that empower regulatory enforcement, initiate open reporting channels, and instill the attitude that patient safety is paramount over the protectionism of a profession. Institutional

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<sup>1011</sup> Hanganu et al., "Reasons for and Facilitating Factors of Medical Malpractice Complaints. What Can Be Done to Prevent Them?"

<sup>1012</sup> Capozzola and Terrence, "Appeals Court Clarifies Standard for Admissibility of Expert Opinion in Medical Malpractice Case."

<sup>1013</sup> Edward Maile, "The Father of Patient Safety," *British Medical Association (BMA)*, 2012, <https://doi.org/https://doi.org/10.1136/bmj.e7763>.

reforms must therefore include the protection of reporters and compliance incentives to create an environment in which safety and ethical responsibility are the top priorities.

Lack of public awareness of patients' rights is another challenge that may prompt providers to withhold information from patients, believing that disclosing it would limit their authority. Non-disclosure of necessary information may lead to the patient's acceptance of sub-standard care, failure to recognise malpractice, healthcare practitioners' reduced accountability, and a decline in healthcare service quality. To address these risks, it is essential to increase the general public's awareness through comprehensive awareness campaigns about their rights and empower patients to be active participants in their healthcare decision-making. Besides, other measures, including public reporting and frequent revision of policies, are also crucial in promoting a just culture and responsibility in the delivery of healthcare services. The approach imposes high standards on healthcare providers and motivates patients to engage in the healthcare decision-making process as active participants rather than passive recipients. Hence, raising awareness among the public is one of the initial steps toward enhancing the quality of healthcare and providing equitable treatment to every patient.

Additionally, despite statutory provisions, the non-operative professional liability insurance is still a hindrance to healthcare accountability. This loophole weakens the implementation of legal and ethical duties, with the liability insurance being necessary to pay out to the patient, in case of malpractice or negligence. Without it, medical professionals will not have sufficient financial protection, which can deter transparency, slow down the process of resolving claims, and undermine accountability models. Also, inadequate or non-operative insurance prevents the possibility of making the providers accountable financially- a crucial aspect in delivering care and developing continuous quality improvement. The solution to this challenge is not just to strengthen the law through legislation, but rather to provide effective mechanisms of implementation and control to make sure that liability insurance functions as it is supposed to, as the gap between statutory mandates and practical enforcement.

### 8.3.2. Operational and systemic issues with proposed solutions

Inadequate healthcare planning has been a systemic problem that undermines the ability to deliver individualised care, considering unique patient conditions. With inadequate planning, the care delivery prioritises 'care in numbers' instead of individual patient cases, which does not put the service user at the centre of service delivery, and thereby compromises treatment outcomes and patient satisfaction.

To address this challenge, healthcare providers' planning should prioritise values such as case severity, risk factors, and patient preferences over the volume of treated patients. Thus, individualised healthcare should be considered in healthcare planning. Additionally, data-driven care planning should also be adopted to ensure that planning is evidence-based.<sup>1014,1015</sup> Electronic

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<sup>1014</sup> Management Sciences for Health (MSH), "REALIZING RWANDA'S VISION FOR HEALTH: Accessible, Accountable, Affordable, and Reliable Health Systems," *Rwanda Health Systems Strengthening (RHSS) Project, 2014-2019* (Medford, 2019), p. 2,11,17-30.

<sup>1015</sup> "Landscaping of District Health Management Teams (DHMT) Governance and Mechanisms" (Kigali, Rwanda, 2024), p. 22-27.

health records (EHRs) should also be used to track individual patient histories, treatment responses, and comorbid conditions. Considering the National Practitioner Data Bank (NPDB), a repository detailing US malpractice payment,<sup>1016</sup> there is a need for a data set of medical malpractice incidents and related compensation tailored for Rwanda to keep an eye on workable measures in mitigating these incidents for the sake of health service consumers' safety.

Moreover, needs-based resource allocation should be institutionalised. In this regard, the Workload Indicators of Staffing Needs (WISN) method could be employed to obtain a systematic, evidence-based tool for determining actual health workforce requirements. The WISN approach was found to be reliable in the South-East Asian countries in ensuring adequate and equitable distribution of resources in their health workforce.<sup>1017,1018</sup> So, it can help improve resource allocation, access to care, and the efficiency of healthcare delivery in Rwanda. In this regard, routine population needs assessments are also helpful in identifying priorities, guiding the planning, commissioning, and providing suitable, equitable, and effective services aligned with each health facility's specific requirements.

Governance and accountability are other vital components to consider in planning. These two may be coined in "leadership and governance", one of the enablers of Rwanda's HSSP V. They enable harmonisation among health stakeholders in planning, implementation, and regular performance reviews.<sup>1019</sup> In this regard, they impose an obligation on health facilities to submit annual performance targets and service delivery improvement plans based on local realities. They also enable the establishment of performance metrics that reward facilities for patient outcomes, rather than just service volume, which aligns with the results-oriented performance management of Rwanda's strategic health planning frameworks. If well implemented, community engagement can be enhanced through health facility governing committees, ensuring that planning reflects the priorities of service users.<sup>1020</sup>

Furthermore, deficiencies and malfunctions of essential medical reagents and equipment pose another problem to be solved. These shortages have been particularly acute in healthcare settings with limited resources and are exacerbated by under-resourcing and irregular distribution, as discussed earlier. This is evident in poor inventory management, stock-outs, and the loss of expired medicines, as documented in the Auditor General's annual reports. These are coupled with broken-down machines beyond a health facility's financial capacity to repair, newly procured machines incompatible with existing infrastructure, or the available skills. Transportation is another issue

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<sup>1016</sup> Bryan A. Liang, James Maroulis, and Tim K. Mackey, "Understanding Medical Malpractice Lawsuits," *Stroke* 54, no. 3 (2023), <https://doi.org/https://doi.org/10.1161/STROKEAHA.122.038559>.

<sup>1017</sup> Thu Thi Hoai Nguyen, Hung Thanh Phung, and Anh Thi My Bui, "Applying the Workload Indicators of Staffing Needs Method in Nursing Health Workforce Planning: Evidences from Four Hospitals in Vietnam," *Human Resources for Health* 19, no. 1 (2022): 1–7, <https://doi.org/10.1186/s12960-021-00668-y>.

<sup>1018</sup> Taufique Joarder et al., "Assessment of Staffing Need through a Workload Analysis in Jhenaidah and Moulvibazar, Bangladesh: A Workload Indicator of Staffing Need (WISN) Study," *The Lancet Global Health* 7 (2019): S37, [https://doi.org/10.1016/s2214-109x\(19\)30122-6](https://doi.org/10.1016/s2214-109x(19)30122-6).

<sup>1019</sup> MoH-Rwanda, "Health Sector Strategic Plan V" (Kigali, 2024), P. 7.

<sup>1020</sup> Seye Abimbola et al., "The Government Cannot Do It All Alone": Realist Analysis of the Minutes of Community Health Committee Meetings in Nigeria," *Health Policy and Planning* 31, no. 3 (2016): 1–12, <https://doi.org/10.1093/heapol/czv066>.

that prevents the timely delivery of the equipment and supplies to the remote areas, thereby limiting access to essential healthcare services and exacerbating inequities within the healthcare system.<sup>1021,1022</sup>

Addressing the challenges of a deficiency in medical reagents and equipment requires the implementation of strategies such as the modernisation of inventory and supply chain management, and nationwide biomedical engineering frameworks for regular maintenance checks and quick repair of equipment. Besides, the procurement of complex medical machinery should be standardised to ensure its cost-effectiveness, interoperability, and compatibility with the existing facility's ability in terms of financial and human resources. Besides, supplier performance management should be enhanced to avoid failures in the medical supply chain.

Furthermore, the government efforts are required to develop and upgrade infrastructures in remote areas to enable the effective delivery of medical supplies. Additionally, upgrading the healthcare transport logistics system and partnering with third-party logistics providers are equally important. Thus, cross-cutting system reforms are necessary to build a skilled and adequately distributed health workforce, ensure financial sustainability, and improve monitoring and evaluation strategies in healthcare service delivery.

Shortage of medical personnel has also been identified. This situation leads to excessive workload and practitioners' burnout,<sup>1023</sup> contributing to medical malpractice incidents due to a lack of adequate clinical attention, delayed emergency responses, or inappropriate supervision. These challenges contravene patient safety, institutional accountability, and compliant healthcare delivery.

Resolving the issue of a workforce shortage in healthcare in Rwanda requires concerted efforts underpinned by effective workforce planning. Rwanda has a plan to quadruple the number of physicians, which involves strategic investments in training and partnerships with international medical schools to address the existing shortage of physicians. However, other retention strategies are crucial to consolidating those efforts. Among other things, fair scheduling, mental health support, and enhanced clinical governance are necessary to reduce burnout.<sup>1024</sup> To ensure patient safety, implementing structured interventions, such as workload redistribution, regular psychological support, and improved staffing ratios, must be considered as they have proven to be effective.<sup>1025</sup>

Another issue highlighted in this study is the **failure to consider a patient's history**, which may lead to the **duplication of clinical tests, inconsistent care, or misdiagnosis**. Various malpractices, including missed diagnoses, medication errors, or incorrect medical interventions, may result from

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<sup>1021</sup> Modestus Amaechi et al., "From A to O-Positive: Blood Delivery Via Drones in Rwanda," *Research Alliance* (Toronto, 2021).

<sup>1022</sup> WHO, "Rwanda's Primary Health Care Strategy Improves Access to Essential and Life-Saving Health Services."

<sup>1023</sup> Gaston Nyirigira et al., "Staff Burnout and Its Risk Factors at King Faisal Hospital Rwanda: A Cross-Sectional Survey," *BMC Health Services Research* 25, no. 508 (2025): 1–7, <https://doi.org/10.1186/s12913-025-12638-4>.

<sup>1024</sup> Tania Holt et al., "Overcoming Sub-Saharan Africa's Health Workforce Paradox," *McKinsey & Company* (New York, November 2024).

<sup>1025</sup> Holt et al.

this failure and can lead to potential patient harm, such as financial loss and emotional suffering, compensable with a substantial amount of money.

To mitigate diagnostic errors and improve healthcare consistency, it could be possible by using documentation systems and fostering integrated electronic health information systems. The already started initiatives, such as “One Patient, One Record,” should be enhanced to enable clinicians to access consolidated patient histories across facilities. These digital systems reduce test duplication and improve diagnostic accuracy. Additionally, standardised clinical guidelines and digital tools that support clinical decision-making are also essential for minimising errors resulting from information flaws.<sup>1026</sup>

Breaches and violations of patient confidentiality have been identified, despite laws and SOPs in place to protect personal health information (PHI).<sup>1027</sup> Those breaches can occur due to limited digital infrastructure, inadequate training, and a lack of process uniformity in Rwanda’s healthcare settings. Addressing the challenge of personal health data breaches or violations of patients’ confidentiality requires an enhancement of digital health governance. The Rwanda Data Protection and Privacy Law (DPP Law) serves as the foundation for institutional data protection compliance in this regard. However, robust cybersecurity frameworks, including access restrictions, data encryption, an incident response plan, regular audits, regulatory compliance, data minimization, transparency with patients, and data backups and disaster recovery, are essential.<sup>1028</sup> Additionally, enhanced authentication protocols and the digital literacy of health practitioners can contribute to these frameworks.

Offensive and dehumanising language in clinical settings is also a challenge that can accelerate harassment or violence. These can also lead to the termination of therapeutic relationships and litigation if not handled. To handle this problem in a clinical environment requires preventive measures, training of the healthcare workforce, and the establishment of institutional policies promoting respectful communication.<sup>1029</sup> Confidential grievance mechanisms should also be established to encourage reporting of offensive conduct. The health workforce training must also include the aspect of anti-harassment as per the ILO Convention C190 which is required to prevent, protect and redress harassment at the workplace. Remarkably, these measures can strengthen trust, promote humane patient interactions, and reduce the risks of malpractice litigation.

Therefore, establishing a resilient, efficient, and equitable healthcare system that meets the diverse needs of patients and improves outcomes requires a shift in the healthcare system from volume-based care to patient-centered and quality-driven care. The above solutions not only address this issue but also tackle the structural issues that lead to patient adverse events and ultimately result in malpractice lawsuits.

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<sup>1026</sup> Wayan Vota, “Rwanda Digital Health Revolution Is Transforming Healthcare Through Technology,” ICT Works, August 2024.

<sup>1027</sup> Sylvere Mugumya, “Exploring Privacy and Security Issues of Centralized Electronic” (University of Rwanda, Center of Excellence in biomedical engineering and eHealth (CEBE), 2023), p. 16-22.

<sup>1028</sup> Ibid., p. 22-24.

<sup>1029</sup> PSI ILO, ICN, WHO, *Framework Guidelines for Addressing Workplace Violence in Health Sector* (Geneva, Switzerland: International Labour Office, 2002).

#### 8.4. Enhancing accountability and compliance: bridging mechanisms with best practices

The Health Sector Strategic Plan V (HSSP V) focuses on quality, safety, governance, and workforce as central pillars in Rwanda's healthcare system. This long-term strategic plan is expected to accelerate the nation's progress toward universal health coverage and a highly reliable healthcare system. Additionally, fostering a transformation of digital health enables the Rwanda Health Information Exchange (RHIE) and the deployment of e-Ubuzima electronic records to achieve the goal of "One Patient, One Record" (OPOR).<sup>1030</sup> This contributes significantly to specialised and evidence-based medicine, as it facilitates continuity of care, clinical decision-making, and data transparency.<sup>1031</sup>

In the same vein, the new Healthcare Law harmonises professional duties, expands patient rights, and mandates professional liability insurance, which establishes the normative baseline for civil liability and regulatory enforcement. Nevertheless, a legal framework alone cannot provide complete protection against patient harm. Significant improvements in patient safety require institutional structures that incentivise compliance, promote learning from errors, and ensure independent quality control, grounded in human error theory.

The experience of the United Kingdom, France and Canada suggests that various national strategies to govern patient-safety can reinforce accountability and daily clinical practice. The case of the United Kingdom,<sup>1032,1033,1034</sup> France and Canada in terms of building their system-wide safety culture and approach to learning, the mandatory certification of the Haute Autorité de Santé (HAS) in France,<sup>1035</sup> and patient-led safety networks, including the Patients for Patient Safety Canada (PFPS),<sup>1036</sup> demonstrate that a concerted effort of standards, regulating bodies, and effective community involvement can be used to improve patient-safety outcomes. Thus,

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<sup>1030</sup> Rahamthulla Shaik, "Connecting the Dots: Rwanda's Digital Healthcare Revolution," *OPenHIE* (Kigali, Rwanda, 2025), <https://ohic.org/wp-content/uploads/2024/08/RawandaHealthExchangeArchitecture.pdf#:~:text=Rwanda's HIE architecture journey%2C from, to building and sustaining interoperability%2C>.

<sup>1031</sup> Eunice Mutindi, Elias Sebutare, and Sowmya Rajan, "Transforming Rural Healthcare in Rwanda with a Centralized Electronic Medical Records System," *Innovations in Healthcare* (Durham, NC, United States: Duke Global Health Innovation Center, Duke University, 2025), <https://dukeghic.org/wp-content/uploads/sites/20/2025/09/Transforming-Rural-Healthcare-in-Rwanda-with-a-Centralized-Electronic-Medical-Records-System-2.pdf>.

<sup>1032</sup> Amina Catherine Ijiga et al., "Ethical Considerations in Implementing Generative AI for Healthcare Supply Chain Optimization: A Cross-Country Analysis across India, the United Kingdom, and the United States of America," *International Journal of Biological and Pharmaceutical Sciences Archive* 07, no. 01 (2024): 55–56, <https://doi.org/https://doi.org/10.53771/ijbpsa.2024.7.1.0015> Abstract.

<sup>1033</sup> Kathryn Steven et al., "Toward Interprofessional Learning and Education: Mapping Common Outcomes for Prequalifying Healthcare Professional Programs in the United Kingdom," *Medical Teacher* 39, no. 7 (2017): 720–744, <https://doi.org/10.1080/0142159X.2017.1309372>.

<sup>1034</sup> Irene Papanicolas et al., "Performance of UK National Health Service Compared with Other High Income Countries: Observational Study," *British Medical Journal* 367 (2019): 1–12, <https://doi.org/10.1136/bmj.l6326>.

<sup>1035</sup> de l'Autonomie et des Personnes handicapées Ministère de la Santé, des Familles, "Periodic Certification of Healthcare Professionals: A New Decree to Support the Quality of Care" (Paris, France, December 2025), <https://sante.gouv.fr/actualites-presse/presse/communiqués-de-presse/article/certification-periodique-des-professionnels-de-sante-un-nouveau-decret-pour>.

<sup>1036</sup> "Patients for Patient Safety Canada," accessed January 3, 2025, <https://www.patients4safety.ca/>.

empowering patients and families to participate in safety decisions can contribute to incident reporting initiatives, including “never events,” and comprehensive safety frameworks. This approach can encourage practical accountability within daily clinical operations and thus strengthen a culture of life-long learning and enhancement.

South Africa’s Office of Health Standards Compliance (OHSC) conducts regular compliance inspections and certification of health facilities (both public and private) to safeguard patient safety and quality care services. Within this mandate, it conducts routine and risk-based inspections, which may be unannounced if necessary. The Office’s monitoring of health service delivery compliance with national core standards, such as patient safety and clinical governance, has been essential. Additionally, the Office has enforcement powers, including issuing compliance notices, recommending service suspension, and referring serious breaches to the Health Ombud, to ensure patients’ grievances can inform regulatory oversight.<sup>1037</sup>

Rwanda’s inspection frameworks involve the Rwanda Agency for Accreditation and Quality Healthcare (RAAQH) and MINISANTE, which conduct the same process more frequent and risk-stratified in high-risk departments, such as ICUs and maternity units. In this regard, Rwanda can benefit from the OHSC’s best practices of shifting beyond periodic accreditation towards continuous compliance monitoring, which better identifies latent system failures before they lead to harm. Additionally, it can enhance the accountability function of the certification through measures such as mandatory corrective action plans and referrals for professional discipline, aligning it with liability prevention rather than mere quality improvement.

Quality of care delivery is affected by various factors, but one of the most important factors is hospital flow. The inefficiency of this flow, like unnecessary delays and frustration on the part of a patient may be a serious deterrent to improved service results. Effective leadership and interventions are necessary in order to improve the output of the patients. Additionally, operational strategies should be created at the system-wide level in a patient-centered approach in order to achieve optimal care coordination and experience.<sup>1038</sup> The literature also suggests that good management requires the ability to measure relevant constructs. In line with this, Zimmerman and Stern argue that professionalism should be understood as not just an attitude, but a set of behaviours that can be measured and enhanced.<sup>1039, 1040</sup>

In this regard, OHSC inspections underscore that adverse outcomes are often the result of systemic failures rather than individual lapses, as founded by the human error theory.<sup>1041</sup> The system-based

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<sup>1037</sup> Linda Pretorius and Jacques Verryn, “‘We Can’t Have Everything.’ What Checks Should SA Use to Rate Health Facilities?,” Bhekisisa Centre for Health Journalism, September 2025, <https://bhekisisa.org/health-news-south-africa/2025-09-11-we-cant-have-everything-what-checks-should-sa-use-to-rate-health-facilities/>.

<sup>1038</sup> Rahul K. Shah and Sandip A. Godambe, *Patient Safety and Quality Improvement in Healthcare: A Case-Based Approach*, *Patient Safety and Quality Improvement in Healthcare: A Case-Based Approach*, 2020, <https://doi.org/10.1007/978-3-030-55829-1>.

<sup>1039</sup> Kanter et al., “What Does Professionalism Mean to the Physician?”

<sup>1040</sup> David T. Stern and Maxine Papadakis, “The Developing Physician — Becoming a Professional,” *The New England Journal of Medicine* 355, no. 17 (2006): 1794–97, <https://doi.org/10.1056/NEJMra054783>.

<sup>1041</sup> Hlombe Azukile Makuluma, “An Analysis of Medical Risk Inspections in the Context of the Office of Health Standards Compliance (OHSC)” (University of Pretoria, 2021), p. 33.

perspective aligns with modern patient-safety theory and could help Rwanda shift from blame-oriented malpractice responses toward preventive risk management. Another point of consideration from the South African model is the linkage of inspection findings with patient complaints and adverse-event reporting mechanisms. One cannot ignore the publication of inspection outcomes, compliance reports, and annual performance reports, as these efforts promote transparency and public trust in the healthcare system.

### **8.5.Proposal for reform**

Potential enhancements are needed in the following areas: Professional insurance needs to be implemented in healthcare service delivery. Additionally, there is a need to foster ADR methods, such as mediation, conciliation, and arbitration, within the healthcare malpractice compensation process to address the issue of delays. Besides, mandatory reporting through adverse event databases should be enhanced, together with patient education campaigns about their rights and adverse event reporting mechanisms.

Moreover, the shortage of healthcare personnel, regulatory gaps, deficiencies in healthcare planning, productivity-driven compensation models, and scarcity of resources suggest reforms in various approaches by incorporating best practices. Training healthcare professionals should incorporate aspects such as skills for practice, which involve several soft skills common to all health professionals, including effective communication with patients, good record-keeping, and practical procedures such as selecting appropriate investigations.

Gaps in patient rights and safety mechanisms have been identified, despite the new healthcare law, which, if well implemented, guarantees a solution. The implementation of healthcare laws in this regard would involve various measures, such as an awareness campaign, to address the awareness gaps identified in patients' rights.

Moreover, systemic issues (lack of preventive safety measures such as near miss and error-reporting systems, and training deficiencies necessitate reforms in the design of healthcare delivery to enable evidence-based clinical practice and evidence in the compensation process.

#### **8.5.1. Adequate healthcare service delivery and compensation model for Rwanda**

A model designed to enhance the safety of healthcare service users and streamline the compensation process in the event of medical malpractice incidents for the Rwanda Healthcare Service Delivery is hereby presented. The model entails the following five layers:

- i. Patient interaction and safety;
- ii. Professional competence and reporting;
- iii. Compensation and institutional governance;
- iv. Ethical and legal aspects; and
- v. Continuous improvement

Within the context of the first layer of “patient interaction and safety”, approaches such as the patient-centred approach and the human rights-based approach should be integrated in all healthcare settings and taught in medical schools. This layer enhances the patient's dignity by respecting their opinions on mode of treatment and involving them in decision-making processes

through informed consent, while also supporting self-care. In this light, the duty of candour and sincere apology, which requires healthcare providers to be honest, open, and transparent with healthcare service users and their families throughout the healthcare delivery process, even in the event of an adverse outcome, is essential. This approach also enables healthcare professionals to recognise and protect ‘at-risk’ patients. Those who might be at risk of clinical worsening, and children and other vulnerable patients who might be at risk of clinical abuse or neglect.<sup>1042</sup> Incorporating the principles of equality, inclusion, risk prevention, and diversity in healthcare delivery is crucial to ensure equitable access, reduce disparities, and enhance patient outcomes, thereby supporting continuous quality improvement. To measure the outcome of patient interactions and safety (the first layer), dimensional tools such as patient-reported experience measures (PREMs) and patient-reported outcome measures (PROMs) can be utilised.<sup>1043</sup>

The second layer is “Service delivery competence and reporting,” which focuses on adherence to SOPs, feedback mechanisms, CPD, and “just culture”. In this regard, pre-qualification (pre-licensure) and post-knowledge assessments of professional knowledge are crucial for maintaining professional competence and ensuring legal and ethical compliance in clinical practice. Both assessments constitute an important tool of a robust healthcare system with competent personnel who can work within a challenging and fast-evolving environment of the medical industry and produce the expected outcomes. In addition, effective teamworking is another essential component in patient safety, as most adverse outcomes result from systemic failures rather than individual lapses. Collaborative practice is essential in healthcare delivery, as high-quality healthcare depends on the coordinated efforts of professionals from different disciplines and areas of expertise. Robust teamwork helps maintain ethical and legal compliance by enhancing communication and accountability, thereby reducing the probability of preventable errors.

Besides, the Patient Safety Incident Response Framework (PSIRF) or PSIRF-style learning is suggested to be employed in obtaining patients’ input to improve healthcare delivery. PSIRF represents a structured approach to managing patient safety incidents within the National Health Service (NHS) in England. This approach prioritises “systemic learning” and “blame-free culture,” a shift from focusing on individual error.<sup>1044,1045</sup> PSIRF-style cultivates a “just culture” and helps healthcare providers balance accountability with learning, creating an environment where healthcare practitioners feel safe reporting errors and system flaws without blame, instead focusing

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<sup>1042</sup> Steven et al., “Toward Interprofessional Learning and Education : Mapping Common Outcomes for Prequalifying Healthcare Professional Programs in the United Kingdom,” p. 723.

<sup>1043</sup> Vaibhavi Walimbe et al., “Patient Reported Experience Measures: A New Scale That Records Another Dimension of Patient Care Quality Important in Clinical Practice–Letter to the Editor,” *European Journal of Physiotherapy* 26, no. 2 (2024): 119–22, <https://doi.org/10.1080/21679169.2024.2305355>.

<sup>1044</sup> Patient Safety Learning, “Patient Safety Incident Response Plans: An Analysis and Reflection by Patient Safety Learning” (England, May 2025), [https://d2z1laakrytay6.cloudfront.net/Report\\_PSIRPS\\_AnalysisandreflectionbyPatient-Safety-Learning\\_Issued.pdf](https://d2z1laakrytay6.cloudfront.net/Report_PSIRPS_AnalysisandreflectionbyPatient-Safety-Learning_Issued.pdf).

<sup>1045</sup> “Patient Safety Incident Response Framework,” NHS England, September 2025, <https://www.england.nhs.uk/long-read/patient-safety-incident-response-framework/>.

on fixing the systemic failure. In the same context, the literature reveals a relationship between positive culture and better outcomes for patients in clinical settings.<sup>1046</sup>

The conceptual foundation of PSIRF-style and just culture aligns with Reason's "Human Error theory," which suggests that errors are typically the result of complex systemic interactions rather than a single root cause or individual professional failings.<sup>1047</sup> These tools also help to reach the patient safety incident response policy or plan, and if adopted, they could help prevent future medical malpractice incidents in Rwanda. In the same context, "feedback loops" are essential in providing feedback or inputs that could influence future actions and outcomes in healthcare delivery, as well as the malpractice compensation process.

Additionally, adherence to Standard Operating Procedures is a crucial aspect of medical professional practice, particularly in reporting and malpractice handling.<sup>1048</sup> These procedures can enable Rwandan health organisations to prevent errors and maintain efficiency. Indeed, they can help ensure consistency, accuracy, uniformity, quality, safety, and regulatory compliance in healthcare service delivery and the compensation process. Besides, other considerations, such as ethical practice, teamworking, pre-qualification assessment of professional knowledge, post-knowledge assessment, enhancement of professionalism through CPDs, and assessment of professional-specific outcomes, are key in the design under layer two.

The third layer entails "institutional governance and compensation". This layer proposes institutional accountability and privacy by design (PbD in healthcare governance. It also suggests fair and transparent compensation that applies transparent criteria instead of using general accident quantum criteria. The latter approach has been general in medical malpractice compensation, but it potentially restricts victims. Applying motor accident "floors" is complex and unreasonable in medical malpractice cases, which often involve medical experts and long-term patients whose genuine losses may exceed the standardised minimums. Additionally, quantifying medical injuries (e.g., damage to internal organs or psychological harm) by applying "material damage" criteria, a common standard in motor accident law, does not fit medical malpractice issues. The compensation process must also reflect legality and proportionality to be legally grounded and proportionate to the risk. Moreover, feasibility and phasing should be incorporated as a core component, enabling the system to adopt updated standards and a phased implementation approach, thereby preventing symbolic compliance.

In addition, the third layer consists of the mandatory professional indemnity insurance, which is essential in clinical practice, given that it offers financial protection to healthcare providers, thus alleviating their bankruptcy risks in cases of malpractice lawsuits and compensation. In addition, liability incentives are highlighted in this layer as a workforce incentive that should be strategically linked to measurable reductions in liability risk. This may involve the use of performance-based

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<sup>1046</sup> Jeffrey Braithwaite et al., "Association between Organisational and Workplace Cultures , and Patient Outcomes :Systematic Review," *British Medical Journal* 7, no. e017708 (2017): 1–11, <https://doi.org/10.1136/bmjopen-2017-017708>.

<sup>1047</sup> van Baarle et al., "Fostering a Just Culture in Healthcare Organizations: Experiences in Practice."

<sup>1048</sup> "Creating Standard Operating Procedures (SOPs) for the Healthcare Industry," *The Manual*, accessed January 5, 2026, <https://trainual.com/manual/standard-operating-procedures-sops-healthcare-industry#:~:text=SOPs%2C or Standard Operating Procedures,reduce errors%2C and increase efficiency>.

bonuses, e.g., PBF, on observing safety measures, reporting on the errors proactively, and being part of the continuous professional development programs aimed at reducing the risk. The model encourages accountability and patient safety culture and lessens institutional and personal liability by encouraging behaviours that help reduce exposure to malpractices.

The early notification concept of medical malpractices and compensation is defined as the act of providers reporting adverse events or occurrences too early, before the victim takes legal action. According to Tom A. Augello, this approach underscores the timely involvement of providers and their insurers. It promotes openness, active disclosure, and apology, despite the determination of fault.<sup>1049</sup> The main goal of such an approach is to speed up the process of compensation claims, minimize litigation expenses, offer prompt services to the patients, and facilitate institutional learning and reforms of policies.<sup>1050</sup> Thus, early notification promotes “open communication” after patient harm, provides early support to affected patients and families, enhances system-wide safety and governance by learning from incidents, and builds trust within the healthcare institutions. It also greatly diminishes defensive medicine, which often results from a circle-the-wagons approach.

Privacy by Design approach in health institutional governance is also incorporated in this layer. This integration plays a crucial role in the delivery of health services, as it has the capacity to enhance patient safety within a healthcare facility and during the adjudication of malpractice claims.<sup>1051</sup> Privacy by Design is about making privacy and data protection a part of how systems, technologies, and even laws are designed and operate- before the personal data is processed at all. PbD is a binding norm that will enhance accountability, mitigate the threat of data breaches, and reinforce the safeguarding of fundamental rights of people, particularly in the healthcare field, which poses significant risks. Dr. Ann Cavoukian developed this concept, which has become a global standard.<sup>1052</sup> It has been adopted by the authorities of data protection in various countries as a necessary response to the increased threats posed by contemporary technologies.<sup>1053</sup> The PbD approach can play a key role in ensuring patient safety and facilitating the adjudication of malpractice claims in Rwanda.

To measure the outcome in the landscape of the third layer, there must be reports on the rates of complaints resolved through ADR, from the filing date (median day) to the ADR resolution (ADR outcome). Additionally, the share of cases with a formal apology should be reported to facilitate the incentivise liability. Additionally, the durability of ADR resolution can be evaluated by the number of settled malpractice claims that do not require further litigation within one year after the settlement resolution.

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<sup>1049</sup> Tom A. Augello, “The Earlier the Better: More MedMal Insurers Offer Real-Time Support After Patient Harm,” CRAICO, January 2021, <https://rmfcd1-prod.rm.f.harvard.edu/Podcasts/2021/Early-Resolution>.

<sup>1050</sup> Augello.

<sup>1051</sup> Cavoukian Aann, *Privacy by Design: The 7 Foundational Principles*, The Sedona Conference Institute (Toronto, Ontario - Canada, 2011).

<sup>1052</sup> Ann Cavoukian, *Operationalizing Privacy by Design: A Guide to Implementing Strong Privacy Practices* (Ontario, Canada: Information and Privacy Commission, 2012).

<sup>1053</sup> Cavoukian.a

The fourth layer integrates both ethical and legal perspectives, while establishing additional remedial forums and mechanisms to address delays in malpractice complaints and compensation procedures. In other words, collectively, the healthcare system and judiciary must guarantee fair and transparent compensation mechanisms, even in cases where evidence is insufficient, by adopting a no-fault compensation approach supported by a dedicated compensation fund for victims of medical malpractice. Moreover, the layer suggests ADR mechanisms—such as conciliation and mediation—to expedite the compensation process and minimise reliance on lengthy and adversarial court proceedings.

There should also be a legal and policy framework to protect apologies, which facilitates learning in a system and encourages the culture of justice. The layer further suggests a time-limited settlement of the medical malpractice claims, which consolidates both fair and timely compensation. This corresponds to and enhances the previous layer of compensation and institutional governance, all of which are designed to provide justice in real-time.

The fifth layer regards “continuous improvement” in healthcare delivery and the malpractice compensation process. It suggests ongoing monitoring and evaluation, quality improvement, public reporting, policy updates, executive pay tied to safety, and healthcare financing to maintain the integrity and resilience of the healthcare system.

Monitoring and evaluation practices with KPIs are essential in patient-centred healthcare delivery and malpractice compensation processes as they enhance accountability and improve healthcare delivery through greater support of the data-driven governance system that promotes operational integrity and patient-focused outcomes. They also streamline the compensation procedures through tracking efficiency, equity, and sustainability. Besides, tying executive pay to safety is an essential approach Rwandan healthcare providers could employ to minimise malpractice incidents. Executive pay tied to safety refers to bonuses or long-term incentives that are paid based on measurable safety performance metrics.<sup>1054, 1055</sup> They have been found helpful in the U.S. Hospitals in reducing injuries or fatalities.<sup>1056</sup>

Furthermore, public reporting is the process that oversees the systemic release of performance measurements, safety signals, and results to the stakeholders, such as patients, regulators, and the general population. This method would increase transparency, accountability, and trust and contribute to high standards of care among the providers. Public reporting of negative occurrences or patient safety indicators permits benchmarking and the development of an organisational culture of openness, which is vital in continuous improvement. In addition, during malpractice compensation, the publication of claims information, settlement periods, and settlement distribution policies by the government encourages fairness and systemic learning. It discourages the fact that mistakes are hidden and extends informed policy-making by pointing out trends in

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<sup>1054</sup> Lucia Meloni and Cemre Aksu, *The State of Pay: ESG Metrics in Executive Remuneration* (New York: CANDRIAM, 2023), p. 6-46.

<sup>1055</sup> Shira Cohen et al., “Executive Compensation Tied to ESG Performance: International Evidence,” ed. Mike Burkart et al., *Journal of Accounting Research*, vol. 61, 2023, <https://doi.org/10.1111/1475-679X.12481>.

<sup>1056</sup> James Rice, Rick Norling, and Jim Conway, *Executive Pay and Quality: New Incentive Links* (San Diego, Boston, Minneapolis: Integrated Healthcare Strategies, 2013), p. 5-6.

negligence action and the sufficiency of cover. Moreover, frequent review of the policies will mean that the governance structures are kept abreast with the changing clinical standards, legalities, and social expectations. The policy changes implemented in healthcare delivery include new safety measures, new technologies, and evidence-based practices to reduce risk and improve patient outcomes. The malpractice compensation policy undergoes regular revisions to procedures on claims handling, ADR mechanisms, and compensation limits, which guarantee effectiveness, fairness, and adherence to international best practices. They also assist in institutionalizing patient-centered strategies, including early notification and apology legislation. Both public reporting and regular policy updates provide transparency of data, which creates an informed policy reform that enhances accountability and safety. They are also essential to the creation of robust healthcare systems and fair compensation systems, which are sensitive to the protection of patients and institutional integrity.

Healthcare financing is another important trait of this layer, which plays a critical role in sustaining safe healthcare service delivery and robust malpractice compensation. Appropriate funding allocates resources to enhance quality care, implement patient safety initiatives, and train medical personnel. It also supports timely and equitable compensation mechanisms, benefiting victims of medical adverse events. Without stable financing, both preventive safety measures and responsive compensation systems risk inefficiency and inequity.

Furthermore, introducing regulatory sandboxes could significantly benefit Rwanda's healthcare system, particularly when implementing innovative legal and governance mechanisms. They can play a crucial role in the development of healthcare through various aspects, including creating a safe testing environment, promoting evidence-based reform, fostering stakeholder engagement, and driving innovation in governance. The public reporting and regular policy updates can use these tools to reach their objectives.

These sandboxes are essential tools that can help establish a safe environment for testing when health regulators are piloting new legal frameworks, such as no-fault compensation funds, ADR mechanisms, and Duty of Candour obligations, before widespread implementation. Thus, they could help reduce risk by limiting the scope to selected hospitals or regions. Additionally, regulatory Sandboxes are crucial tools for collecting real-world data on key performance indicators (KPIs), such as compensation timeliness, ADR resolution rates, and disclosure compliance, before the adoption of any healthcare bill. This could help facilitate progressive improvement of compensation models and the enforcement of patients' rights. The regulatory sandboxes can also encourage the stakeholders' engagement and inclusion in healthcare by involving providers, insurers, patient rights advocates, and regulators in designing the solution. This creates an environment of trust and transparency, enabling sensitive reforms, such as protection of apology and liability incentives, to be effectively implemented. Regulatory Sandboxes are also crucial to innovation governance, where digital tools for complaints management, ADR scheduling, and compensation fund management are used. They could also encourage risk-based regulation in line with the country's health system modernisation goals, reducing clinical adverse outcomes.

Table 6. Suggestive model for enhancing patient safety and healthcare accountability in Rwanda

<b>Patient interaction and safety</b>	<b>Service delivery competence and reporting</b>	<b>Institutional governance and compensation</b>	<b>Ethical and legal aspects</b>	<b>Continuous improvement</b>
<ul style="list-style-type: none"> <li>• Informed consent</li> <li>• Patient dignity</li> <li>• Information access</li> <li>• Duty of Candour</li> <li>• Safe apology</li> <li>• Ensure equality, inclusion, risk-prevention, and diversity</li> <li>• Protection of vulnerable individuals</li> <li>• Human rights-based care</li> <li>• Patient-centred care</li> <li>• PREMs and PROMs</li> </ul>	<ul style="list-style-type: none"> <li>• Pre-qualification assessment</li> <li>• Post-knowledge assessment</li> <li>• Teamworking</li> <li>• CPDs</li> <li>• Adherence to SOPs</li> <li>• Feedback mechanisms (Feedback loops)</li> <li>• PSIRF-style learning</li> <li>• Just culture</li> </ul>	<ul style="list-style-type: none"> <li>• Institutional accountability</li> <li>• Privacy by Design</li> <li>• Mandatory professional insurance                             <ul style="list-style-type: none"> <li>• No-fault compensation funds</li> </ul> </li> <li>• Liability incentives</li> <li>• Fair compensation</li> <li>• Transparent quantum criteria</li> <li>• Early notification</li> <li>• Feasibility and phasing</li> <li>• Evaluation of post-settlement durability</li> </ul>	<ul style="list-style-type: none"> <li>• Provision of specific redresses pathways</li> <li>• Incorporates ADR (conciliation, mediation)</li> <li>• No-fault compensation system</li> <li>• Apology protections</li> <li>• Time-bound settlements</li> </ul>	<ul style="list-style-type: none"> <li>• Ongoing monitoring and evaluation (with KPIs)</li> <li>• Quality improvement (QI reviews)</li> <li>• Public reporting</li> <li>• Regular policy updates</li> <li>• Regulatory Sandbox</li> <li>• Executive pay tied to safety</li> <li>• Healthcare financing</li> </ul>

## 8.6. Conclusion

Patient-safety remains a major concern in the Rwandan healthcare system. Medical malpractice remains prevalent across various healthcare facilities. However, the rate of malpractice incidents is always underreported despite a higher actual occurrence of medical injuries. This underreporting stems from various factors, including lack of public awareness on patient rights, fear of retaliation and social stigma, costs of litigation and cultural practices which favour reconciliations. The shortages in the existing legal and regulatory framework that has no proper corporate liability and effective enforcement mechanisms are additional factors which hinder the successful implementation of laws and policies that provide professional liability insurance, consumer rights for healthcare user as a consumer of healthcare service and pharmaceutical products. The clinical shortages induced by systemic shortfalls in healthcare planning, resources, and staff exacerbate practitioner burnout and negatively affect safety.

To solve these problems, a five-layered model has been suggested to reinforce the patient safety and enhance the process of malpractice compensation. It facilitates patient-centred and human rights-based practices, informed consent, and the duty of candour, and improved service delivery via CPDs, SOP compliance and a non-punitive culture of reporting errors. Other components of the model include more institutional governance, obligatory insurance of liability, transparent redress channels, ADR, no-fault compensation, ongoing monitoring, public reporting and regulatory sandboxes.

## CHAPTER NINE

### CONCLUDING REMARKS

#### 9.1. Conclusion

This dissertation is designed to answer the central research question: **“How does Rwanda implement its medical liability framework, and what can be done to strengthen healthcare accountability and patient safety?”** The dissertation is structured in nine chapters to enable a deep and systematic investigation of all the research questions. Throughout this analysis, which integrates doctrinal and non-doctrinal approaches, the research shows that Rwanda has gone a long way in creating a medical liability regime, but there are still structural, regulatory and operational loopholes that undermines the regime’s effectiveness.

The first or preliminary part of this dissertation comprises of three chapters, providing the background, conceptual, theoretical, and methodological foundation for the inquiry. The second part of the dissertation engages directly with sub-research questions and composes five chapters including chapters four, five, six, seven, and eight, some of which are exclusively designed to answer specific sub-research questions. Then, the last part is Chapter Nine which embodies the concluding remarks.

The research began with an introductory chapter, which plays a pivotal role in the background of the subsequent chapters. It lays down the context of this research by providing a brief introduction to Rwanda and its legal system. It also provides a historical evolution of the Rwandan healthcare system, which brings the rationale for choosing Rwanda as a case study. It is important to note the country’s efforts, after the 1994 Genocide against the Tutsi, in the establishment and empowerment of healthcare institutions so that they work towards assuming accountability, safeguarding patient rights and safety, as well as promoting ethical standards in medical practice.

The second chapter explores the conceptual framework and paradigmatic part of the entire research by diving into various concepts necessary to understand the research and theories, and the paradigm that underpins the study. Some of the key concepts discussed in this section include medical malpractice, medical negligence, duty of care, and medical standards of care. These concepts enable adequate comprehension of the research as they contribute much to the core discussion of the topic. Besides, the chapter presents the Kantian deontological paradigm, which underscores the moral duties and principles that healthcare professionals must uphold, irrespective of outcomes. It is worth noting that this paradigm, if adhered to, can provide a robust ethical foundation for medical practice in Rwanda. Besides, Chapter Two also presents professional liability theory, which is the framework for establishing liability and accountability of professionals such as medical practitioners for their acts or omissions causing harm to healthcare service users. This spirit of professional liability has also been found crucial to guide this research, as has been found practical in Rwanda through various institutions such as healthcare professional

councils, the Rwanda FDA, and the Ministry of Health. Another paradigm that underpins this research is ‘human error theory’ introduced by James Reason. This theory is systemic-focused by acknowledging the organizational failures instead of attributing the causes of errors to personal deficiencies and appealing to punishment. The adoption of this model can significantly cultivate a “just culture” within healthcare organisations. In Rwanda, its implementation into hospital management can create an opportunity to reduce preventable harms, support accountability, and foster a culture of safety and continuous improvement. The chapter concludes by highlighting the importance of adopting those models as they corroborate compliance with accepted international medical standards to ensure the safety of healthcare service users and accountability within the Rwandan healthcare system.

Chapter Three described the mixed-method approach utilised to examine the legal framework and to evaluate its realisation in the broader context of the Rwandan socio-legal framework. The doctrinal part focuses on a systematic analysis of relevant legal and regulatory sources to establish the legal basis and identify gaps or uncertainties. A non-doctrinal approach has enabled the evaluation of the actual functioning and effectiveness of legal and regulatory frameworks in practical settings, considering socio-legal contexts and stakeholders' perspectives. The chapter further details methods and techniques utilized throughout both the data collection and analysis stages.

Addressing the first sub-research question, **‘To what extent do medical malpractice and negligence cases occur in Rwanda, and what are their predominant forms and underlying contributing factors?’** was done throughout Chapter Four, which discusses particularly the landscape of medical malpractice in Rwanda. It examines the common forms of medical malpractice, their contributing factors, and remedial pathways. This chapter presents empirical data collected from healthcare professional councils, the Ministry of Health, and the judiciary throughout this study.

The chapter begins with a global view on medical malpractice by citing the 2018 report of the World Bank, WHO, and OECD, which documented that medical malpractices occur in all countries, with exceptionally high intensity in low- and middle-income countries, where the situation worsens. This is not a unique problem for the developing world; the 2020 OECD report on the economics of patient safety also indicates that unsafe health care claims the lives of 4 out of every 100 patients in the developed world and that more than 1 in 10 patients incur injury due to safety lapses in their treatment.

After offering a global overview of medical malpractice, the chapter provides a short literature review on medical malpractice and some of the underlying factors in Rwanda. It further presents the findings from data collected under the present study. The findings reveal that prevalent forms of medical malpractice include diagnostic errors, medication errors, wrong-site surgeries, maternal and neonatal injuries and deaths, postoperative care and monitoring, documentation lapses, and

breaches of informed consent. Obstetrics/Gynaecology has been documented to be the leading source of complaints. In addition, several factors that contribute to medical malpractice incidents, were discussed under this chapter through three main arrays including systemic factors, organisational factors, and human factors.

Furthermore, the discussion goes to the effects of medical malpractice and negligence in patients and their families, where they experience the loss of human lives, iatrogenic injuries, reduced quality of life, prolonged hospital stays and readmissions, and extra-health costs. This discussion also extends to the effects of medical malpractices on healthcare providers, including professional consequences and changes in practice resulting in defensive medicine. The discussion does not cease without highlighting the effects of medical malpractices on the healthcare system and the community, including posing a burden on the legal system through litigations, increased costs, erosion of public trust, and influence on healthcare access and cultural behavioral shift.

The discussion concludes by raising some concerns about the compensation system, which is challenging due to a fault-based model, which typically requires a guilty conviction against the defendant to obtain compensation. This leaves the victims without adequate compensation despite the injury suffered. The research makes a call for systematic re-examination of the current medical and legal frameworks to ensure patient safety and justice to improve the victim's reparation, reduce blame on individual practitioners' actions, and focus on systemic weaknesses' correction, as outlined in Human Error Theory.

Chapters Five and Six covered the second sub-research question: **'How do Rwanda's legal and regulatory frameworks establish a liability regime for malpractice and negligence, and what challenges undermine its effectiveness?'** These chapters dive into efforts of the Government of Rwanda in pursuing a legal and regulatory environment that prevents unsafe healthcare practices and outline challenges that hinder its implementation. Chapter Five examines various legal, regulatory, and institutional frameworks available to safeguard the healthcare users' rights and safety. This entails various patient rights enshrined in the constitution and the healthcare law, together with the duties and responsibilities of medical practitioners towards their patients. It also highlights the gaps existing within the medical liability system. The same chapter discusses the complaint pathways and institutional process towards the medical liability complaints. Besides, Chapter Six is core to the subject matter of this research. This discusses the liability of medical malpractice in depth. It begins with a historical background of medical liability and its rationale. In this regard, it provides a foundation for medical liability since the era of the Law of Hammurabi (1794 BC), Chinese Confucian precepts (515-476 BC), to the Rwandan pre-colonial kingdom era, where disputes over harmful treatment were informally resolved through a community-based process handled by elders or local councils applying customary law. This has progressed with modern medicine under the German and Belgian colonial periods, whereby Rwanda's medical liability system followed European civil and penal codes (Belgian law), applied mainly to Europeans and formal institutions, while the related disputes for native patients could be resolved

informally and rarely went to courts. The discussion underscores the role of laws from the colonial legacy in addressing medical malpractices as either a civil or criminal issue. Such continuous evolution led to the establishment of the medical council in 2003 and notable law reforms after the Genocide against the Tutsi, which accelerated the recent consideration of the foreign precedents and doctrines in Rwanda's medical liability system.

Besides, the discussion turned to the rationale justifying medical liability including protection of healthcare users, legal compliance, deterrence, accountability, and reparation. It further explores the ethical dilemma in healthcare accountability, including injury without damage (*Injuria sine damnum*), where a doctor's opting to undergo a painful procedure while there is a less painful option may raise a legal claim. This ethical dilemma extends to accountability without injury, where medical lapses (near misses) could be punished based on the likelihood of causing medical harm next time.

The models of medical liability have been investigated, including tort-based systems, no-fault compensation, and a hybrid system. The fault-based compensation system is discussed, and various case laws in Rwanda and abroad were referenced to substantiate the discussion. Vicarious liability and grounds for excluding medical practitioner fault and liability are outlined. It should be noted that the Rwandan system of liability supports the fault-based liability mechanism through mandatory insurance and the establishment of committees responsible for addressing disciplinary faults in healthcare facilities, although it is expensive in terms of procedure and stressful in proving the breach of duty of care owed due to its adversarial nature and time cost. On the other hand, the no-fault compensation system, which is dominant in Denmark, Finland, New Zealand, and Sweden, facilitates healthcare users who suffered harm to receive compensation without having to prove negligence through the technicalities of a court case.

The discussion extended to various liability principles and rules, including the application of the doctrine of '*novus actus interveniens*,' which limits or excludes the defendant's liability by reducing the causal remoteness in the chain of events that resulted in an adverse outcome, when any act or event interrupts the causal chain between the defendant's original event and outcome. The eggshell skull rule has also been discussed. This imposes the defendant's liability for the full extent of the claimant's unforeseeable and common reaction to the defendant's negligent or intentional wrongful acts, as long as they constitute a proximate cause.

Moreover, the '*Bolam test*,' the common law doctrine, and the Bolitho addendum, which redefined the *Bolam test*, were examined to enable the understanding of the standards of care in civil law. It is worth noting that although Rwandan courts do not recall the *Bolam test*, their practice reveals it as medical expert reports play a pivotal role in the assessment of the defendant's conduct against the standards of professional norms.

Various forms of medical liability in Rwanda were examined, including professional liability, administrative liability, civil liability, criminal liability, and corporate liability. Professional liability is exercised by professional medical councils through professional disciplinary measures based on the nature of the fault, while administrative or disciplinary liability (disciplinary sanctions) are imposed by Government institutions, such as the Ministry of Health and public service commission, after administrative disciplinary proceedings determined by the Presidential Order on Professional Ethics.

Furthermore, both civil and criminal liabilities are imposed through court proceedings. For civil liability, the basis for determining civil damages may be based on the contractual relationship between healthcare providers and healthcare service users. Civil damages may also be based on the vicarious liability, also known as imputed liability, as providers could be held liable for the torts of their employed medical practitioners. Additionally, if the criminal court convicts a medical practitioner of committing a criminal act against the patient, the latter is sentenced. This is similar to the situation where the court finds the suspect guilty of an overwhelming negligence (gross negligence) that harmed the patient, such as involuntary manslaughter, the practitioner is sentenced under the general criminal code of Rwanda, despite the lack of intention to cause that harm. Besides, the chapter extends the discussion about medical liability in Rwanda by analyzing how the damages in civil actions arising from medical crimes are assessed with a comparative approach, in which various approaches in different jurisdictions, including France, Hungary, South Africa, and Canada, were considered.

Corporate liability is another approach in place that contributes to medical liability within the context of tort law. This is also known as institutional liability, which aims to promote high-quality care and enhance organizational accountability for systemic failures. It evokes the doctrine of “respondeat superior” in the context of hospital liability. In this regard, behaviours such as the organisation’s shortage of occupational safety and health measures could be punished. In the Rwandan context, providing a safe care environment to patients is a “non-delegable duty” for healthcare providers. This compels them to fulfill their obligation to implement risk assessment systems that reduce the incidence of medical malpractice, whose failure may invoke corporate liability notwithstanding a lack of medical practitioners’ negligence.

Medical liability was also analysed from a human rights perspective, where the Constitution of Rwanda recognizes fundamental rights such as the right to life and physical and mental integrity, and various international and regional legal instruments, such as ICCPR and Banjul Charter, to which Rwanda is part, acknowledge the principles of restitution, compensation, rehabilitation, satisfaction, and guarantees of non-repetition. With a human rights approach, a victim who is not content with the decisions of the local courts may seek justice from regional or international courts such as the African Court of Human and Peoples’ Rights.

The doctor-patient relationship (professional-patient relationship) is a contractual relationship that also may be the basis for medical liability. This contract is implied as it is founded on the doctor's acceptance to treat a patient, with an obligation to provide medical care aimed at restoring the patient's state of health or for medical needs. It imposes an obligation to provide care with reasonable skill and knowledge, diligence, and compliance with medical standards. This contractual relationship has far-reaching implications. From this angle, even third parties, such as hospital visitors and the patient's family members affected by medical treatment, fall within the protective scope of the patient's contractual rights and may invoke claims for breach of contractual obligations owed to the primary patient. Although this is not common in Rwanda, it is another avenue that could be explored to obtain compensation resulting from medical malpractice harm.

Under consumer protection act, medical liability is also possible. In this regard, a healthcare service user is considered a 'consumer' while a healthcare service is a consumer transaction and a business that sells services and products, including medical devices and medications. Although this framework is not well developed in the context of healthcare service provision, consumers of healthcare services who have been harmed by a deficiency of healthcare services may take action against the providers. Such liability could also be extended to healthcare-providing corporations that fail to comply with consumer safety standards in healthcare. Additionally, strict liability for failure to warn and failure to counsel could be imposed on a medical practitioner who fails to prescribe an appropriate medication or who does so without informing the healthcare service user of the associated risk information could also be held liable. In the same vein, pharmacists could be held liable for patients' harm resulting from dispensing the wrong medication. There is also a possibility of their liability when they fail to identify clear prescription errors, cause mass drug injuries, or practice off-label marketing. This liability may also extend to pharmaceutical manufacturers for drug defects in design, manufacturing, or labeling.

In Rwanda, the recoverable damages in medical malpractice cases include both pecuniary liabilities (economic damages) and non-pecuniary liabilities (emotional damages). Pecuniary damages are objective and involve both *damnum emergens* (direct loss) and *lucrum cessans* (prospective loss) while emotional damages cover subjective, non-monetary harm or human cost that cannot be precisely measured, although it has a significant impact on the victim's quality of life. This comprises 'pain' and 'emotional suffering' endured by the victims of medical malpractice.

A comparative approach was used to assess how civil damages are awarded in jurisdictions of France, Hungary, South Africa, and Canada. In France, any harm suffered without limitation, known as "tout préjudice doit être réparé," could be awarded based on Article 1382 of the 1804 French Civil Code, which was revised to Article 1240 in 2016. Thus, even future economic losses (*lucrum cessans*), such as long-term care costs, could be awarded. The French framework of handling medical malpractice claims could involve judicial courts and the administrative branch, dealing with the state bodies in the event of a medical accident.

In France, pecuniary damages involve direct financial losses and future economic losses, such as long-term care costs, and consequential harm. Additionally, non-pecuniary damages are awarded for a wide range of harms, encompassing pain and suffering (*pretium doloris*) or loss of enjoyment of life, and forms of stand-alone harm (*préjudice moral pur*), including violations of personality rights, honor, dignity, or emotional integrity.

In Hungary, the liability system is strictly restorative. Courts can award pecuniary damages (*vagyoni kár*) and non-pecuniary damages (*nemvagyoni kár*). While monetary damages are to compensate monetary losses suffered by the aggrieved party due to negligence or medical malpractice, non-pecuniary damages are provided within the judge's discretionary power and have been replaced by restitution under the 2013 civil code. This enables any person whose personality rights were infringed upon to take action. When the patient's death results from medical malpractice, dependents of the deceased can petition for the loss of maintenance.

In South Africa, Courts can award both pecuniary and non-pecuniary damages based on fault (*culpa*) under tort law. The liability system is founded in the 1957 State Liability Act (Section 1). They also apply common law principles supported by legal precedents to award damages for harm suffered resulting from medical malpractice. Courts can also grant damages for the suffering endured due to infringements of the constitutional rights of others and for psychiatric injury or emotional shock. The compensation in kind is also possible in the form of delivering healthcare services in a public health institution.

In Canada, both pecuniary and non-pecuniary damages may be awarded in medical malpractice cases, which are governed by a fault-based liability system rooted in tort law. Medical malpractice claims and liability are based on provincial procedural rules and regulations. Liability is assessed against reasonable standards of care. As in Rwanda, proving the practitioner's failure to meet the standards of care as outlined under the 1956 case of *Crits v. Sylveste* has always been hard and requires medical expert reports. The evidentiary and procedural complexities of such claims necessitate claimants' legal counsels while physician-defendants are commonly represented by the Canadian Medical Protective Association (MPA), which provides legal defense and risk-management support to its members.

This chapter has extended the analysis by examining the available remedial avenues and dispute-resolution forums accessible to healthcare users in Rwanda, to which they can take action before the expiry of five years from the occurrence of the adverse event. The regulatory and professional bodies have complaint mechanisms in which patients who suffered harm can formally report alleged malpractices or medical practitioners' misconduct. Those bodies carry out thorough investigations and can take disciplinary measures against the healthcare practitioner who is found guilty through suspension, revocation of licenses, or other disciplinary sanctions provided by the governing law. Besides, ADR is an alternative approach for resolving medical malpractice disputes. This is done independently or as a court-annexed mediation, which is formally done

through a pretrial conference and judge-facilitated mediation. Then, courts remain the main forums for adjudicating medical malpractice cases, applying principles of tort law, contract law, or criminal law. However, court proceedings are criticized for their length and procedural complexity, which may compromise the timely access to justice.

The chapter highlights that liability is crucial for ensuring accountability, deterrence, reparation, and law compliance. At the same time, the imposition of liability is associated with several challenges, including the appearance of Medical Malpractice Stress Syndrome (MMSS), defensive medicine, and malpractice-induced exit, career transition, and change in practice.

The third sub-question, **‘What mechanisms can promote healthcare accountability and patient safety in Rwanda?’** is well answered under Chapter Eight, which is the last part of this dissertation before conclusion. This part entails the mechanisms aimed to avail a comprehensive framework that safeguards accountability and patient safety in the Rwandan healthcare system. It begins by recalling the available remedial situation on medical malpractice and tries to concoct the solutions for identified problems, including limited healthcare accountability and loopholes in the regulatory framework, as well as systematic and operational challenges.

While there is a journey towards patient safety and fair compensation, the growth of healthcare services commercialization presents the complex dynamics between profit motives and patient welfare. This poses a regulatory issue that lacks the healthcare service consumers’ protection and corporate liability to hold healthcare providers liable alongside individual medical practitioners. There is a lapse of institutional oversight in this respect, which exposes patients to risks, with no special public regulatory authority to enforce adherence to the standards of quality and safety in healthcare delivery. The situation is exacerbated by the non-operative professional liability insurance.

The proposed solutions include the establishment of an enforcement mechanism that ensures transparent quantum criteria, settlement of malpractice claims within a time-bound framework, provision of apology protection, and implementation of a no-fault compensation system. To address those issues, the researcher proposes the expansion of regulatory framework underpinning medical liability in Rwanda, to include corporate responsibility and human rights obligations. Besides, the researcher proposes the enactment of ministerial orders implementing the healthcare law to promote accountability and transparency in healthcare service delivery and adequate compensatory regime for malpractice victims. In this respect, the establishment of a standardized process for vetting and accrediting medical experts for medical litigation was found necessary. However, such legal framework should cope with the gap between statutory mandates and their practical enforcement. For example, it must create an environment that enables the liability insurance functioning. Furthermore, alternative dispute resolution approaches such as mediation and negotiation in medical malpractice cases have been proposed to avoid a compromise to the legitimacy of practitioners through adversarial and prolonged proceedings and criminalization.

Therefore, the findings of the dissertation support the hypothesis that medical liability is an essential factor in protecting the rights of patients, healthcare quality, and the confidence of the population in the health system. Rwanda has developed a substantive base to such a system, but much reform is needed to make it more consistent, available, and equitable. The process of enhancing the accountability of healthcare will need not only legal reforms but also cultural and institutional change, i.e., systems thinking, supporting a just culture, strengthening ethical practice, and making sure that remedies for harm are effective and expedient. Finally, this study adds to the ongoing debate on patient safety and medical responsibility in that a robust medical liability system should create equilibrium between deterrence and learning, punishment and prevention, and personal blame and systemic study. In the case of Rwanda, pursuing this equilibrium is not only a legal requirement but a move towards high quality, equitable, and safe healthcare to all.

## 9.2. Recommendations

The findings of this research highlight various implications for both policy and practice. Each malpractice case signals an urgent need to strengthen and refine systemic safeguards. Following that, I propose various actions below. If the recommended actions are implemented, particularly the suggested model for strengthening patient safety and healthcare accountability in Rwanda, the optimal healthcare system can be realised. The system that prioritises safe and reliable service delivery, upholds patient-centered care, ensures rigorous regulatory compliance, and incorporates effective mechanisms guaranteeing timely and fair compensation for patients who suffer harm from medical malpractice and negligence.

The Government of Rwanda is recommended to strengthen legal and regulatory frameworks to reinforce patient protection and empower regulatory enforcement. For example, there is a need for clear statutory definitions of malpractice and negligence to remove ambiguity and improve consistency in adjudication. This goes with updating the healthcare laws and professional regulations to align with modern medical standards involving clearer duties of care, informed consent rules, and obligations for documentation. This goes with standardization of clinical protocols to meet the current legal expectations and revising the disciplinary codes to ensure proportionality of sanctions and transparent procedures. Legal and regulatory reforms should streamline fostering a culture of safety, transparency, accountability, and reporting in healthcare delivery. They should also enhance the value of expert evidence in malpractice litigation.

Healthcare professional bodies jointly with the Government of Rwanda are recommended to improve complaints and redress mechanisms. There is a need for chamber specialized for medical malpractice complaints in Rwandan courts and a reinforcement of ADR mechanisms to accelerate resolutions of these cases. Besides, mandating institution level grievance offices in hospitals with defined timelines for response, reporting obligations, and oversight is another approach they could expediate malpractice complaints. This implies the implementation of patient support units to help victims understand processes and access medical records and encouragement of broader use of ADR (mediation, expert review panels) to reduce court loads and uphold patient-provider

relationships. Additionally, open reporting channels should be initiated and the attitude that patient safety supersedes protectionism of a profession should be instilled.

The Ministry of Health and healthcare professional bodies are also recommended to enhance professional accountability and standards as well as encourage reporting. This can be done by improving CPDs by focusing on patient safety, ethics, and documentation. It should be taken together with mandatory adverse-event reporting systems that are protected, confidential, and non-punitive to encourage learning. In this regard, it is important to put in place the regulatory mechanisms enhancing transparency and accountability to accelerate the underreporting of malpractice incidents, which underestimates the true scope of the malpractice problem. In addition, these mechanisms should provide legal protection for whistleblowers to discourage the culture of silence and concealment, which hinders the testimonies from peer medical practitioners. The possibility of these requires various practical strategies including the health facilities' adoption of clinical governance structures, such as morbidity–mortality audits, peer-review systems, and safety committees. They should also improve supervision, staffing norms, and workload management, as overburdened practitioners are more prone to errors. However, incentivising compliance, promotion of learning from errors, and establishment of independent quality control, grounded in human error theory constitute part of enablers for the achievement of these initiatives.

It is recommended that the Ministry of health, professional healthcare bodies, and providers establish strategies for strengthening patient protection and empowerment. The guaranteed patients' rights to access medical records and patients' participation in decision-making through informed consent should be enhanced. In this regard, the routine hospital procedures should incorporate patient-centred communication standards. Healthcare providers should introduce patient information sheets or leaflets and improve the informed consent forms to incorporate multiple languages to serve diverse populations. Besides, there should be national patient education programs and guidelines on informed consent and other patient rights to empower patients to become active participants in their healthcare decision-making. This will improve the quality of healthcare and provide equitable treatment to every patient.

To harmonise the process for compensating harm resulting from medical malpractices, the Government of Rwanda is recommended to enforce medical liability insurance. The mandatory professional liability insurance for healthcare practitioners is provided by healthcare law, but it should be implemented. This will enable healthcare providers and practitioners to integrate risk management frameworks that facilitate to compensate for malpractice incidents. In this regard, legal and insurance compliance should necessitate clear documentation and adherence to protocols. Besides, no-fault compensation scheme should be introduced for certain categories of injuries in order to reduce the reliance on court proceedings.

Moreover, it is recommended that the Government of Rwanda, healthcare professional bodies, and health care service providers cooperate to improving data transparency and monitoring. In this regard, there is a need for development of a national database of malpractice claims, disciplinary actions, and adverse events. Besides, all facilities must adopt electronic health records, standardized incident reporting tools, and regular audits. Adapting new technologies in healthcare recording and reporting will mitigate some medical errors resulting from information flaws. They

will also enable evidence-based medicine and specialized medicine, which are based on data from documentation systems and integrated electronic health information systems. Public reporting on patient safety indicators must be periodic, and the usage of data analytics can guide training priorities, staffing needs, and targeted interventions.

Furthermore, it is recommended that the Ministry of Health, healthcare professional bodies, and healthcare providers align healthcare service delivery with international standards. There should be a continuous harmonization of national frameworks with WHO patient safety guidelines, African regional health instruments, and best practices from well-functioning liability systems. In this regard, Rwandan healthcare should incorporate best practices from various jurisdictions such as Canada and France on the compliance and safeguards for patient safety and quality care services. Additionally, the promotion of cross-border learning through benchmarking, regional conferences, and academic collaborations is equally important. This should also include interdisciplinary collaboration such as legal and medical professionals. Besides, apart from local accreditation, Rwandan hospitals should seek international accreditation models such as Joint Commission International (JCI) and SafeCare, to raise standards and reduce risks. They should also adopt evidence-based clinical guidelines compatible with international norms.

Finally, to enhance patient safety and effective compensation of victim of harm resulting from medical malpractice and negligence, it is recommended that relevant stakeholders including the Government of Rwanda and major healthcare stakeholders such as the private sector, non-governmental organisations, academic and research institutions, and other development partners institutionalise effective cooperation. This partnership must focus on aligned efforts in health financing, professional training, research, data sharing, digital health innovation and technology transfer, which lead to safer care settings and more credible compensation systems. The multi-sectoral collaborative model must also extend to the justice sector, especially the Judiciary and the Rwanda Bar Association, to facilitate consistent and effective handling of medico-legal claims and increase the availability and integrity of remedies to patients.

### **9.3. Suggestions for future research**

Future research could include the reasons behind underreporting medical incidents that undermine the actual injuries caused by medical malpractice and negligence. It may also involve comparative research with countries where medical liability systems are established, and empirical research to capture the views of patients, practitioners, and regulators to gain a better insight into how the law works in practice. Additional scrutiny of insurance mechanisms and alternative dispute resolution might shed some light on their functions in enhancing the accessibility of remedies. The interdisciplinary collaboration between the legal analysis and the area of public health and health-systems management would also assist in formulating more adequate reforms on patient safety and professional responsibility. The topic of medical liability during the age of artificial intelligence should also be explored in future studies, especially as the system of algorithmic decision-making is more likely to enter the field of healthcare service provision. This investigation would yield useful information about the distribution of the responsibility to clinical decision-making through

AI and aid in creating the accountability models that would allow the safe, ethical, and transparent implementation of these technologies in clinical practice.

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## Appendix I: Interview Guide

1. What are the RMDC's responsibilities vis-a-vis the claims involving medical practitioners?
2. Have you dealt with cases of medical malpractice and negligence in your workload?
3. If you dealt with cases of medical malpractice and negligence, how many cases have you handled to date? This entails the annual statistics years on those resolved and those reached the prosecution and courts. (for 10 years if applicable)
  - (a) How many cases have you received from 10 years ago?
  - (b) Could you demonstrate the number of complaints per annum and their related areas of specialties/departments?
  - (c) How many of them were confirmed medical malpractice and negligence?
  - (d) Among the received cases, how many of them are involving the medical practitioners?
  - (e) Which actions were taken by RMDC as a remedial approach?
  - (f) How many cases are still pending?
  - (g) Why are they still pending or what are the factors contributing to the delay?
  - (h) What do you propose for speeding up the process?
3. By which means does a medical malpractice complaint reach your organization? Tell us the process.
4. Do you see any effects of medical malpractices and negligence on Rwandan healthcare or Rwandan society at large? If any, what are they?
5. If annually calculated, what is the social and economic value of medical malpractice in Rwanda?
6. How often do you receive medical malpractice complaints (*daily/weekly/monthly/or annually*)?
7. Do you find it normal or very high concern?
8. What is the nature of those medical malpractice and negligence cases? — *E.g.: diagnostic error, failure of counselling, patient mistreatment, wrong procedure, wrong-site surgery, violation of informed consent, lack of aftercare, unsuitable health management, or other?*
9. Have you ever dealt with any medical malpractice or negligence claim related to the violation of personal health data protection? If any, tell us about it shortly. How have you handled it?

10. Is there any other type of medical malpractice claim, which is not described here, that you have received? If any, what was it and how have you solved it?
11. Which clinical department is likely to have many cases of patient adverse events?
12. Are there any defensive medicine issues in Rwanda as a clinical strategy for avoiding medical malpractice lawsuits and compensation in the future?
13. What do you see as the main factors contributing to medical malpractice and negligence in Rwanda?
14. Are there any household health-related malpractices contributing to medical malpractices in Rwanda? *(Those may include the patient's history of, for example, improper medication management, failure to seek timely medical care, unhealthy dietary habits, cultural beliefs and practices, negative lifestyle health choices, and improper sanitation and hygiene).*
15. If any, what are they and how could they contribute to patient adverse events?
16. Is a cost-benefit standard an issue in Rwandan healthcare? *(Cost-benefit standard means providing health care services based on the patient's financial capability. This has been influenced by other actors like insurers and pharmaceutical companies to increase the imbalance of healthcare services)*
17. What are the conducts that could lead to the liability of a medical practitioner?
18. Are there any legal or policy frameworks regarding patients' safety?
19. Do medical practitioners adequately understand patient rights and respect them?
20. What do you understand from informed consent and how could it be appropriately employed in Rwandan health care institutions?
21. Is there any medical code of conduct? If any, what does it provide in this regard?
22. What are the sanctions for a medical practitioner who is found guilty of malpractice or negligence in his or her professional career? Administratively, civilly, and criminally.
23. What do you think about the proportionality of the fault/offence and the sanctions? Are they suitable or not? Is there any harm scale?
24. Is there any professional liability insurance for medical practitioners?
25. If any, does insurance cover medical malpractices and negligence?
26. What are the remedial recourses for a victim of medical malpractice and negligence?
27. Are there excuses for medical liability in case the practitioner's malpractice or negligence resulted in patient harm?

28. What are the Committees for Conciliation and Compensation for Health Risks and how do they assist in medical malpractice and negligence cases?
29. What do you think are the appropriate legal or policy measures that could improve the patient's safety and prevent medical malpractice and negligence in Rwanda?
30. What do you think could be the remedial forums for medical malpractice and negligence claims? (*E.g: with administration, courts, ADR*).
31. What do you think could be the best approach? (*E.g.: no-fault and fault-based liability approaches*)
32. Do you think of any legal or regulatory gaps in this regard? If any, what is it?
33. (a) Who do you propose to be the actors in ensuring patient safety and access to justice?  
(b) How should they be involved? (*Probe for all possible actors but also ask for the possibility of inclusiveness and a patient-centered approach if it doesn't come out naturally*).
34. Could you give me an example of what should be done to prevent medical malpractice and thus medical liability?
35. Are there any worries or concerns about the liability of medical practitioners? What are your hopes and concerns?
36. What are the challenges you experience when you are dealing with medical malpractice cases?
37. Should there be any input or concern, please, let us know.