Medical Liability and the Use of Remote Patient Monitoring

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TABLE OF CONTENTS

ABSTRACT

More than ever before, information and communication technologies are playing an important role in the provision of health care services. Since the onset of the COVID-19 pandemic, the use of telehealth modalities in health care has significantly increased. As a form of telehealth, remote patient monitoring (RPM) uses information technologies and telecommunication tools to collect health data from patients outside of traditional health care institutional settings and transmit the data to health care providers for monitoring and evaluation purposes. While there are many benefits to the clinical use of RPM, there are many challenges to its greater implementation in health care. One such challenge is the uncertainty regarding the liability for physicians who use RPM with their patients. As is often the case when novel technologies are introduced into health care, uncertain medical liability may have a chilling effect on the greater clinical use of RPM. To date, medical liability issues regarding RPM have not been addressed by courts and there is a paucity of literature on the topic. Our thesis aims to elucidate this uncertainty by examining how medical liability rules may apply to RPM, under both the Anglo-Canadian common law and Quebec civil law traditions.

RÉSUMÉ

Plus que jamais, les technologies de l'information et de la communication jouent un rôle important dans la prestation des services de santé. Depuis le début de la pandémie de COVID-19, l'utilisation des modalités de télésanté dans les soins de santé a considérablement augmenté. En tant que forme de télésanté, la surveillance à distance des patients (RPM) utilise les technologies de l'information et les outils de télécommunication pour recueillir des données sur la santé des patients en dehors des établissements de soins traditionnels et les transmettre aux prestataires de soins à des fins de surveillance et d'évaluation. Si l'utilisation clinique de la télésurveillance des patients présente de nombreux avantages, sa mise en œuvre à plus grande échelle dans le secteur des soins de santé se heurte à de nombreux obstacles. L'un d'entre eux est l'incertitude concernant la responsabilité des médecins qui utilisent la RPM avec leurs patients. Comme c'est souvent le cas lorsque de nouvelles technologies sont introduites dans les soins de santé, l'incertitude concernant la responsabilité médicale peut avoir un effet dissuasif sur l'utilisation clinique de la RPM. À ce jour, les questions de responsabilité médicale concernant la RPM n'ont pas été abordées par les tribunaux et la littérature sur le sujet est peu abondante. Notre thèse vise à élucider cette incertitude en examinant comment les règles de responsabilité médicale peuvent s'appliquer à la RPM, selon les traditions de la common law anglo-canadienne et du droit civil québécois.

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"Medicine is a science of uncertainty and an art of probability".[1]

[1] William Osler, cited in "Uncertainty in Medicine" (2010) 375:9227 The Lancet 1666.

INTRODUCTION

Historically, health care was primarily provided in patients' homes, either by family members or by physicians who made house calls.[2] By the late nineteenth century, however, the provision of health care had largely shifted from the home setting to health care institutions, such as hospitals. Socioeconomic changes and advances in modern medicine and science largely prompted this shift in the provision of health care services.[3] Whereas scientific and medical advancements contributed to the institutionalization of health care over a century ago, recently we have begun to witness a move back towards home-based care, facilitated by scientific and technological innovations which now allow health care providers to reach patients outside of institutional settings, such as hospitals or clinics.[4] In particular, advances in communication and information technologies have been instrumental in the surging prevalence of remote health care.

The use of communication and information technologies to provide health care services, referred to collectively as "telehealth",[5] is now a burgeoning and expanding field, encompassing a vast range of health care modalities, including virtual health care consultations and remote patient monitoring (RPM). As a subset of telehealth, RPM refers to the use of information technologies and telecommunication tools to collect health data from patients in their own environment, outside

[2] See e.g. Thomas S Nesbitt & Jana Katz-Bell, "History of Telehealth" in Karen S Rheuban & Elizabeth A Rubinski, eds, *Understanding Telehealth* (New York: McGraw-Hill Education, 2018) 1 at 1.
[3] See *ibid*.
[4] For examples of the increased use of telehealth technologies in Canada, especially since the onset of the COVID-19 pandemic, see R Sacha Bhatia et al, "Virtual care use before and during the COVID-19 pandemic: a repeated cross-sectional study" (2021) 9:1 CMAJ 107; Claire Johnson et al, "Changes to telehealth practices in primary care in New Brunswick (Canada): A comparative study pre and during the COVID-19 pandemic" (2021) 16:11 PLoS One e0258839.
[5] The terms "telehealth" and "telemedicine" are often used interchangeably to refer to the remote provision of health care services through the use of information and communications technologies. However, the term "telehealth" is often considered to be a broader, more inclusive term, encompassing a range of health care services, such as telenursing and telepharmacy. "Telemedicine", on the other hand, is often used strictly to refer to the remote provision of medical services by a physician. See e.g. Ronald S Weinstein et al, "Telemedicine, Telehealth, and Mobile Health Applications That Work: Opportunities and Barriers" (2014) 127:3 Am J Med 183 at 183.

of traditional health care institutional settings and electronically transmit the data to health care providers for monitoring, assessment, and treatment purposes.[6]

The capacity to remotely monitor patients has long been envisioned as a model of health care delivery. An 1879 article in *The Lancet*, for instance, described the use of the telephone – a recent invention at the time – as a means of transmitting medical information to and consulting with physicians to avoid unnecessary office visits.[7] However, the uptake of RPM in clinical care has only recently begun to accelerate. Now more than ever, scientific innovations have enabled the remote monitoring of patients using sophisticated and state-of-the-art technologies, well beyond the realm of imagination in the nineteenth century.

One key driver in the increasing adoption of RPM and other forms of telehealth has been the COVID-19 pandemic, with public health measures and restrictions significantly limiting the number of in-person interactions in health care settings.[8] While telehealth was already playing a growing role prior the pandemic, it experienced an exponential surge after the onset of the

[6] See e.g. Zineb Jeddi & Adam Bohr, "Remote patient monitoring using artificial intelligence" in Adam Bohr & Kaveh Memarzadeh, eds, *Artificial intelligence in healthcare* (London: Academic Press, 2020) 203 at 203; Ashok Vegesna et al, "Remote patient monitoring via non-invasive digital technologies: a systematic review" (2017) 23:1 Telemedicine & e-Health 3 at 3.

[7] See Thomas S Nesbitt, "The Evolution of Telehealth: Where Have We Been and Where Are We Going?" in Tracy A Lustig & Institute of Medicine, Board on Health Care Services, eds, *The Role of Telehealth in an Evolving Health Care Environment: Workshop Summary* (Washington, DC: National Academies Press, 2012) 11 at 11.

[8] See Khayreddine Bouabida et al, "Remote Patient Monitoring Program for COVID-19 Patients Following Hospital Discharge: A Cross-Sectional Study" (2021) 3 Frontiers in Digital Health 1 at 2; Darren Roblyer, "Perspective on the increasing role of optical wearables and remote patient monitoring in the COVID-19 era and beyond" (2020) 25:10 J Biomedical Optics 102703-1 at 102703-1.

pandemic.[9] The use of RPM, in particular, has increased significantly since the beginning of the pandemic and the RPM market is projected to double within the next five years.[10]

While catalyzed by the pandemic, RPM will continue to grow post-pandemic, holding great potential to transform the health care sector, providing potential benefits not only to patients, but to health care systems as well.[11] Indeed, the effects of an increasingly aging population and the growing prevalence of chronic diseases are expected to be the main drivers in the growing RPM market.[12] With chronic diseases, such as diabetes and chronic obstructive pulmonary disease (COPD) having become the leading causes of death and disability worldwide,[13] RPM is anticipated to become more widespread in the coming years.

This expansion presents an opportunity to not only tackle these growing health issues and concerns, but to harness the potential benefits of RPM in other health care contexts and address many of the infrastructural and systemic issues that affect our health care systems. For instance, one critical factor in the future clinical utility of RPM will be its promotion of data-driven clinical

[9] According to Canada Health Infoway's Digital Health Survey, 73% of Canadians had at least one virtual interaction with a health care provider in 2021, an increase from 67% in 2020, the first year of the COVID-19 pandemic. See Canada Health Infoway, "Canadian Digital Health Survey 2021: What Canadians Think" (November 2021), online (pdf): <https://www.infoway-inforoute.ca/en/component/edocman/4011-canadian-digital-health-survey-2021-what-canadians-think/view-document> at 14.

[10] See Joshua Claman, "How COVID-19 revealed the strong need for remote patient monitoring" (4 September 2020), online: *Becker's Health IT* <https://www.beckershospitalreview.com/healthcare-information-technology/how-covid-19-revealed-the-strong-need-for-remote-patient-monitoring.html>; Kat Jercich, "RPM market will double in next five years, predict stakeholders" (5 August 2020), online: *Healthcare IT News* <https://www.healthcareitnews.com/news/rpm-market-will-double-next-five-years-predict-stakeholders>.

[11] See Jercich, *supra* note 10.

[12] See *ibid*.

[13] See World Health Organization, "WHO reveals leading causes of death and disability worldwide: 2000-2019" (9 December 2020), online: *World Health Organization* <https://www.who.int/news/item/09-12-2020-who-reveals-leading-causes-of-death-and-disability-worldwide-2000-2019>; World Health Organization, "Noncommunicable diseases" (13 April 2021), online: *World Health Organization* <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>.

decision-making.[14] Clinical data are crucial to the management and operation of modern health care systems.[15] RPM's ability to allow clinicians to have access to patients' clinical data in real-time provides a more accurate portrait of patients' state of health, thereby allowing clinicians to modify treatment plans accordingly.[16] The capacity to monitor a patient's state of health over time is especially beneficial for both the elderly and chronic disease patients, who require ongoing care and monitoring and are not well-served by episodic care models.[17]

The benefits of RPM, however, are not limited to its data-centric approach to health care provision. For one, and this is true of telehealth more generally, RPM improves access to care, especially for underserved populations, such as the socioeconomically disadvantaged or populations who live in rural or remote regions.[18] This issue of health care access, and the barriers that impede such access, have long been the subject of intense discussions. The COVID-19 pandemic, which has exacerbated pre-existing disparities, has shed renewed light on these discussions.[19] Telehealth solutions, including the adoption of RPM for patients who may benefit from it, can help improve access to health care and mitigate many barriers and disparities, especially as health care systems begin to recover from the effects of the pandemic. Consequently,

[14] See e.g. Rachael C Walker et al, "Clinicians' experiences with remote patient monitoring in peritoneal dialysis: A semi-structured interview study" (2020) 40:2 Peritoneal Dialysis Int 202 at 204.
[15] See e.g. Francesco Sanmarchi, "Distributed Solutions for a Reliable Data-Driven Transformation of Healthcare Management and Research" (2021) 9 Frontiers in Public Health 1 at 1.
[16] See Walker et al, *supra* note 14 at 204.
[17] See Sandra Mierdel & Kirk Owen, "Telehomecare Reduces ER Use and Hospitalizations at William Osler Health System" (2015) 209 Stud Health Technol Inform 102 at 102.
[18] See e.g. Abigail Baldwin-Medsker, Jessie Holand & Elizabeth S Rodriguez, "Access to Care: Using eHealth to limit location-based barriers for patients with cancer" (2020) 24:3 Clinical J Oncology Nursing 16 at 17; Farzan Sasangohar et al, "Remote Patient Monitoring and Telemedicine in Neonatal and Pediatric Settings: Scoping Literature Review" (2018) 20:12 J Med Internet Research 1 at 2.
[19] See e.g. David Blumenthal et al, "Covid-19 — Implications for the Health Care System" (2020) 383:15 New Eng J Med 1483 at 1486; Aaron van Dorn, Rebecca E Cooney & Miriam L Sabin, "COVID-19 exacerbating inequalities in the US" (2020) 395:10232 The Lancet 1243 at 1243.

both federal and provincial governments have been paying increased attention to the policy aspects of telehealth.[20]

Indeed, RPM reduces the burden of hospital visits and stays, especially for patients with chronic health issues who not only require long-term care, but who also report high use of acute hospital care.[21] RPM allows health care providers to detect and address potential health issues earlier, thereby reducing the number of hospital admissions and facilitating early discharges from hospitals.[22] Reductions in the number of hospital admissions not only benefit patients, but are also beneficial to health care systems. Unplanned acute hospital use, for instance, is a major financial burden on health care systems, which have become increasingly overburdened since the onset of the COVID-19 pandemic which has created significant delays in various services, such as hospital inpatient care, surgeries, and emergency care.[23] The benefits provided by RPM can result in significant cost savings for health care systems, which can then be allocated to other resources.

Despite the projected expansion of the RPM and its purported benefits to patients and health care systems alike, there are many challenges and barriers which may hinder its greater adoption. For instance, significant disparities exist concerning access to technology and digital

[20] See e.g. Government of Canada, "British Columbia Virtual Care Action Plan" (26 July 2022), online: < https://www.canada.ca/en/health-canada/corporate/transparency/health-agreements/bilateral-agreement-pan-canadian-virtual-care-priorities-covid-19/british-columbia-action-plan.html>; Health Canada, "Virtual Care – Policy Framework" (7 July 2021), online (pdf): <https://www.canada.ca/content/dam/hc-sc/documents/corporate/transparency/health-agreements/bilateral-agreement-pan-canadian-virtual-care-priorities-covid-19/policy-framework/policy-framework-eng.pdf>.

[21] See e.g. Monica L Taylor et al, "Does remote patient monitoring reduce acute care use? A systematic review" (2021) 11:e040232 BMJ Open 1 at 4.

[22] See *ibid* at 2; Sreekar Mantena & Salmaan Keshavjee, "Strengthening healthcare delivery with remote patient monitoring in the time of COVID-19" (2021) 28:1 BMJ Health & Care Informatics 1 at 2.

[23] See *ibid*. For further information on the impacts of COVID-19 on Canadian health care systems, see "Overview: COVID-19's impact on health care systems" (9 December 2021), online: *Canadian Institute for Health Information* <https://www.cihi.ca/en/covid-19-resources/impact-of-covid-19-on-canadas-health-care-systems/the-big-picture>.

literacy among certain population groups which may lead to inequities in the implementation of telehealth services. Digital equity is required to allow all population groups to benefit from telehealth services, including RPM.[24] Clinicians have raised concerns over the extra time and effort the implementation of RPM will require, including training staff and patients on how to use RPM.[25] Another significant challenge to the greater adoption of RPM is that of uncertain medical liability in the use of RPM. This challenge will be the focus of our thesis.

As is often the case when new technologies are introduced into clinical care, uncertainty with regard to the liability that may result from adverse events related to technology uptake may have a chilling effect on the greater adoption of RPM by physicians. This has been raised, for instance, in the case of the integration of artificial intelligence (AI) in health care.[26] The literature has highlighted the effects uncertain liability may have on the greater adoption of RPM by health care professionals. For instance, despite the mainly positive clinician views reported in a systemic review of clinician and staff views of RPM published by Davis et al. (2014), the authors reported clinicians' concerns over uncertain medico-legal liability in six different studies.[27]

[24] See e.g. Yohualli Balderas-Medina Anaya et al, "Post-Pandemic Telehealth Policy for Primary Care: An Equity Perspective" (2022) 35:1 J Am Board Fam Med 588.
[25] See Melina Davis et al, "A Systematic Review of Clinician and Staff Views on the Acceptability of Incorporating Remote Monitoring Technology into Primary Care" (2014) Telemedicine & E-Health 20:5 428 at 430; Nora El-Rashidy, "Mobile Health in Remote Patient Monitoring for Chronic Diseases: Principles, Trends, and Challenges" (2021) 11:607 Diagnostics 1 at 6; Ariane M Fraiche et al, "Patient and Provider Perspectives on Remote Monitoring of Pacemakers and Implantable Cardioverter-Defibrillators" (2021) 49 Am J Cardiology 42 at 44; Sarah J Rhoads et al, "Exploring Implementation of m-Health Monitoring in Postpartum Women with Hypertension" (2017) 23:10 Telemedicine & e-Health 833 at 839.
[26] See Mélanie Bourassa Forcier, Lara Khoury & Nathalie Vézina, "Liability issues for the use of artificial intelligence in health care in Canada: AI and medical decision-making" (2020) 46:2 Dal Med J 7 at 7.
[27] See Davis et al, *supra* note 25 at 436.

Concerns over their potential liability may make health care providers hesitant to implement RPM, despite their overall favorable views of these technologies.[28] Without adequate clinician buy-in and support, the potential benefits RPM has to offer patients and health care systems will remain unrealized, and patients who may benefit from these technologies will be deprived of their advantages. An analysis of the medical liability issues raised by RPM technologies is therefore timely and relevant.

The relevance and timeliness of this analysis is exemplified by the fact that there is a paucity of legal scholarship on RPM.[29] Despite being raised in the literature, questions of medical liability over the use of RPM have not, to our knowledge, been explored in-depth. Moreover, medical liability issues related to RPM have yet to be addressed by Canadian courts.[30] This is also true internationally, with only few identified cases of liability lawsuits related to telehealth by 2019.[31] Given the relative recency of RPM, it is not unsurprising that it has yet to be litigated. However, with its anticipated exponential growth in the coming years, it is foreseeable that medical liability issues may eventually come before the courts. For now, in the absence of Canadian case

[28] See *ibid*.

[29] In Canadian legal scholarship, Roskams-Edris (2018) explores how data recorded by remote biosensing technologies can be used in the contexts of informed consent, search warrants and personal injury cases and how patient autonomy and privacy can be protected in such cases. See Dylan Roskams-Edris, "The Eye Inside: Remote Biosensing Technologies in Healthcare and the Law" (2018) 27 Dal J Leg Stud 59. However, analyses of the medical liability issues raised by RPM have, to the best of our knowledge, yet to be explored in legal scholarship, Canadian or international.

[30] A search conducted on August 16th, 2022 on Lexis Advance Quicklaw using the primary search terms "remote patient monitoring" and "liability" yielded 0 cases. Telehealth, specifically virtual consultations, has begun to be addressed by professional disciplinary tribunals, though cases are very few to date. See Suzanne Philips-Nootens & Robert P Kouri, *Éléments de responsabilité civile médicale – Le droit dans le quotidien de la medicine,* 5th ed (Cowansville, QC: Yvon Blais, 2021) at para 360.

[31] See Kar-wai Tong, "Telehealth as a Double-Edged Sword: Lessons from Court Cases to Gain Understanding of Medico-Legal Risks" (2019) 38:1 Med & L 85 at 91—92.

law, analyses of medical liability connected to RPM require using analogy to already established medical liability rules.[32]

This uncertainty is further compounded by the paucity of professional standards and guidelines specific to the use of RPM in clinical care in Canada.[33] Though not legally binding, soft law instruments such as professional guidelines may be indicative of the professional norms required of health care professionals and may be used by courts when assessing whether health care professionals have met the accepted standards of practice in liability lawsuits.[34] However, while some professional associations and professional colleges have adopted guidelines on telehealth,[35] there are no RPM-specific standards and guidelines, though guidelines on the use of mobile health applications may be applicable to RPM, as will be discussed later in our thesis. While more general standards and guidelines may be relevant to the RPM context, they do not address many of the specificities and characteristics of RPM. The absence of definitive case law and guidance from professional standards and guidelines makes it more difficult to predict legal standards for medical professionals.

Accordingly, the objective of our thesis is to provide a clearer understanding of the medical liability risks surrounding the implementation and use of RPM in clinical care. By identifying

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[32] See *ibid*.

[33] Though, in the United States, the American Medical Association (AMA) has adopted guidelines on RPM. See American Medical Association, "Remote Patient Monitoring Playbook" (2022), online (pdf): <https://www.ama-assn.org/system/files/ama-remote-patient-monitoring-playbook.pdf> [American Medical Association].

[34] See Angela Campbell & Kathleen Cranley Glass, (2001) "The Legal Status of Clinical and Ethics Policies, Codes and Guidelines in Medical Practice and Research" 46 McGill LJ 473 at 5.

[35] See e.g. "Guiding Principles for Physicians Recommending Mobile Health Applications to Patients" (2015), online (pdf): *Canadian Medical Association* <https://www.cma.ca/sites/default/files/2018-11/cma_policy_guiding_principles_for_physicians_recommending_mobile_health_applications_to_patients_pd1-e.pdf> [*Canadian Medical Association*]; "Télémedicine" (last updated 13 June 2022), online: *Collège des médecins du Québec* <http://www.cmq.org/page/fr/telemedecine.aspx> [*Collège des médecins du Québec*].

these risks and assessing how liability may be incurred, we hope to address some of the concerns that could hinder the greater adoption of RPM in clinical care. It is hoped that this will contribute to paving the way to more favourable clinical outcomes for patients who may benefit from the implementation of RPM in their care. Our analyses will be limited primarily to the legal liability of physicians who use these technologies with their patients, though liability issues the involvement of multiple health care providers within a multidisciplinary team raise will also be explored.

To conduct these analyses, our thesis will primarily adopt the method of doctrinal legal research.[36] We will draw on existing case law and legal commentary to identify how courts assess breaches of the standard of care (common law) or contractual obligation of means (civil law) and causation when dealing with medical liability claims involving RPM. The lack of case law dealing directly with RPM will require us to use analogy with existing cases to interpret how RPM-related liability issues may be addressed. Given this lack of jurisprudential guidance, where relevant, we will propose the adoption of professional standards and guidelines to address some of these issues. We will adopt a comparative legal approach, analyzing the medical liability issues raised by RPM under both Anglo-Canadian common law principles and Quebec civil law liability principles.

Our thesis will be divided into four chapters. In the first chapter, we will provide a cursory typology of the different RPM technologies and their clinical applications. This typology will serve not only to lay out the current RPM clinical landscape but will set up the legal analyses in

[36] See e.g. Terry Hutchinson & Nigel Duncan, "Defining and Describing What We Do: Doctrinal Legal Research" (2012) 17 Deakin L Rev 83; Jan Vranken, "Methodology of Legal Doctrinal Research: A Comment on Westerman" in Van Hoecke, Mark, ed. Methodologies of Legal Research: Which Kind of Method for What Kind of Discipline? (Portland: Hart Publishing, 2011) 111.

the subsequent chapters. In particular, the distinction between active and passive collection of data and the patient's role therein will be critical to the legal analyses of this thesis. In the second chapter, we will examine the conditions for imposing medical liability under both legal traditions and the risks of patient injury raised by the clinical use of RPM.

In the third chapter, we will analyze the determination of the standard of care stage under the common law tort of negligence and the determination of fault under Quebec's civil liability rules. Finally, in the fourth chapter, we will look at the causal issues that are raised by the clinical use of RPM. The challenges raised by the technical components of RPM, the involvement of multiple health care providers, and the institutional issues raised by the implementation of RPM will all be explored.

CHAPTER I
OVERVIEW OF REMOTE PATIENT MONITORING TECHNOLOGIES AND THEIR CLINICAL APPLICATIONS

Given its clinical utility, RPM will likely be used in many clinical applications in the near future, as many patients have health conditions which require ongoing monitoring and personalized care. However, RPM can be beneficial in other clinical applications, including when treating patients with mobility issues, the elderly, and patients in post-surgical recovery.[37] RPM is conducive to the long-term, continuous, and personalized care required by these patients, who are not well-served by existing episodic models of care.[38] In this chapter, we will describe the clinical applications and fundamental components of RPM, as well as provide a typology of the different types of RPM technologies that are used in clinical care.

1. Remote Patient Monitoring: Clinical Applications and Fundamental Components

Whereas frequent medical consultations in health care institutions constitute significant burdens to patients, RPM makes it possible to monitor patients on a more continual basis, from the comfort of their own homes or in any other external, non-clinical environment. In addition to reducing patient burden, RPM allows health care providers to more regularly assess and evaluate their patients' medical conditions. This allows them to make more accurate and interactive treatment decisions, which is more challenging under episodic care models.[39] Indeed, one of the

[37] See e.g. Lakmini P Malasinghe, Naeem Ramzan & Keshav Dahal, "Remote patient monitoring: a comprehensive study" (2019) 10:1 J Ambient Intelligence & Humanized Computing 57 at 58.
[38] See Sandra Mierdel & Kirk Owen, "Telehomecare Reduces ER Use and Hospitalizations at William Osler Health System", (2015) 209 Stud Health Technol Inform 102 at 102; Tomasz Szydło & Marek Konieczny, "Mobile and wearable devices in an open and universal system for remote patient monitoring" (2016) 46 Microprocessors & Microsystems 44 at 44.
[39] See e.g. Ashley Elizabeth Muller & Rigmor C Berg, "A flexible protocol for a systematic review of remote patient monitoring" (2020) 21:e45 Primary Health Care Research & Development 1 at 1.

unique features and advantages of RPM is that it is tailored to the patient's specific condition and health needs.[40] For instance, if transmitted data alerts the physician to a specific health issue, the data's evaluation may lead the physician to recommend that the patient visit the hospital, take certain preventive or cautionary steps, or take certain medications.[41] All this can occur without the need for regular in-person medical consultations.

In order to functionally operate and provide these benefits, RPM setups rely on the ability to electronically acquire and transmit health data from the patient's location to the health care provider's location.[42] Technological devices or apparatuses are therefore required to enable this transfer of data between parties and between locations. RPM systems vary not only in the types of technologies that are employed, but also in their clinical applications (e.g., the types of diseases or health conditions for which they are intended).[43]

RPM technologies can range from mobile health applications on smartphones, to wearable body sensors and wireless enabled implanted devices.[44] As for clinical applications, they range from chronic disease management to cardiac monitoring and post-surgical monitoring. However, most RPM systems entail the use of a single type of technology and target a single disease or health

[40] See e.g. Reed D Gurchiek, "open-Source Remote Gait Analysis: A post-Surgery patient Monitoring Application" (2019) 9:17996 Scientific Reports 1 at 1; Peter J Pronovost, Melissa J Cole & Robert M Hughes, "Remote Patient Monitoring During COVID-19: An Unexpected Patient Safety Benefit" (2022) 327:12 JAMA 1125 at 1125; Susanna Spinsante & Ennio Gambi, "Remote health monitoring for elderly through interactive television" (2012) 11:1 Biomedical Engineering Online 54 at 57.
[41] See Malasinghe et al, *supra* note 37 at 58.
[42] See Bobby Gheorghiu & Fraser Ratchford, "Scaling up the use of remote patient monitoring in Canada" (2015) 209 Stud Health Technology & Informatics 23 at 23.
[43] See Jeddi & Bohr, *supra* note 6 at 204.
[44] See e.g. Ashish Atreja et al, "Remote Patient Monitoring in IBD: Current State and Future Directions" (2018) 20:6 Current Gastroenterology Reports 1 at 2; Muhammad Safwan Riaz & Ashish Atreja, "Personalized Technologies in Chronic Gastrointestinal Disorders: Self-monitoring and Remote Sensor Technologies" (2016) 14:12 Clinical Gastroenterology & Hematology 1697 at 1697; Roskams-Edris, *supra* note 29 at 61.

condition.[45] An RPM system may comprise the use of standalone devices that monitor data for a specific condition. For instance, this is the case of implantable cardiovascular devices (ICDs) used to treat cardiac arrhythmias and monitor heart failure, of glucometers for the monitoring of patients with diabetes, and of pulse oximeters to measure blood oxygen saturation levels.[46] In certain cases, however, RPM technologies can be used in conjunction with other telehealth modalities, such as virtual consultations. They can also be integrated into comprehensive care management programs where patient data is collected from multiple sources.[47] The choice of technology generally depends upon the patient's specific condition and circumstances.

This diversity of technologies and clinical applications is illustrative of the heterogeneous and segmented nature of the current RPM landscape. Indeed, there is no agreed-upon definition of RPM or standard model of what makes up an RPM setup.[48] This variability is not only acknowledged by commentators, but by professional organizations as well. The American College of Physicians, for example, notes these variabilities in their online telehealth practice resources.[49] In particular, they highlight the variations in the functionality of different RPM technologies, in how data is collected from patients, and in how data is transmitted to health care providers.[50]

[45] See Jeddi & Bohr, *supra* note 6 at 208.
[46] See Ahmed Alboksmaty et al, "Effectiveness and safety of pulse oximetry in remote patient monitoring of patients with COVID-19: a systematic review" (2022) 4:4 The Lancet Digital Health e279 at e279; Amy L Tucker, "Remote Patient Monitoring and Care Coordination" in Karen S Rheuben & Elizabeth A Krupinski, eds, *Understanding Telehealth* (New York: McGraw-Hill Education, 2018) 1 at 3.
[47] See Bouabida et al, *supra* note 8 at 2; Tucker, *supra* note 46 at 3.
[48] See Jeddi & Bohr, *supra* note 6 at 208; Malasinghe et al, *supra* note 37 at 58.
[49] See "Variations among RPM Solutions" (last accessed 12 July 2022), online (pdf): *American College of Physicians* <https://www.acponline.org/system/files/documents/practice-resources/business-resources/teleheath/variations_among_rpm_solutions.pdf>.
[50] See *ibid.*

Irrespective of the types of technologies that are employed or how they are implemented, RPM setups generally consist of the following core components: (1) a data acquisition system; (2) a data processing system; (3) an end-terminal at the hospital or other health care institution; and (4) a communication network.[51] Generally, RPM systems also generally follow the same data process flows, which comprise the following steps: (1) acquire; (2) transmit; (3) analyze; (4) notify; and (5) intervene.[52]

The fundamental component of an RPM system, upon which the other components depend, is the data acquisition system, which comprises the different devices or technologies that collect the health data from the patient.[53] The data processing system, in turn, receives and transmits the data to the end-terminal, where the data can then be analyzed by the patient's health care provider or team of health care providers.[54] The communication network serves to connect the patient with their health care provider or clinical staff. This network provides a communication system that may include telecommunication pathways, such as online chats, videoconferencing, or, at the most basic level, telephone communication.[55]

The acquisition of patient data via the data acquisition systems described above best exemplifies the segmentation and heterogeneity of the current RPM ecosystem. The methods by which data are acquired largely depend upon the type of technology employed. One crucial area of distinction here is the role that the patient plays in the data acquisition step, which can be active

[51] See Jeddi & Bohr, *supra* note 6 at 204; Malasinghe et al, *supra* note 37 at 59.
[52] See Tucker, *supra* note 46 at 3.
[53] See *ibid*.
[54] See Jeddi & Bohr, *supra* note 6 at 204.
[55] See *ibid* at 204; Malasinghe et al, *supra* note 37 at 58.

(the patients input the data themselves into the RPM system) or passive (the data is collected automatically by the RPM system). The manner and frequency of data transmission generally depends upon the health condition of the patient, the type(s) of data that are collected, and the complexity of the data.[56] Patients who present higher-risk conditions or symptoms generally require more frequent monitoring.[57] Therefore, the variabilities we see among RPM systems are due to the fact that the degree of monitoring and the choice of technology must be tailored to the patient's specific circumstances.[58]

Accordingly, we will provide an overview of the different types of technologies which make up the fragmentary and heterogeneous realm of RPM. Given this heterogeneity and the difficulties in neatly categorizing RPM systems, our typology is not meant to be exhaustive or representative of all existing RPM technologies. Rather, it is meant to provide some concrete examples of RPM technologies. This typology also serves two additional purposes. From a practical standpoint, it serves as an introduction to the various technologies that can be used to remotely monitor patients and describes their clinical applications. Moreover, and perhaps more importantly, this typology provides the foundation for our analyses of the medical liability risks raised by the implementation of RPM in clinical care. In order to identify these risks and study their legal implications for both patients and physicians who employ RPM technologies, it is important to first understand the basic characteristics and functionalities of these technologies.

2. Typology of Current Remote Patient Monitoring Technologies

[56] See Jeddi & Bohr, *supra* note 6 at 204.
[57] See e.g. Provonost et al, *supra* note 40 at 1125.
[58] See Jeddi & Bohr, *supra* note 6 at 204; Malasinghe et al, *supra* note 37 at 59.

RPM technologies vary in their data acquisition modalities, as well as in their level of invasiveness and in whether they are contact-based or contactless. Our typology systematically classifies RPM technologies first into two broad categories described in the literature and which are based on their methods of data acquisition: (1) passive (or automatic) data collection and (2) active data collection. Within these two categories we then distinguish the different RPM technologies based on the types of devices or apparatuses they use. The core distinction between passive and active data collection has important implications for the determination of liability in the event of potential patient injury. Therefore, it will be important to consider this distinction and how it translates into the clinical implementation of these different technologies before analyzing issues of medical liability. Figure 1 below provides an overview of our typology of current RPM technologies:

Remote Patient Monitoring (RPM) Technologies	
Passive (Automatic) Data Collection	Active Data Collection
1. Wearable Devices with Passive Data Collection Modalities 2. Implantable Devices 3. Contactless Devices	1. Wearable Devices with Active Data Collection Modalities 2. Mobile Health Applications

Figure 1: Typology of Current RPM Technologies

2.1 *Passive (or Automatic) Data Collection Modalities*

Passive or automatic data collection refers to the passive role that the patient plays in the data acquisition. The patient does not actively engage in the collection of the data, rather this is done

automatically or autonomously by the device or technology employed.[59] Within this general category, we find the following types of technologies: 1) wearable devices which use passive data collection modalities; 2) implantable devices; and, 3) contactless devices, such as image-based and radar-based technologies. We describe each of these technologies in turn.

2.1.1 *Wearable Devices with Passive Data Collection Modalities*

The field of wearable devices is a rapidly growing and promising area in health care today. While the use of wearable devices can be traced back to the late 1940s,[60] wearable devices have seen a major upsurge in clinical use in recent years and have seen tremendous growth and development since the onset of the COVID-19 pandemic.[61] Perhaps reflective of this fast-growing and evolving domain, there is no standard or agreed-upon definition of what constitutes a wearable device.[62] Wearable devices encompass both passive and active data collection modalities.[63] In this section, we will describe examples of passive wearable devices, whereas as active wearable devices will be addressed in section 2.2.1.

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[59] See Lampros C Kourtis et al, "Digital biomarkers for Alzheimer's disease: the mobile/wearable devices opportunity" (2019) 2:9 NPJ Digital Medicine 1 at 2.

[60] See Danielle Arigo et al, "The history and future of digital health in the field of behavioral medicine" (2019) 42 J Behavioral Med 67 at 71; Filippo Piccinni, Giovanni Martinelli & Antonella Carbonaro, "Accuracy of Mobile Applications versus Wearable Devices in Long-Term Step Measurements" (2020) 20:21 Sensors 1 at 2.

[61] See Chia-Yi Hou, "Four areas of health innovation boosted by the pandemic" *Nature Medicine* (13 June 2022) 1 at 1.

[62] See e.g. the definitions provided by the following authors: Elena S Ismailova, John A Wagner & Eric D Perakslis, "Wearable Devices in Clinical Trials: Hype and Hypothesis" (2018) 104:1 Clinical Pharmacology & Therapeutics 42 at 42 ("We define here wearable technologies as sensors and/or software applications (apps) on smartphones and tablets that can collect health-related data remotely, i.e., outside of the healthcare provider's office"); Matthew Smuck et al, "The emerging clinical role of wearables: factors for successful implementation in healthcare" (2021) 4:1 NPJ Digital Medicine 1 at 1 ("Wearable technology, also known as 'wearable devices' or simply 'wearables', generally refers to any miniaturized electronic device that can be easily donned on and off the body, or incorporated into clothing or other body-worn accessories").

[63] See e.g. Joshua M Pevnick et al, "Wearable technology for cardiology: An update and framework for the future" (2018) 28:2 Trends in Cardiovascular Medicine 144 at 145.

Irrespective of the data collection modalities, in their most basic form wearable devices can be defined as "advanced sensor and computing technologies that a person can wear on their body during daily activity to generate, store, and transmit data".[64] Wearable devices can be worn directly on the user's body or on an article of clothing or other type of worn accessory.[65] While wearable devices can be employed for personal use by individuals for self-diagnosis and self-monitoring,[66] they can also be employed by physicians for integration within an RPM system.[67]

In addition to consumer wearables, such as smart watches and fitness trackers, wearable devices include blood pressure monitors, glucometers, electrocardiograms (ECGs), and other types of body sensors.[68] They can be used to measure a variety of data and health parameters, such as heart rate, blood pressure, blood oxygen levels, and body temperature.[69]

Wearable devices provide numerous potential benefits that can be harnessed and integrated into patient care. Research has shown, for instance, that the collection of resting heart rate data by wearable devices provides more precise and consistent depictions of patients' resting heart rate that measurements obtained in the clinic.[70] Moreover, research has shown that vital sign data collected from wearable devices can "more accurately predict several clinical laboratory

[64] See Jesse V Jacobs et al, "Employee acceptance of wearable technology in the workplace" (2019) 78 Applied Ergonomics 148 at 148.
[65] See Smuck et al, *supra* note 62 at 1.
[66] See e.g. Lin Lu et al, "Wearable Health Devices in Health Care: Narrative Systematic Review" (2020) 8:11 JMIR Mhealth Uhealth 1 at 2.
[67] See Roblyer, *supra* note 8 at 102703-2; Szydło & Konieczny, *supra* note 38 at 44.
[68] See Roblyer, *supra* note 8 at 102703-2.
[69] See Mirza Mansoor Baig et al, "A Systematic Review of Wearable Patient Monitoring Systems – Current Challenges and Opportunities for Clinical Adoption" (2017) 41:115 J Med Systems 1 at 2; Sumit Majumder, Tapas Mondal & M Jamal Deen, "Wearable Sensors for Remote Health Monitoring" (2017) 17:1 Sensors 130 at 131.
[70] See Jessilyn Dunn et al, "Wearable sensors enable personalized predictions of clinical laboratory measurements" (2021) 27 Nature Medicine 1105 at 1107.

measurements with lower prediction error than predictions made using clinically obtained vital sign measurements".[71] One critical factor in this enhanced or improved outcome is the length of time over which the health data is monitored, which provides a more accurate overview of the patient's state of health in real time.[72]

The ability of these technologies to be worn makes them especially conducive to continuous monitoring and passive data acquisition. For instance, ECGs can be used in cardiovascular monitoring programs to continuously record fluctuations in heart beat rate.[73] Wearable sensors can be used in blood oxygen saturation monitoring systems, with built-in pulse oximeters that can measure levels oxygenated haemoglobin in the patient's bloodstream.[74] These devices connect to Bluetooth and transfer collected data to the patient's health care provider via the Internet.[75]

However, wearable devices entail certain risks and inconveniences for patients. For one, measurements or readings may be inaccurate or misleading, which can negatively affect the patient's treatment and care.[76] They can often restrict personal movement or mobility, leading to patient discomfort which may subsequently influence readings of their physiological data.[77] They can also often be difficult to use for elderly populations or for patients with skin injuries.[78]

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[71] See *ibid* at 1105.
[72] See *ibid* at 1107.
[73] See T Sivani & Sushruta Mishra, "Wearable Devices: Evolution and Usage in Remote Patient Monitoring System" in Sushruta Mishra, Alfonso González-Briones, Akash Kumar Bhoi, Pradeep Kumar Mallick & Juan M Corchado, eds, *Connected e-Health: Integrated IoT and Cloud Computing* (Cham: Springer, 2022) 311 at 314.
[74] See *ibid* at 318.
[75] See *ibid* at 325.
[76] See "Safety Risks with Wearable Technologies" (last accessed 10 April 2023), online: *ECRI* <https://www.ecri.org/safety-risks-with-wearable-technologies>.
[77] See National Research Council Canada, "New contactless technology shifts health monitoring between hospital and home" (1 October 2020), online: *Government of Canada* <https://nrc.canada.ca/en/stories/new-contactless-technology-shifts-health-monitoring-between-hospital-home>; Malasinghe et al, *supra* note 37 at 59.
[78] See e.g. Bernd Hettich & Shuai Jiang, "Delivering contactless health monitoring through radar sensors" (6 March 2023), online: <https://www.embedded.com/delivering-contactless-health-monitoring-through-radar-sensors/>.

Furthermore, as is inherent in digital health technologies, there are significant privacy and security risks in the use of wearable devices.[79] We will revisit the question of privacy and security risks in Chapters II and III.

2.1.2 *Implantable Devices*

Implantable devices refer to those devices which are introduced, in whole or in part, into the human body. These invasive interventions allow for the direct measurement of biometric data, such as heart rate and pulmonary artery pressures, which can then be transmitted to the patient's health care provider.[80] Examples of such devices include pacemakers, which are used to regulated abnormal cardiac rhythms, and implantable cardioverter defibrillators (ICDs) which are used in patients at high risk of cardiac arrest. Other examples of implantable devices include implanted sensors, which are implemented inside the patient's body, underneath the skin, to allow for the real-time observation of their vital signs.[81]

Overall, implantable devices have been shown to play an important role in the management of cardiac disease.[82] Examples of the use of implantable devices for RPM include a clinical trial at the Medical University of Graz, Austria, which tested the safety, efficacy and reliability of RPM in pacemaker (PM) and implanted cardioverter defibrillator (ICD) patients.[83] Data was collected

[79] See e.g. Liezel Cilliers, "Wearable devices in healthcare: Privacy and information security issues" (2020) 49:2-3 Health Information Management J 150.
[80] See Taylor et al, *supra* note 21 at 1.
[81] See Osamah S Albahri et al, "Systemic Review of Real-time Remote Health Monitoring System in Triage and Priority-Based Sensor Technology: Taxonomy, Open Challenges, Motivation and Recommendations" (2018) 42:80 J Med Systems 79 at 80; Nora El-Rashidy, "Mobile Health in Remote Patient Monitoring for Chronic Diseases: Principles, Trends, and Challenges" (2021) 11:607 Diagnostics 1 at 6.
[82] See e.g. Niraj Varma & Renato Pietro Ricci, "Telemedicine and cardiac implants: what is the benefit?" (2013) 34:25 European Heart J 1885 at 1890.
[83] See S Perl et al, "Socio-economic effects and cost saving potential of remote patient monitoring (SAVE-HM trial)" (2013) 169:6 Int J Cardiology 402 at 402.

via a mobile transmission device, which transmitted data regarding the functioning of the implanted devices (PM or ICD), as well as the patient's clinical status to the patient's health care team.[84] A similar multi-centre study based in the Netherlands tested an RPM system for remote follow-up of patients with implantable cardioverter defibrillator (ICD) and cardiac resynchronisation therapy (CRT) devices.[85] Enrolled patients were provided with a home transmitter which interrogated the implanted devices and transmitted the data to the hospital, where the study team retrieved and analyzed it.[86]

Despite their benefits, there are inherent risks in the clinical use of implantable devices. As with all digital health technologies, implantable devices entail privacy and security risks for patients.[87] However, one risk that is unique to implantable devices is the risk of internal physical injury.[88] For instance, the patient's body might reject or have an adverse reaction to the implantable device.[89] ICDs may inappropriately issue electrical shocks which can harm patients.[90] The use of implantable devices may also have psychological impacts on patients, who may experience stress or anxiety over concerns about the presence of the device in their body.[91]

2.1.3 *Contactless Devices*

[84] See *ibid* at 403.
[85] See H Versteeg et al, "Patient perspective on remote monitoring of cardiovascular implantable electronic devices: rationale and design of the REMOTE-CIED study" (2014) 22:10 Netherlands Heart J 423 at 423.
[86] See *ibid* at 425.
[87] See e.g. Carmen Camara, Pedro Peris-Lopez & Juan E Tiapador, "Security and privacy issues in implantable medical devices: A comprehensive survey" (2015) 55 J Biomedical Informatics 272.
[88] See e.g. Nuffield Council on Bioethics, "Bioethics Briefing Note: Medical Implants" (June 2019), online (pdf): <https://www.nuffieldbioethics.org/assets/pdfs/Medical-implants.pdf> at 3.
[89] See *ibid.*
[90] See *ibid*
[91] See e.g. Shawn HE Harmon, Gill Haddow & Leah Gilman, "New risks inadequately managed: the case of smart implants and medical device regulation" (2015) 7:2 Law Inn Tech 231 at 248.

As RPM technologies which entail contact with the patient's body, such as wearable and implantable devices, can raise a number of difficulties for patients, contactless methods are increasingly being researched and explored as potential options for patients, though this field is still very much in its infancy.[92] Contactless RPM technologies include ambient technologies and sensors which require the patient to be present within a certain distance of the sensor.[93] Contactless technologies are generally classified into two categories: image-based methods, which have been more fully explored to date, and radar-based methods.[94] Moreover, they are often more cost-efficient than other types of technologies.[95]

Image-based methods include video cameras, infrared sensors, and time-of-flight cameras.[96] They can detect a number of visual cues, such as facial expressions or physical movements.[97] These functionalities are especially relevant in fall detection, sleep monitoring, epilepsy monitoring, as well as respiration and apnea monitoring.[98] Radar-based methods include respiration sensing technologies and Impulse Radio Ultra-Wideband (IR-UWB) devices for measuring heart rate.[99] Whether image- or radar-based, contactless RPM devices do not require the patient to actively input their health data. While contactless monitoring methods represent a

[92] See Malasinghe et al, *supra* note 37 at 59.
[93] See *ibid*.
[94] See *ibid* at 60.
[95] See *ibid.*
[96] See Supriya Sathyanarayana et al, "Vision-based patient monitoring: a comprehensive review of algorithms and technologies" (2018) 9:2 J Ambient Intelligence and Humanized Computing 225 at 226.
[97] See *ibid.*
[98] See *ibid;* Malasinghe et al, *supra* note 37 at 59.
[99] See e.g. Shekh Md Mahmudul Islam, "Radar-based remote physiological sensing: Progress, challenges, and opportunities" (2022) 13 Frontiers in Physiology 1 at 2; Faheem Khan et al, "An Overview of Signal Processing Techniques for Remote Health Monitoring Using Impulse Radio UWB Transceiver" (2020) 20:9 Sensors 1 at 7.

novel and innovative domain within the larger RPM ecosystem, further research will be required to test their efficiency and feasibility.[100]

2.2 *Active Data Collection Modalities*

Active data collection modalities encompass technologies in which the patient plays a role within the RPM data acquisition system.[101] In this modality, the patient self-monitors and collects their health data themselves, which is then transmitted and reported to their health care provider or health care staff. RPM technologies or devices which may fall into this category include 1) wearable devices which use active data collection modalities and 2) mobile health applications.

2.2.1 *Wearable Devices with Active Data Collection Modalities*

While the functionalities of wearable devices are especially conducive to continuous monitoring of patient through passive data collection, some have active data collection modalities which prompt the patient to input their health data themselves. One relevant example is the post-surgical monitoring program implemented by the University of California, Los Angeles (UCLA) for thoracic surgery patients.[102] After hospital discharge, surgical patients were provided with a tablet, blood pressure monitor, heart rate monitor, weight scale, and pulse oximeter.[103] Patients were instructed to use these devices daily to measure their vital signs and to transmit their readings on a daily basis via their tablet.[104] Additionally, they were required to complete a daily

[100] See Malasinghe et al, *supra* note 37 at 72.
[101] See Kourtis et al, *supra* note 59 at 1.
[102] See Stesha Selsky & Sean M Reed, "Non-Invasive Remote Monitoring to Decrease 30-Day Unplanned Readmissions in Thoracic Surgery Patients" (2022) 7:2 J Informatics Nursing 43.
[103] See *ibid* at 44.
[104] See *ibid* at 45.

questionnaire on their tablet, including questions related to their pain and post-operative symptoms.[105]

Another example of an RPM program employing wearable devices with active data collection modalities is the Cardiac Telehealth Program at the UCLA. Similar to the thoracic surgical program, cardiac surgery patients were provided with a cardiac telehealth kit, which includes wearable devices, such as heart rate monitors, blood pressure monitors and pulse oximeters, as well as a tablet.[106] Patients could use these devices to measure their daily health numbers, including heart rate, blood pressure and blood oxygen levels, electronically submit them to their health care provider using the tools provided in their telehealth kits.[107]

Additionally, patients could complete questionnaires via their tablets, providing daily updates about their recovery process, as well as photos and videos of their incision sites.[108] This information served to help staff detect any potential issues or deteriorations in patients' conditions, such as abnormal heart rhythms or shortness of breath, and take the appropriate course of action.[109] Overall, the post-surgical monitoring program helped to lower patient hospital readmissions with

[105] See *ibid.*
[106] See Aetonix, "10 Remote Patient Monitoring Programs from 10 Different States", (last accessed 4 April 2023), online: <https://aetonix.com/telehealth-remote-patient-monitoring/10-remote-patient-monitoring-programs-from-10-different-states/>.
[107] See Acuma Health, "Can Remote Patient Monitoring Improve Post-Surgical Care and Recovery?" (29 April 2022), online: <https://acumahealth.com/can-remote-patient-monitoring-improve-post-surgical-care-and-recovery/>.
[108] See Altexsoft, "Remote Patient Monitoring Systems: Components, Types, Vendors, and Implementation Steps" (3 November 2020), online: <https://www.altexsoft.com/blog/remote-patient-monitoring-systems/>.
[109] See Aetonix, *supra* note 106.

post-surgical complications.[110] The positive clinical outcomes of RPM in the post-surgical recovery context have also been described in the literature.[111]

2.2.2 *Mobile Health Applications*

Similar to wearable devices, the area of mobile health is growing rapidly and becoming increasingly sophisticated. Mobile health applications (also referred to as "mobile health apps" or "mHealth apps") can be broadly defined as "health applications based on mobile terminal systems such as Android and iOS that provide services such as medical information inquiry and symptom self-examination".[112] Mobile health applications comprise a diverse array of technologies that include general health and information applications that are not targeted to individual users, individualized illness prevention and management applications, and "symptom checker" applications.[113] While mobile health applications are not all intended for use by physicians with their patients,[114] mobile health applications can figure within RPM systems and are increasingly being integrated into clinical care. One example of the use of mobile health applications within an RPM system is the CareSimple-Covid app program, which involves the monitoring of COVID-19 patients post-discharge at the Hospital Centre of the Université de Montréal (CHUM).

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[110] See *ibid.*
[111] See e.g. Kivanç Atiglan et al, "Remote patient monitoring after cardiac surgery: The utility of a novel telemedicine system" (2021) 36:11 J Cardiac Surgery 4426 at 4231—33; Steven M Kurtz et al, "Patient Perceptions of Wearable and Smartphone Technologies for Remote Outcome Monitoring in Patients Who Have Hip Osteoarthritis or Arthroplasties" (2022) 37:7 J Arthroplasty S488 at S490—92.
[112] See e.g. Chen Wang & Huiying Qi, "Influencing Factors of Acceptance and Use Behavior of Mobile Health Application Users: Systematic Review" (2020) 9:3 Healthcare 357 at 357.
[113] See e.g. Michael Lang & Ma'n H Zawati, "The app will see you now: mobile health, diagnosis, and the practice of medicine in Quebec and Ontario" (2018) 5:1 JL & Biosciences 142 at 157.
[114] See *ibid* at 145, 153.

The Centre of Network Flow Optimization (CNFO) at the CHUM implemented the CareSimple-Covid app program to remotely monitor patients with COVID-19 to ensure continuity and quality of care for patients who were "medically stabilized but at risk of decompensation".[115] The implementation of the program also served to evaluate the user-friendliness of the program and identify patient perspectives of the program.[116] Patients download the CareSimple-Covid application on Android and iOS smartphone and tablet systems. Patient users of the application are then required to enter and submit data on their symptoms as well as relevant clinical information twice daily. Inputted information can then be analyzed and processed automatically by the system. If any deterioration in the patient's condition is discerned, it alerts a nurse, who would then contact and follow-up with the patient. The CareSimple-Covid app program involves a 24/7 team of nurses, medical residents and physicians, and the assistance of a technical support team. Patient satisfaction with the system was high, with patients finding the system user-friendly and appropriate to their health care needs.[117]

The safety of mobile health applications has been described as an "emerging public health issue".[118] Mobile health applications are becoming increasingly ubiquitous, both in clinical care settings and amongst consumers, and calls have been made for stricter regulation of these applications.[119] Authors have noted the privacy and security risks in the use of mobile health

[115] See Bouabida et al, *supra* note 8 at 3.
[116] See *ibid.*
[117] See *ibid* at 7.
[118] See Saba Akbar, Enrico Coiera & Farah Magrabi, "Safety concerns with consumer-facing mobile health applications and their consequences: a scoping review" (2020) 27:2 J Am Med Informatics Association 330 at 330.
[119] See e.g. Maria Jogova, James Shaw & Trevor Jamieson, "The Regulatory Challenge of Mobile Health: Lessons for Canada" (2019) 14:3 Healthcare Policy 19.

applications[120] and professional guidelines recommend that physicians be cognizant of these risks when recommending these applications to their patients.[121] We will address the question of physician disclosure of risks in our analysis of the duty to inform in Chapter III.

In brief, RPM encompasses a broad range of technologies which are continually evolving and developing, a fact which often makes it difficult to neatly classify or categorize them. The example of wearable devices illustrates such difficulties, as they can be categorized within both the active and passive data collection categories. Irrespective of these challenges, RPM systems all have the following features in common: (1) a data acquisition system; (2) a data processing system; (3) an end-terminal where the health care provider can access the data; and, (4) a communication network.[122] The specific type of technology employed and the data collection method (as well as collection frequency) will generally depend upon the patient's specific circumstances and the health condition for which the monitoring is intended.[123]

In all cases, active patient engagement and compliance are important factors for achieving high user retention and, as a result, improved adherence and clinical outcomes.[124] Studies have shown that the degree of patient compliance with their prescribed RPM system correlates with the degree

[120] See e.g. Bakheet Aljedaani & M Ali Babar, "Challenges With Developing Secure Mobile Health Applications: Systematic Review" (2021) 9:6 JMIR mHealth & uHealth 1; Gioacchino Tangari et al, "Mobile health and privacy: cross sectional study" (2021) 373 BMJ 1.
[121] See *Canadian Medical Association, supra* note 35 at 4.
[122] See Jeddi & Bohr, *supra* note 6 at 204; Malasinghe et al, *supra* note 37 at 59.
[123] See Jeddi & Bohr, *supra* note 6 at 204.
[124] Patient engagement is critical to the overall operation and success of RPM systems. Variable patient engagement is a key challenge to the greater adoption of RPM in clinical care and can be influenced by socioeconomic factors and the patient's location setting. See e.g. Elizabeth Kirkland et al, "Patient Demographics and Clinic Type Are Associated With Patient Engagement Within a Remote Monitoring Program" (2021) 27:8 Telemedicine & e-Health 843 for a detailed discussion of the factors that can influence patient adherence to RPM protocols. This is essential where the device or apparatus used requires active patient input of data. See e.g. Tien Bui et al, "Remote patient monitoring for improving outpatient care of patients at risk for sepsis" (2016) 2016 IEEE Systems and Information Engineering Design Symposium 136 at 138.

of derived clinical benefit.[125] One major issue is that patients may lack motivation to continually adhere to RPM protocols.[126] Given that poor adherence reduces the clinical utility and efficiency of these systems, ensuring patient engagement and compliance is crucial, something that is often overlooked in the implementation of RPM systems.[127]

Patient engagement and adherence is especially important for RPM, as it is essential that patients act in such a manner as to aid their physician to properly treat them.[128] It also has important legal implications. Patients are required to collaborate with their physician, including providing information to the physician and following given instructions.[129] As for physicians, they have a duty to instruct their patients, which requires them to provide patients with sufficient information to enable them carry out the provided instructions.[130] The duty to instruct the patient (and the patient's corollary duty to collaborate with their physician) are likely to become more important with the rise of telehealth, as more locus of responsibility is likely to shift to the patient regarding adherence and compliance with the physician's instructions. These issues and other legal implications of RPM will be explored and elaborated upon in the subsequent chapters of this thesis.

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[125] See e.g. Dejan Su et al, "Diabetes Management Through Remote Patient Monitoring: The Importance of Patient Activation and Engagement with the Technology" (2019) 25:10 Telemedicine & e-Health 952 at 957.
[126] See Jeddi & Bohr, *supra* note 6 at 208.
[127] See e.g. Leila S Rezai, Gerard Torenvliet & Catherine M Burns, "Increasing Patient Adherence to Home Health-Monitoring Systems" (2014) 3:1 Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care 8 at 8.
[128] See Philips-Nootens & Kouri, *supra* note 30 at para 30.
[129] See e.g. *Crossman v Stewart* (1977), 5 CCLT 45, 82 DLR (3d) 677 (BCSC) [*Crossman*]; *Leadbetter v Brand (1980)*, 37 NSR (2d) 581, [1980] NSJ No 376 (SC); *Bergeron c Faubert*, [1996] RRA 820, JE 96-1420 (QCCS), aff'd [2000] JQ no 6164 (CA); *Lamarre c Hôpital du Sacré-Coeur,* [1996] RRA 496, [1996] JQ no 663 (SC); *Therrien c Launay,* [2005] RRA 349, 34 CCLT (3d) 6 (QCCS) [*Therrien*].
[130] See Gerald B Robertson & Ellen I Picard, *Legal Liability of Doctors and Hospitals in Canada,* 5th ed (Toronto: Thomson Reuters, 2017) at 348.

CHAPTER II
REMOTE PATIENT MONITORING, THE PHYSICIAN-PATIENT RELATIONSHIP, AND RISKS OF PATIENT INJURY

The ability for physicians to remotely monitor patients outside of traditional health care settings presents new challenges in the delivery of patient care. In particular, the clinical use of RPM may challenge the nature and scope of the legal duties that physicians owe towards their patients. The unclear scope of these duties in the RPM context in particular may create risks of patient injury, for which physicians may be held liable.

Given that patients cannot succeed in a medical liability action without proving they have suffered injury, in this chapter we will consider the types of risks that may arise from the clinical implementation of RPM. For this purpose, we will first provide an overview of the nature of the physician-patient relationship under both Anglo-Canadian common law and Quebec civil law, including a description of the legal duties of physicians. Next, we will outline the basic conditions required for the determination of physician liability under both legal systems. Having summarized these conditions, we will describe the types of risks which may be engendered by the clinical use of RPM. As such, this chapter's analyses will contextualize our discussions of breach of the standard of care (common law) and the contractual obligation of means (civil law) in Chapter III.

1. The Nature of the Physician-Patient Relationship

The physician-patient relationship has been described as "a consensual relationship in which the patient knowingly seeks the physician's assistance and in which the physician knowingly

accepts the person as a patient."[131] The conceptual nature of the physician-patient relationship has changed throughout history, from initially being characterized as a paternalistic model of patient dependency and physician authority**,** to an informative and patient-centred model of shared decision-making between the physician and the patient, characterized by patient agency and autonomy.[132]

Under Quebec law, the physician-patient relationship is generally characterized as an *intuitu personae* contractual relationship,[133] which is formed by the "sole exchange of consents" between the physician and the patient.[134] At common law, the physician-patient relationship, which generally begins as soon as the physician agrees to the treat the patient, is characterized as both contractual and fiduciary in nature.[135] The contractual relationship is established through the patient's request for and obtainment of professional medical services.[136]

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[131] See *Bovara v Francis Hospital*, 298 Ill App 3d 1025 (App Ct 1998) at 1030.

[132] See e.g. Ezekiel J Emanuel & Linda L Emanuel, "Four models of the physician-patient relationship" (1992) 267:16 JAMA 2221 at 2221; R Kaba & P Sooriakumaran, "The Evolution of the Doctor-Patient Relationship" (2007) 5:1 Int J Surgery 57 at 61—62; Mark Siegler, "The Progression of Medicine: From Physician Paternalism to Patient Autonomy to Bureaucratic Parsimony" (1985) 145:4 JAMA 713 at 714—15.

[133] See e.g. *X c Mellen,* [1957] BR 389 (QC) at 408.

[134] See art 1385 CCQ. There are circumstances, however, in which a patient may not be capable of entering into a medical contract. This may occur, for instance, where a patient is unconscious following an accident or has a pre-existing incapacity. In these circumstances, the legal relationship between the physician and the patient is extracontractual in nature and is therefore governed by the *Civil Code of Québec*'s extracontractual liability regime (art 1457 CCQ). See Philips-Nootens & Kouri, *supra* note 30 at para 42**.** Within the RPM context, the nature of the physician-patient relationship will generally be contractual, given that the introduction of RPM within the patient's care will require that the physician assess the clinical benefit of the system, prescribe it to the patient, and configure it to meet the patient's specific needs.

[135] See e.g. *Norberg v Wynrib*, [1992] 2 SCR 226, 92 DLR (4th) 449 at 485—86 [*Norberg*]. However, not every physician-patient relationship is fiduciary in nature, and the nature and extent of the physician's fiduciary obligations towards their patients may differ from case to case. See Robertson & Picard, *supra* note 130 at 8—9.

[136] See *Norberg, supra* note 135 at 485. See also *McInerney v MacDonald*, [1992] SCR 138, 93 DLR (4th) 415 at para 7 [*McInerney*].

The fiduciary nature of the relationship, which has been described by the Supreme Court of Canada as the "most fundamental characteristic" of the physician-patient relationship, arises both from the special relationship of trust and confidence between the physician and patient and from the power imbalance between the two parties.[137] This relationship consequently imposes certain obligations on physicians, including the duties to act with utmost loyalty and good faith when dealing with their patients, to hold information received from or about their patients in confidence, to make proper disclosure of information to patients, and to avoid conflicts of interest.[138]

Under both legal traditions, the formation of the physician-patient relationship gives rise to a number of legal duties, which are similar in both systems. Under Quebec law, these duties generally comprise: (1) the duty to inform; (2) the duty to treat; (3) the duty to follow-up; and (4) the duty to maintain professional secrecy.[139] At common law, the physician's duties are comparable to their civil law counterparts and include, alongside the duty to inform,[140] the duties to attend, diagnose, refer, treat, follow-up, and instruct.[141]

The clinical implementation of RPM may challenge the nature and scope of these duties. It also challenges the scope and content of physicians' duties due to the lack of judicial precedent

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[137] See e.g. *Halushka v University of Saskatchewan* (1965), 53 DLR (2d) 436, 52 WWR 608 (Sask CA) at para 29*; Kenny v Lockwood,* [1932] 1 DLR 507, [1932] OR 141 (CA) at para 86*; McInerney, supra* note 136 at para 19; *Norberg, supra* note 135 at 485—86.

[138] See *McInerney, supra* note 136 at para 19; Robertson & Picard, *supra* note 130 at 5.

[139] See Philips-Nootens & Kouri, *supra* note 30 at Title II. Authors Jean-Louis Baudouin, Patrice Deslauriers and Benoît Moore list the following four duties of physicians: 1) the duty to inform; 2) the duty to diagnose ("poser un diagnostic juste sur la condition du patient"); 3) the duty to treat; and 4) the duty to maintain confidentiality ("maintenir le secret professionel"). They do not consider the duty to follow-up ("l'obligation de suivi") to be an independent duty, but rather a component of the duty to treat. See Jean-Louis Baudouin, Patrice Deslauriers & Benoît Moore, *La responsabilité civile*, 9th ed, II (Cowansville, QC: Yvon Blais, 2021) at paras 2-45, 2-80.

[140] See *Hopp v Lepp*, [1980] 2 SCR 192, 112 DLR (3d) 67 at 196 [*Hopp*]; *Reibl v Hughes,* [1980] 2 SCR 880, 114 DLR (3d) 1 at 889 [*Reibl*].

[141] See Robertson & Picard, *supra* note 130 at 269.

and professional guidelines specific to RPM. This lack of clarity, in turn, may create risks for patients, who may suffer injury from the use of RPM, and for physicians, who may be held liable for causing these injuries. Before discussing these risks, we will first outline the conditions for medical liability rules under both legal traditions.

2. Conditions for Imposing Medical Liability

Under both the civil law and common law, the primary objective of liability is compensation, i.e. to indemnify those who have suffered injury through the fault or negligence of another.[142] The conditions required to determine medical liability differ slightly between the two legal traditions, though their fundamental components are similar.

Even though the physician-patient relationship is qualified as contractual under Canadian common law, medical liability is generally determined through the tort of negligence.[143] The legal principles that apply in medical liability actions are the same as those that govern all types of negligence claims for reparation of personal injury. In order to succeed in a medical negligence action, the patient must demonstrate, on a balance of probabilities, that:

1. The physician owed them a duty of care;
2. The physician breached the standard of care;

[142] See Allen M Linden et al, *Canadian Tort Law: Cases, Notes & Materials,* 16th ed (Toronto: LexisNexis Canada, 2022) at 9 for the compensation functions of tort law. For civil law, see arts 1457 (extracontractual liability) and 1458 CCQ (contractual liability).

[143] While negligence constitutes the main common law cause of action for physician liability, liability may also be found under other causes of action in tort, such as battery and false imprisonment, or grounded in breach of contract. See Robertson & Picard, *supra* note 130 at 543.

3. The patient suffered legally cognizable injury; and
4. The physician's negligence was the factual and legal cause of the patient's injury.[144]

Under Quebec civil law, there is no special regime for the treatment of medical liability claims, which instead fall under the general civil liability regime of the *Civil Code of Québec.* In both contractual and extracontractual liability cases, the patient must prove, on a balance of probabilities,[145] that:

1. The physician committed a fault ("*faute*")[146];
2. The patient suffered an injury ("*préjudice*"); and
3. There is a causal relationship between the fault and the injury, i.e. that the physician's fault caused the patient's injury ("*lien causal*" or "*lien de causalité*").[147]

Additionally, in contractual claims the plaintiff must prove that the damages suffered were "foreseen or foreseeable at the time the obligation was contracted".[148]

To date, courts have never evaluated how these conditions may be interpreted in medical liability claims involving RPM. Commentators have noted the challenges in the determination of

[144] See e.g. *Mustapha v Culligan of Canada Ltd*., 2008 SCC 27 at para 3 [*Mustapha*].
[145] See art 2804 CCQ.
[146] Under the *Civil Code of Québec*, the breach of a contractual undertaking constitutes a contractual fault. See art 1458 para 1 CCQ: "Every person has a duty to honour his contractual undertakings". As will be discussed in Chapter III, physicians' contractual obligations to their patients are generally obligations of means. In the extracontractual regime of the *Civil Code of Québec*, the fault comprises a breach of the general duty of abiding by the rules of conduct so as not to cause harm to others. See art 1457 para 1 CCQ: "Every person has a duty to abide by the rules of conduct incumbent on him, according to the circumstances, usage or law, so as not to cause injury to another."
[147] See art 1458 CCQ.
[148] See art 1613 CCQ.

medical liability where novel medical technologies or models of patient care are utilized, such as the use of AI, for instance.[149] Some commentators have even suggested modifications to existing liability regimes for novel health care technologies.[150] Nonetheless, the basic conditions for imposing medical liability described above apply to RPM, though they may be challenged by the novel aspects of RPM.[151]

Having summarized the conditions for medical liability, we will now direct our attention to the risks of patient injury created by the clinical use of RPM. As we will demonstrate, there are significant risks of patient injury in RPM. While some risks may arise from the actual technologies themselves, many risks are associated with the unclear nature and scope of physicians' duties in the usage of RPM technologies.

3. Risks of Patient Injury in Remote Patient Monitoring

Proof of patient injury[152] is central to the determination of physician liability, in both civil law and common law.[153] As authors Robertson and Picard note in their treatise on the liability of physicians

[149] See e.g. Forcier et al, *supra* note 26 at 7; Michael Lang, Alexander Bernier & Bartha Maria Knoppers, "Artificial Intelligence in Cardiovascular Imaging: "Unexplainable" Legal and Ethical Challenges?" (2021) 38 Can J Cardiology 225 at 230; Hannah R Sullivan & Scott J Schweikart, "Are current tort liability doctrines adequate for addressing injury caused by AI?" (2019) 21:2 AMA J Ethics 160 at 160.

[150] See e.g. Iria Giuffrida, "Liability for AI Decision-Making: Some Legal and Ethical Considerations" (2019) 88 Fordham L Rev 439 at 443; Sullivan & Schweikart, *supra* note 149 at 164.

[151] See *Médecins (Ordre professionnel des) c Delmar-Greenberg*, 2020 QCCDMD 17 at para 83: "Au moment où la télémédecine devient de plus en plus importante, et en particulier dans le contexte de la crise de la COVID-19, *le médecin doit réaliser que toutes ses obligations déontologiques et légales s'appliquent lorsqu'il a recours à cette technologie*." (emphasis is ours). Though grounded in professional law rather than tort law or civil liability, this statement indicates that, contrary to what is proposed by certain commentators, existing legal principles can inform us about physicians' duties when relying on telehealth technologies, despite the novel aspects and issues that these technologies raise.

[152] Injury may also be referred to as "loss" or "damage". See Robertson & Picard, *supra* note 130 at 257.

[153] See *ibid*.

and hospitals at common law, proof of the other elements in a medical negligence action "will be of no avail unless the plaintiff also satisfies the court that he or she has suffered a loss which was caused by the defendant's actions".[154] Under both legal traditions, patient injury may comprise both physical and psychological or mental injuries.[155]

The clinical use of RPM may be beneficial to patients, but it may also create risks of injury. Some of these risks are associated with the RPM technologies themselves. Poorly designed or negligently manufactured devices can cause injury and, in extreme cases, death.[156] Consider, for instance, the case of a manufacturing defect affecting RPM for cardiac monitoring causing a delay in the transmission of data or the data to not be transmitted altogether.[157] A delay in treatment due to the device's failure to indicate a cardiac arrhythmia or irregular heartbeat may have "disastrous consequences" for the patient's health.[158]

Indeed, delays in treatment are the focus of much scholarly attention concerning risks of patient injury in RPM. These delays may not only ensue from technical issues, but also from improper data management or improper use of the RPM system by the physician or clinical care team (or a combination of these factors). As previously discussed, one of the key features of RPM is the ability to collect large volumes of clinical data from patients and transmit them to the patient's

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[154] See *ibid*.
[155] For common law, see *Mustapha, supra* note 144 at para 8. The *Civil Code of Québec* refers to bodily, moral, material injuries. This applies to both the extracontractual and contractual regimes. See arts 1457 para 1, 1458 para 1 CCQ.
[156] See Angela Ryan, Brendan Loo Gee, Susan H Fenton & Meredith Makeham, "The Impact on Safety and Quality of Care of the Specialist Digital Health Workforce" in Kerryn Butler-Henderson, Karen Day & Kathleen Gray, eds, *The Health Information Workforce: Current and Future Developments* (Cham: Springer, 2021) 201 at 202.
[157] See e.g. Rebecca Kowalski et al, "Optimizing usability and signal capture: a proactive risk assessment for the implementation of a wireless vital sign monitoring system" (2017) 41:8 J Med Engineering & Technology 623 at 626.
[158] See e.g. Sara Gerke et al, "Regulatory, safety, and privacy concerns of home monitoring technologies during COVID-19" (2020) 26:8 Nature Medicine 1176 at 1181.

health care providers. This gives providers greater access to relevant information regarding their patients' conditions, often on a continuous real-time basis, thereby allowing providers to better monitor patients' health. Patient surveillance requires the monitoring of vital signs, early recognition of any deterioration in the patient's health status, and timely responses to potential patient harms.[159] RPM's unique features allow physicians to have more detailed insights into patients' health status and the evolution of their health conditions, which can allow for earlier and more responsive detection of potential health issues.[160] The liability issues related to delayed treatment, whether due to technical issues or improper data management, will be revisited in our discussions of causation in Chapter IV.

Nonetheless, RPM devices are not infallible and may transmit inaccurate data, including false positives, which incorrectly indicate that a patient has a particular condition, and false negatives, which fail to detect a critical event.[161] These false results may result, for instance, from battery issues or calibration problems in the RPM device.[162] In addition to technical issues, inaccurate data transmission can result from improper device usage by patients.[163] The improper placement of continuous glucose monitoring wearable devices by the patient on their body, for example, may lead to inaccurate data collection.[164] The use of body sensors, as another example, may create patient discomfort, which in turn may influence their device's reading of their physiological

[159] See Kowalski et al, *supra* note 157 at 623.
[160] See e.g. Dhruv R Seshadri et al, "Wearable Sensors for COVID-19: A Call to Action to Harness Our Digital Infrastructure for Remote Patient Monitoring and Virtual Assessments" (2020) 2:8 Frontiers in Digital Health 1 at 3.
[161] See e.g. Neil Charness et al, "Metrics for Assessing the Reliability of a Telemedicine Remote Monitoring System" (2013) 19:6 Telemedicine J & E-Health 487 at 487.
[162] See e.g. Priyanka Kakria, NK Tripathi & Peerapong Kitipawang, "A Real-Time Health Monitoring System for Remote Cardiac Patients Using Smartphone and Wearable Sensors" (2015) Int J Telemedicine & Applications 1 at 2.
[163] See Charness et al, *supra* note 161 at 487.
[164] See Robab Abdolkhani et al, "Patient-generated health data management and quality challenges in remote patient monitoring" (2019) 2:4 JAMIA Open 471 at 474.

data.[165] In both examples, the data transmitted to the physician provide an inaccurate description of the patient's health. This, in turn, may lead to inappropriate clinical responses which could potentially lead to patient injury.

A French study on the use of implantable cardioverter-defibrillations (ICDs) is illustrative of the challenges related to inaccurate diagnoses and inappropriate clinical responses.[166] ICDs, which are implanted into the chest, detect irregular heartbeats and, where necessary, use electrical shocks to restore the patient's regular heart rhythm.[167] The study, which recruited participants from a registry of patients who had been implanted with ICDs as part of their clinical care, examined the prevalence of inappropriate diagnoses and inappropriate treatments in these patients, who were followed over a fifteen month period.[168] The study found that inappropriate diagnoses occurred in 9% of patients, 36% of which suffered at least one inappropriate electrical shock.[169] Though the overall rate of inappropriate shock in patients was found to be low (3%), this study demonstrates the potential for inappropriate treatments or clinical responses in RPM, which may be prejudicial to patients.[170]

Overall, while the ability to frequently monitor large volumes of patient data may be beneficial for patients, it does raise question regarding some of physicians' legal duties, including the duties to treat and to follow-up. For instance, depending upon the type of RPM technology and how it is

[165] See Malasinghe et al, *supra* note 37 at 59.
[166] See Tilman Perrin et al, "Role of medical reaction in management of inappropriate ventricular arrhythmia diagnosis: the inappropriate Therapy and HOme monitoRiNg (THORN) registry" (2019) 21:4 EP Europace 607.
[167] See National Heart, Lung and Blood Institute, "What are Defibrillators?" (24 March 2022), online: <https://www.nhlbi.nih.gov/health/defibrillators>.
[168] See Perrin et al, *supra* note 166 at 608.
[169] See *ibid* at 610.
[170] See *ibid* at 612.

implemented, numerous types of data can be transmitted, making management and surveillance difficult.[171] Some of the patient's data may be superfluous or of insignificant clinical utility. The time required to sort through the transmitted data to determine which variables are most relevant or critical to the patient's health in such cases can be onerous.[172] Physicians could be exposed to liability if any important variables are missed or overlooked amid the data influx, leading to delayed diagnoses, incorrect clinical responses, or delayed interventions potentially prejudicial to the patient's health.[173]

The management of large volumes of patient data leads to a further challenge connected to possible clinician fatigue or cognitive overload.[174] Clinicians may become distracted or desensitized to these large volumes of data which could potentially lead to clinical errors that could harm patients.[175] Conversely, there may be clinician overreliance on the RPM technologies, whereby the data transmission and detection features of these technologies are overestimated.[176] Overreliance could potentially create a "false sense of complacency should the technology not detect a problem".[177] Indeed, risks of patient injury due to overreliance on RPM may be amplified where the physician and clinical care team are not adequately trained and prepared in using the RPM technologies, a common concern where novel technologies are introduced into clinical

[171] See e.g. Eric L Wallace et al, "Remote Patient Management for Home Dialysis Patients" (2017) 2:6 Kidney Int Reports 1009 at 1013.
[172] See *ibid.*
[173] See *ibid.* See also Laura Blackburn et al, "Citizen generated data: the ethics of remote patient monitoring" (May 2019), online (pdf): *Foundation for Genomics and Population Health* <https://www.phgfoundation.org/briefing/ethics-of-remote-patient-monitoring>; Davis et al, *supra* note 21 at 430; Nicolas P Terry & Lindsay F Wiley, "Liability for Mobile Health and Wearable Technologies" (2016) 25 Annals Health L 62 at 75; Kowalski et al, *supra* note 157 at 623.
[174] See Wallace et al, *supra* note 171 at 1013.
[175] See "Top 10 Health Technology Hazards for 2020: Expert Insights from Health Devices" (2019), online (pdf): *ECRI Institute* <http://www.smsendo.com/wp-content/uploads/2019/10/ECRI_Top_Ten_Health_Technology_Hazards_2020.pdf>.
[176] See Blackburn et al, *supra* note 173.
[177] See *ibid.*

care.[178] Sufficient training and clinician's consequent preparedness in using novel health technologies have been highlighted as key factors in ensuring a well-skilled and competent health workforce.[179]

In addition to patient harms related to the use and management of data, the clinical use of RPM also entails privacy risks for patients. One significant privacy risk is the potential for data breaches, which refer to the unauthorized disclosure of confidential information to third parties, whether intentionally or inadvertently.[180] Data breaches could occur, for instance, if the patient's data is not properly encrypted when transmitted.[181] Given that RPM involves the collection and transmission of health-related data, which are of a sensitive and confidential nature, the potential for unauthorized access to this information can be prejudicial to patients.[182]

Illustrative of the privacy risks in RPM is a Norwegian study involving the design and use of a home-based chronic disease rehabilitation and education platform, which included the use of a manual pulse oximeter and a blood glucose metre.[183] The study, which involved the performance of risk assessments of the privacy and security aspects of the platform, identified approximately 50 security threats and unwanted incidents related to the integrity of the platform and the

[178] See Mi Ok Kim, Enrico Coiera & Farah Magrabi, "Problems with health information technology and their effects on care delivery and patient outcomes: a systematic review" (2017) 24:2 J Am Med Informatics Association 246 at 248.
[179] See Ryan et al, *supra* note 156 at 202.
[180] See e.g. Adil Hussain Seh et al, "Healthcare Data Breaches: Insights and Implications" (2020) 8:2 Healthcare 1 at 3.
[181] See e.g. Giselle S Mosnaim et al, "Digital Inhalers and Remote Patient Monitoring for Asthma" (2022) 10:10 J Allergy & Clinical Immunology: In Practice 2525 at 2532.
[182] See e.g. Gerke et al, *supra* note 158 at 1180; Timothy M Hale & Joseph C Kvedar, "Privacy and Security Concerns in Telehealth" (2014) 16:12 AMA J Ethics 981 at 981.
[183] See Eva Henriksen et al, "Privacy and information security risks in a technology platform for home-based chronic disease rehabilitation and education" (2013) 13:85 BMC Medical Informatics and Decision Making 1.

confidentiality of the information stored in the platform, such as interception of data during transmission and denial-of-service attacks.[184] The implementation of robust data encryption techniques and privacy safeguards are therefore critical in helping to mitigate these privacy risks.[185] Nonetheless, risks to patient privacy are inherent in all digital health technologies and the confidentiality of patient's information can never be fully safeguarded, even with the implementation of robust protective measures.[186] As will be discussed in the next chapter, disclosure of privacy risks will be a key component of the disclosure of risks related to RPM by physicians to patients.

In short, existing legal principles apply to the medical liability cases involving RPM, including proof of patient injury, but courts have yet to apply these principles in light of the novel facets of RPM. We will now discuss how courts may use analogy with existing principles to address medical liability actions involving RPM. While essential to the determination of liability, the occurrence of patient injury is not, on its own, sufficient.[187] Other requirements include, under common law, the breach of the standard of care and, under civil law, the commission of a fault.

[184] See *ibid* at 6—8.
[185] See Malasinghe et al, *supra* note 37 at 59.
[186] See e.g. Liang Hong et al, "Big Data in Health Care: Applications and Challenges" (2018) 2:3 Data and Information Management 175 at 191.
[187] See Robertson & Picard, *supra* note 130 at 259.

CHAPTER III
CHALLENGES IN THE DETERMINATION OF BREACH OF THE STANDARD OF CARE OR OF THE CONTRACTUAL OBLIGATION OF MEANS

While proof of patient injury is essential to a finding of medical liability, physicians are not liable for every unfavourable outcome a patient may have.[188] It must also be demonstrated, on a balance of probabilities, that the physician either breached the standard of care (common law) or breached the contractual obligation of means thereby committing a fault (civil law).[189] Despite its increased clinical uptake in recent years, RPM is still very much a burgeoning health care modality and has yet to become standard medical practice. When new medical technologies are adopted, there is often a period of uncertainty as to what medical standards of practice must be followed when using them.[190] In turn, this creates challenges in defining the applicable legal standard of care for physicians who adopt these technologies.[191] In this chapter, we will postulate which factors courts may consider when determining whether physicians who use RPM have met the appropriate standards of medical practice.

Our analysis will begin with an overview of the concept of standard of care at common law and the contractual obligation of means to which physicians are held under civil law. Next, to illustrate the challenges courts may have in determining whether physicians have met these standards in their use of RPM, we will examine the legal duties of physicians which we anticipate

[188] See e.g. *Bafaro v Dowd*, [2008] OJ No 3474, 169 ACWS (3d) 437 at para 24, aff'd 2010 ONCA 188: "An unfortunate outcome does not constitute proof of negligence".
[189] As discussed in Chapter II, by its very nature, the clinical use of RPM implies that there is an ongoing physician-patient relationship. Medical liability cases involving the use of RPM under Quebec law will therefore be contractual (see art 1458 CCQ).
[190] See e.g. Scott J Schweikart, "Who Will Be Liable for Medical Malpractice in the Future? How the Use of Artificial Intelligence in Medicine Will Shape Medical Tort Law" (2021) 22:2 Minn J L Sci & Tech 1 at 14.
[191] See *ibid* at 13.

will be the most implicated in medical liability cases involving RPM: the duties to inform, to treat, to follow-up, and to instruct. We will summarize the attendant standards of care for each duty and identify how the scope and content of these duties may be challenged by the use of RPM. We will then postulate how courts may evaluate physicians' discharge of these duties in RPM and what factors they are likely to consider in their evaluations. Finally, to conclude this chapter, we will emphasize the role of professional guidelines in the establishment of standards of medical practice, on which courts can rely to evaluate the conduct of physicians.

1. Breach of the Standard of Care (Common Law)

In negligence actions, the plaintiff must prove, on a balance of probabilities, that the defendant's conduct fell short of the required standard of care.[192] The standard of care required of physicians is that of a prudent and diligent practitioner in the same circumstances, in accordance with accepted medical practice.[193] Failure to meet the applicable standard of care may arise from both negligent actions and omissions.[194]

The identification of the applicable standard of care in a medical negligence action is a question of law.[195] The determination of whether the physician breached the applicable standard of care is a question of fact (or a mixed question of fact and law).[196] This is mainly an objective

[192] See *Mustapha,* supra note 144 at para 7.
[193] This is known as the "reasonable physician" standard. See *ter Neuzen v Korn*, [1995] 3 SCR 674, 127 DLR (4th) 577 at para 33 [*ter Neuzen*]. If the physician is (or holds themselves out to be) a specialist, their conduct will be measured against that of a reasonable specialist in their field. See *Wilson v Swanson*, [1956] SCR 804, 5 DLR (2d) 113 at 119 [*Wilson*]. There are cases, however, where general practitioners and specialists may be held to the same standard of care. See e.g. *Ares v Venner,* [1970] SCR 608, 14 DLR (3d) 4 at 614—15.
[194] See e.g. *Gemoto v Calgary Regional Health Authority*, 2006 ABQB 740 at para 474.
[195] See e.g. *Kent v MacDonald,* 2021 ABCA 196 at para 26.
[196] See *ibid.* See also Robertson & Picard, *supra* note 130 at 287.

determination, but the trier of fact will also consider the particular circumstances at the time of the alleged negligence to determine whether the physician's conduct deviated from the required standard of care.[197] Courts do not impose standards of perfection on physicians, but rather assess whether the physician exercised a reasonable degree of skill, care and judgment in their treatment of the patient.[198] Physicians are not liable for errors in judgment if their judgment was exercised honestly and intelligently.[199]

Generally, if a physician acts in accordance with generally approved professional practices, negligence will not be found, unless the practice is fraught with obvious risk, such that anyone could find the practice negligent "without the necessity of judging matters requiring diagnostic or clinical expertise".[200] Whether a practice is considered an "approved practice" is assessed at the relevant time and circumstances of the alleged act of negligence.[201] Overall, courts determine whether a physician has breached the standard of care on a case by case basis, considering the relevant facts and circumstances of the case.[202]

2. Breach of the Contractual Obligation of Means (Civil Law)

Under Quebec law, physicians have a duty to honour their contractual undertakings to their patients.[203] Where the physician fails in this duty, they are liable for any bodily, moral or material

[197] See Robertson & Picard, *supra* note 130 at 288.
[198] The standard of care is not a gold standard. See e.g. *Hillis v Meineri*, 2017 ONSC 2845 at para 54 [*Hillis*].
[199] See *Wilson, supra* note 193 at 119. If the physician applied appropriate clinical judgment, an error of judgement will generally not amount to negligence. See e.g. *Leckie v Chaiton,* 2021 ONSC 7770 at para 18.
[200] See *ter Neuzen, supra* note 193 at paras 38, 41.
[201] See *ibid* at para 34. The physician's conduct is not to be judged in hindsight. See e.g. *Brough v Yipp,* 2016 ABQB 559 at paras 122—25 [*Brough*].
[202] See *Hillis,* supra note 198 at para 57.
[203] See art 1458 para 1 CCQ.

injury they cause to the patient and are bound to make reparation for the injury.[204] In order to assess the physician's discharge of their contractual undertakings, the nature and intensity of their obligations must be ascertained.[205] Under Quebec contract law, an obligation may involve one of three levels of intensity: it may be of result, of warranty, or of means (or diligence).[206]

As at common law, physicians are not, in most cases, held to standards of perfection and are not required to guarantee a desired result or outcome to their patients.[207] The obligation of physicians is therefore usually one of means.[208] Accordingly, they must use reasonable and practicable means in the attainment of the desired result.[209] To determine whether a physician has failed in their contractual obligation of means, their conduct is assessed against that of a prudent and diligent doctor placed in the same circumstances.[210] The burden is on the plaintiff to prove, on a balance of probabilities, that the physician breached the contractual obligation of means.[211] The determination of whether the physician breached this obligation is a mixed question of law and fact.[212]

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[204] See arts 1458 para 2, 1607 CCQ.
[205] See Jean-Louis Baudouin, Pierre-Gabriel Jobin & Nathalie Vézina, *Les obligations,* 7th ed. (Cowansville, QC: Yvon-Blais, 2013) Title III, Chapter II, Section II at para 720.
[206] See Baudouin et al, *supra* note 139 at para 1-190.
[207] Indeed, the Quebec *Code of Ethics of Physicians* affirms that physicians "must refrain from guaranteeing, explicitly or implicitly, the effectiveness of an examination, investigation or treatment, or the cure of a disease". See CQLR c M-9, r 17, art 83 [*Code of Ethics of Physicians*].
[208] See Baudouin et al, *supra* note 139 at para 2-34.
[209] See Philips-Nootens & Kouri, *supra* note 30 at para 55. However, if the physician guarantees a specific result, they may be found liable if the result was not attained. See e.g. *Fiset c St-Hilaire,* [1976] CS 994, EYB 1976-183027 (QC).
[210] See e.g. *Lapointe v Hôpital Le Gardeur,* [1992] 1 SCR 351, 90 DLR (4th) 7 at para 25 [*Lapointe*]; *St-Jean v Mercier*, 2002 SCC 15 at para 53 [*St-Jean*]; *Bougie c Morency*, 2019 QCCS 4325 at para 35.
[211] See art 2804 CCQ. The physician's breach of the contractual obligation of means may either be directly proven or established through the use of presumptions of fact. See arts 2846, 2849 CCQ.
[212] See e.g. *St-Jean, supra* note 210 at para 60.

3. Remote Patient Monitoring: Relevant Duties and Attendant Standards of Care

Having introduced the above general concepts, we will now consider how they may be applied to RPM through an examination of the legal duties of physicians which will be implicated in the clinical use of RPM: the duties to inform, to treat, to follow-up, and to instruct.[213] For each duty, we will describe their attendant standards of care,[214] identify elements of the use of RPM that may challenge how physicians carry out these duties, and consider how courts may address whether physicians have breached the standard of care or contractual obligation of means in their discharge of these duties. Where relevant, we will use examples of RPM technologies from the literature to illustrate how physician liability may be incurred.

3.1 *The Duty to Inform*

We begin our analysis with the duty to inform for two key reasons. Firstly, the duty to inform is paramount to the physician-patient relationship and the recognition of patient autonomy.[215] Secondly and most importantly, the duty to inform will be implicated before the patient begins using the RPM system, as the patient will have to consent to its use. The remaining duties will only come into play after the RPM system is in use.

In both legal traditions, physicians have a duty to provide patients with adequate information regarding the proposed treatment in order to obtain their informed consent.[216] This information

[213] Though the duty to maintain confidentiality (professional secrecy) will not be discussed in our thesis, considerations related to privacy and confidentiality will be treated at length in our discussion of the duty to inform.
[214] We use the term "attendant standard of care" here to encompass the standards by which physician conduct is assessed under both legal traditions.
[215] See Philips-Nootens & Kouri, *supra* note 30 at para 181; Robertson & Picard, *supra* note 130 at 155
[216] See e.g. *Vaillancourt c Bishop*, 2016 QCCA 316 at para 13; Robertson & Picard, *supra* note 130 at 162.

must include, *inter alia*, the nature and objectives of the proposed treatment, alternative treatment options, expected benefits, and potential risks.[217] Risk disclosure in particular has been emphasized by scholars as being necessary for patients to make "rational and balanced" medical decisions.[218]

In therapeutic settings, physicians are not required to inform patients of all possible risks engendered by the proposed treatment.[219] At common law, the physician's duty of disclosure encompasses risks which are considered material, special or unusual.[220] Material risks are defined as those which a reasonable person in the patient's position would want to know before deciding whether to proceed with the proposed treatment, considering the probability of occurrence and magnitude of potential injury.[221] Common law courts have generally taken "liberal and expansive" views in interpreting the scope of physician disclosure of risks.[222]

Under Quebec law, physicians are required to disclose material risks that a reasonably prudent and diligent physician would have disclosed.[223] To determine specifically which risks are material, courts will consider the statistical probability of the materialization of the risks and the severity of

[217] See e.g. *Hopp*, *supra* note 140; *Reibl*, *supra* note 140; Philips-Nootens & Kouri, *supra* note 30 at para 185.
[218] See Maximilian Kiener, "Artificial intelligence in medicine and the disclosure of risks" (2021) 36:3 AI & Society 705 at 706; Nadia N Sawicki, "Modernizing Informed Consent: Expanding the Boundaries of Materiality" (2016) U Ill L Rev 821 at 828.
[219] See Baudouin et al, *supra* note 139 at para 2-57; Philips-Nootens & Kouri, *supra* note 30 at para 193; Robertson & Picard, supra note 130 at 166.
[220] See *Hopp, supra* note 140 at 210.
[221] See e.g. *Van Dyke v Grey Bruce Regional Health Centre*, [2005] OJ No 2219, 255 DLR (4th) 397 (CA) at para 63, leave to appeal to SCC refused, [2005] SCCA No 335; *Revell v Chow,* 2010 ONCA 353 at para 42; *DD v Wong Estate*, 2019 ABQB 171 at para 259. Courts employ a modified objective test based on the view of the reasonable person in the patient's position. The objective "reasonable physician" standard of care does not apply to negligence actions founded on a breach of the duty of disclosure. See e.g. *Prevost v Ali*, 2011 SKCA 50 at para 49.
[222] See Robertson & Picard, *supra* note 130 at 166.
[223] See Patrice Deslauriers & Emmanuel Préville-Ratelle, "La responsabilité médicale et hospitalière" in Responsabilité, Collection de droit 2022-2023, École du Barreau du Québec, vol 5 (2022) at 6.

their consequences.[224] In both legal traditions, the court's determination of whether the physician breached the duty to inform will be based on the circumstances of the case before it.[225]

Two elements that are likely to be important in physicians' disclosure of information concerning RPM are: (1) the disclosure of the limitations and risks of the proposed RPM system and (2) the patient's comprehension of this information. The American Medical Association's RPM guidelines, for instance, emphasize the importance of the discussion of the "benefits, risks, alternatives, and potential consequences in choosing to use (or not) digital health solutions".[226] The *Collège des médecins du Québec*'s guidelines on telemedicine also underscore the importance of disclosing the limitations and risks of telemedicine.[227]

Despite its purported benefits, RPM raises several risks of patient injury,.[228] For one, the inability to conduct in-person physical examinations of the patient may affect the quality of the patient's care, including potential misdiagnoses or delays in diagnosis or treatment.[229] Technical malfunctions may also compromise the quality of care and, in certain cases, could lead to significant injury if vital signs or critical symptoms are missed.[230] Patients' ability to comfortably

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[224] See *Drolet c Parenteau,* [1994] no 167, [1994] RJQ 689 (CA) at 706, revg in part [1991] JQ no 2583, [1991] RJQ 2956 (SC), Baudouin JA; *Ferland c Ghosn*, 2008 QCCA 797 at para 45; *Frenette c Clément*, 2023 QCCA 109 at para 11; Baudouin et al, *supra* note 139 at para 2-57. Despite Baudouin JA's rejection of a single standard of risk disclosure in *Drolet*, courts have generally used a benchmark of one percent of probability of risk in evaluating which risks should have been disclosed. See Philips-Nootens & Kouri, *supra* note 30 at para 193.

[225] See e.g. *Videto v Kennedy* (1981), 125 DLR (3d) 127, 17 CCLT 307 (Ont CA) at 133—34; Deslauriers & Préville-Ratelle, *supra* note 223 at 6.

[226] See American Medical Association, *supra* note 33 at 95.

[227] See *supra* note 35.

[228] See e.g. Shilpa N Gajarawala & Jessica N Pelkowski, "Telehealth Benefits and Barriers" (2021) 17:2 J Nurse Practitioners 218 at 219.

[229] See e.g. E Ray Dorsey & Eric J Topol, "State of Telehealth" (2016) 375:2 New England J Med 154 at 156; Lauren A George & Raymond K Cross, "Remote Monitoring and Telemedicine in IBD: Are We There Yet?" (2020) 22:12 Current Gastroenterology Reports 1 at 5.

[230] See e.g. Gajarawala & Pelkowski, *supra* note 228 at 219.

use RPM is crucial, as inability to properly utilize the prescribed technologies could impact their physician's capacity to properly monitor and assess their health condition.[231] Moreover, the use of clinical technologies may also raise a number of privacy risks for patients.[232]

Though the specific risks and limitations that physicians will need to disclose will generally depend on the types of devices they recommend to their patients,[233] RPM technologies present appreciable risks which fall within the scope of disclosure for both legal traditions. In determining the materiality of risks, common law and civil law courts consider both the probability of occurrence of the risk and the severity of injury. Studies on RPM provide us with examples of the potentiality and severity of patient injury, which are indicative of the types of risks physicians should disclose.

For instance, in their study on the use of ICDs, Perrin *et al* found that nearly 1 in 10 patients received an inappropriate diagnosis and more than one-third of these patients received an inappropriate electrical shock.[234] Though the overall rate of inappropriate shock was low and no death case directly related to inappropriate diagnosis or treatment was reported in the study, inappropriate ICD shocks are nonetheless associated with increased mortality.[235] In this scenario, a physician prescribing the use of an ICD would need to disclose the likelihood of inappropriate diagnosis and shock associated with this device and, although low, the potential for increased mortality associated with the administration of inappropriate shocks. Both the probability of

[231] See e.g. Dorsey & Topol, *supra* note 229 at 158.
[232] See *Collège des médecins du Québec*, *supra* note 35.
[233] Though general risks, such as limitations due to absence of physical examinations, are inherent to all RPM technologies.
[234] See *supra* note 166 at 610. Specifically, 9% of patients enrolled in the study received an inappropriate diagnosis, 36% of whom suffered at least one inappropriate electrical shock.
[235] See *ibid* at 608, 611.

occurrence and severity of injury in this example are sufficiently significant to warrant disclosure.[236]

Another example of the types of risks raised by RPM is a study of the security issues of mHealth apps, which found that "significant fractions" of the studied applications exposed users to "serious security risks".[237] Furthermore, the study found that the majority of app users are "largely unaware" of the security and privacy risks raised by these apps.[238] Though, again it will depend on the type of technology used, this provides us with some indication of risk occurrence in RPM, which should be disclosed to patients.

These scenarios accord with the guidance provided by organizations such as the *Collège des Médecins du Québec* and the American Medical Association, which, as mentioned above, emphasize the importance of the disclosure of the risks and limitations in these technologies. Though at common law the relevance of professional guidelines in determining the physician's standard of disclosure is minimal, as the standard is assessed relative to what a reasonable person in the patient's position would want to know,[239] these guidelines are nonetheless indicative of the types of information physicians should disclose.[240] As patients may be largely unaware of the

[236] Indeed, as the Supreme Court of Canada indicated in *Reibl, supra* note 140 at 885, "even if a certain risk is a mere possibility which ordinarily need not be disclosed, yet if its occurrence carries serious consequences, as for example, paralysis or even death, it should be regarded as a material risk requiring disclosure".
[237] See Gioacchino Tangari et al, "Analyzing security issues of android mobile health and medical applications" (2021) 28:10 J Am Med Informatics Association 2074 at 2074. Specifically, the study found that 1.8% of packaged suspicious codes, 45& relied on unencrypted communication, and 23% of personal data was sent on unsecured traffic.
[238] See *ibid* at 2082.
[239] See Robertson & Picard, *supra* note 130 at 165.
[240] Compare the common law standard of disclosure with the civil law standard, which focuses on the risks that a reasonable physician would disclose. See Deslauriers & Préville-Ratelle, *supra* note 223 at 6.

risks and limitations of digital health technologies, as the mHealth app study suggests, professional guidelines can help physicians navigate the types of information they should disclose to patients.

In addition to the information disclosure, the physician's duty to inform also comprises the duty to ensure that the information was understood by the patient.[241] Physicians are required to take reasonable steps to ensure that patients have understood the provided information.[242] In the context of RPM, the issue of digital literacy is important, as many groups, including older adults and low socioeconomic groups, have limited proficiency in using digital technologies and limited understanding of their risks and limitation.[243]

The limitations and risks of RPM, especially those related to technological issues, must therefore be disclosed in a manner that is comprehensible to the patient. Courts may likely scrutinize the steps taken by the physician to make sure that the patient properly understood the provided information and its implications. In the mHealth app study, for example, the "serious security risks" identified by the authors, which, based on our preceding analysis, physicians would have to disclose should they recommend these apps to their patients, included unencrypted communication, suspicious codes, and the transmission of data on unsecure traffic.[244] It is likely that many patients, especially those for whom digital literacy is low, may not understand what these terms mean and what the implications of these risks may be for their privacy. In addition to

[241] See *Ciarlariello v Schacter,* [1993] 2 SCR 119, 100 DLR (4th) 609 at 140*; Provost c L'Abbée,* 2015 QCCQ 2024 at para 39*;* Philips-Nootens & Kouri*, supra* note 30 at para 199.
[242] See Philips-Nootens & Kouri, *supra* note 30 at para 199; Robertson & Picard, *supra* note 130 at 202.
[243] See e.g. Anaya et al, *supra* note 24 at 588; Clemens Scott Kruse et al, "Evaluating barriers to adopting telemedicine worldwide: A systematic review" (2018) 24:1 J Telemedicine & Telecare 4 at 7; Austin J Triana et al, "Technology Literacy as a Barrier to Telehealth During COVID-19" (2020) 26:9 Telemedicine and e-Health 1118 at 1118.
[244] See Tangari et al, *supra* note 237 at 2074.

disclosing these risks, courts would likely require that physicians explain these risks and their implications in simple, comprehensible language.

3.2 *The Duty to Treat*

One of the main objectives of RPM is to improve patient treatment through monitoring their health status on a frequent basis, gather relevant health data, and make adjustments to improve patient care outcomes.[245] Whether data is collected actively by the patient or passively by the RPM apparatus, access to data in RPM may help physicians optimize and tailor treatment options for patients.[246] Nevertheless, the clinical use of RPM can raise multiple challenges which may compromise the physician's treatment of their patients.

At common law, physicians have a duty to treat their patients in accordance with the standard of skill expected of physicians placed in the same circumstances.[247] Under Quebec law, physicians must use reasonable means at their disposal to treat the patient.[248] They must provide patients with conscientious and attentive care, in accordance with accepted standards of medical science ("*les règles de l'art*").[249] In both legal traditions, the treatment provided must be appropriate to the patient.[250]

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[245] See e.g. Jeddi & Bohr, *supra* note 6 at 203.
[246] See Pronovost et al, *supra* note 40 at 1125; Spinsante & Gambi, *supra* note 38 at 57.
[247] See e.g. *Peppler Estate v Lee,* 2019 ABQB 144 at para 267, aff'd 2020 ABCA 282 [*Peppler*]; *Waap v Alberta*, 2008 ABQB 544 at para 33.
[248] See Philips-Nootens & Kouri, *supra* note 30 at para 303.
[249] See Deslauriers & Préville-Ratelle, *supra* note 223 at 8. See also *Code of Ethics of Physicians*, *supra* note 207 at s 44.
[250] See e.g. *Thibert v Zaw-Tun*, 2006 ABQB 423 at para 118 [*Thibert*]; Deslauriers & Préville-Ratelle, *supra* note 223 at 7.

Under Quebec law, the duty to treat is often considered to encompass the duty to diagnose,[251] whereas the common law generally treats them as distinct duties.[252] Physicians have a duty to take reasonable steps to detect a patient's signs and symptoms to arrive at a diagnosis.[253] This includes examining the patient, taking their medical history, using appropriate tests, and employing available scientific equipment facilities.[254] Physicians must also collect the best factual data to arrive at their diagnosis and treat their patients.[255]

Patient treatment and diagnosis involving RPM is predicated on the collection and analysis of a patient's data. However, as discussed in Chapter II, the management of large volumes of patient data can be challenging for physicians. If the patient's data is not properly managed, their care and treatment can be compromised. In RPM, there may be cases, for instance, where potential deteriorations in the patient's state of health are not indicated by punctual, urgent alerts, but rather by a gradual pattern as indicated by the data over time.[256] Clinical judgment must be used to discern these cases, rather than merely relying on the device to signal a potentially critical situation.

Overreliance on RPM technologies, without exercising professional judgment, may compromise the care and treatment of the patient. Health care technologies do not replace patient

[251] Authors Baudouin, Deslauriers and Moore, however, consider the duty to diagnose as a separate duty from the duty to treat, whereas Philips-Nootens and Kouri consider diagnosis as a component of the duty to treat. See *supra* note 139.
[252] See Philips Nootens & Kouri, supra note 30 at Title II; Robertson & Picard, *supra* note 130 at 377. For our purposes, the duty to diagnose will be addressed as part of the duty to treat for both legal traditions.
[253] See *Brough*, *supra* note 201 at para 126.
[254] See *Peppler*, *supra* note 247 at 207; *Waters v Wong*, 2019 ABQB 51 at para 59.
[255] See *Boyd v Edington*, 2014 ONSC 1130 at para 11; *Wade v Sisters of Saint Joseph of the Diocese of London*, [1978] OJ No 413, [1978] 1 ACWS 262 (SC) at para 22.
[256] See Atreja et al, *supra* note 44 at 8.

treatment or the use of clinical judgment.[257] However, where these technologies are perceived as reliable, clinicians may become complacent and may be less likely to question their efficacy and accuracy and, consequently, may not be able to discern technical malfunctions. Clinicians must therefore implement "appropriate monitoring and verification strategies" to offset the effects of overreliance and complacency and ensure the use of critical thinking and professional judgment in the use of these technologies.[258]

How physicians achieve this goal is something we anticipate courts will consider in determining whether the physician discharged their duty to treat to the appropriate standards of practice. One option available to them is to implement measures to manage the patient's data, monitor trends in the evolution of the patient's health, address technical efficacy issues, and address issues which require medical attention. In RPM, this can be largely dealt with through the implementation of a team-based or shared care approach, involving multiple actors, including the treating physician, nurses and technicians.[259] The CareSimple-Covid system at the CHUM, for instance, includes a team of nurses, medical residents, and technicians who undertake many of the monitoring responsibilities.[260] This shared care approach, which is becoming increasingly common in health care,[261] allows for the allocation of roles and tasks among multiple providers.[262] Physicians are, by law, entitled to delegate certain tasks to other health care providers and even to

[257] See e.g. Matthew Grissinger, "Understanding Human Over-Reliance on Technology" (2019) 44:6 Pharmacy and Therapeutics 320 at 320.
[258] See *ibid* at 321.
[259] See Emma E Thomas et al, "Factors influencing the effectiveness of remote patient monitoring interventions: a realist review" (2021) 11:8 BMJ Open 1.at 5 for a discussion of the importance of collaborative and coordinated care in multidisciplinary teams for RPM.
[260] See e.g. Bouabida et al, *supra* note 8 at 2.
[261] See Robertson & Picard, *supra* note 130 at 441.
[262] See e.g. Robyn Cody et al, "Complexity as a factor for task allocation among general practitioners and nurse practitioners: a narrative review" (2020) 21:1 BMC Family Practice 1 at 1.

entrust the care of their patients to others if they are absent or unavailable to treat them.[263] A significant portion of the monitoring responsibilities can therefore delegated to other personnel.[264]

Courts do not hold physicians to unreasonable standards. It is not possible for, nor do we expect courts to require, physicians to consistently monitor patient data flows and respond to all potential alerts themselves. In evaluating the physician's discharge of the duty to treat and to diagnose, we anticipate courts will focus on the delegation of monitoring responsibilities to other personnel, such as nurses and technicians. Delegating monitoring tasks to nurses and technicians can help to decrease overreliance on RPM by ensuring continual human oversight in duties which the physician would otherwise not have the time to perform. For example, a nurse or technician may be responsible for reviewing the data collected by RPM devices, identifying any concerning changes in a patient's health status or technical issues, and informing the treating physician accordingly. In determining the applicable standard of care for treatment involving RPM, courts are therefore likely to consider whether these work flows are implemented such that the patient's data can be addressed in a timely, accurate manner to ensure they receive their required level of treatment. Indeed, the ability to have greater access to patient data, often on a continual basis, may be an important consideration for courts when tackling the duty to treat.

Nonetheless, while physicians are entitled to rely on these other individuals in the discharge of these delegated tasks, they remain responsible for the ultimate care and treatment of their patients.[265] The objective of delegating tasks in RPM is to reduce physician workload and improve

[263] See e.g. *White v Turner* (1981), 31 OR (2d) 77e, 120 DLR (3d) 269 (SC) at 105, aff'd (1982) 47 OR (2d) 764*n,* 12 DLR (3d) 319*n* (CA).
[264] See Davis et al, *supra* note 25 at 431.
[265] See e.g. Bouabida et al, *supra* note 8 at 2.

clinical efficiency.[266] Issues which require medical attention, such as deteriorations in the patient's health, must be communicated to the physician, who will take the appropriate courses of action. Delegating data management responsibilities can lead to greater efficiency and ensure that physicians are provided with the relevant information to care for and treat their patients appropriately, but they retain ultimate responsibility for the patient's treatment and care.

3.3 *The Duty to Instruct*

In Chapter I, we postulated that the duty to instruct is likely to become more important in the age of telehealth. In RPM, patients play an important self-management role, which is greater where they actively report their own data. This shift in locus of responsibility to patients in self-management will implicate the physician's discharge of the duty to instruct, as patients will need to be given sufficiently detailed instructions to be able to execute the RPM set-up efficiently and effectively.

Courts have described the duty to instruct as a corollary of the duty to treat.[267] Physicians have the duty to provide sufficient instructions and adequate direction to ensure that any tasks delegated to their patients are properly discharged.[268] They must take reasonable steps to ensure that the patient is capable of performing these tasks, including making sure they have all the necessary tools and resources, and ensure that they have properly understood the provided

[266] See Davis et al, *supra* note 25 at 430.
[267] See e.g. *Anderson v Harari,* 2019 ABQB 75 at para 194; See *Peppler, supra* note 247 at para 267.
[268] See e.g. *Rollin v Baker,* 2010 ONCA 569 at paras 75—76.

information.[269] Nonetheless, physicians are not expected to follow-up on every instruction given to the patient and have the right to expect that the patient will follow their instructions.[270]

One task that is often delegated to patients is that of symptom management. In such cases, physicians have a duty to instruct patients about any potentially significant complications or symptoms.[271] Indeed, physicians have been found negligent for failing to adequately educate patients about potential danger signs during the post-operative period.[272] Authors Robertson and Picard speculate that the delegation of responsibility towards patients will become an increasingly important issue as the provision of home care services increases.[273] The increasing implementation of RPM will only further the importance of this issue.

Indeed, the increased reliance on patient self-management will likely present courts with many opportunities to assess physicians' discharge of the duty to instruct in accordance with the appropriate standards of practice. Patients must be able to properly use these technologies, understand how they work, and be able to recognize potential malfunctions or other issues that need to be reported. This will largely depend upon the level of detail and instruction provided by the physician. Where patients use technologies involving active data collection modalities, the level of instruction will likely be even more important as patients will more heavily rely on the physician to properly execute their responsibilities.

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[269] See *Peppler, supra* note 247 at para 270; *Thibert, supra* note 250 at para 122.
[270] See *Wei Estate*, [1998] OJ No 1411, 78 ACWS (3d) 1021 Ct J (Gen Div) at para 109; *Topliceanu c Bojanowski*, 2018 QCCS 658 at paras 152, 161.
[271] See *Paterson c Rubinovich,* [2000] RRA 26, JE 2000-184 (QCCA); Philips-Nootens & Kouri, *supra* note 30 at para 373; Robertson & Picard, *supra* note 130 at 445.
[272] See e.g. *Moore v Getahun,* 2014 ONSC 237 at paras 400—17.
[273] See Robertson & Picard, *supra* note 130 at 445.

We hypothesize that courts will examine the scope, level of detail, and comprehensibility of instructions provided to patients to determine whether they are sufficiently adequate to ensure that the patients can properly follow and implement them. Comprehensibility will be an especially important component. The novelty and technical aspects of RPM, coupled with the fact that many patients have limited digital literacy, may likely heighten the scope of the physician's duty to instruct the patient so that they can properly use the technology.[274] Courts will also likely look at whether the physician periodically checks in with the patient to ascertain if they are experiencing any difficulties or if they have specific issues they wish to discuss with the physician. Though physicians are not required to "chase" or "hunt down" patients to follow-up with them,[275] it is conceivable that, due to the novelty of RPM, courts may expect a physician to more regularly check-in with the patient to ensure they are complying with their instructions. Again, this will be determined on a case-by-case basis considering all the facts and circumstances of the case.

3.4 *The Duty to Follow-Up*

In the preceding section, we posited that physicians may be required to follow-up with patients to ensure ongoing compliance with instructions on how to use their prescribed RPM devices. However, patient follow-up is a broader process, encompassing the ongoing provision of health care services to the patient.[276] As with other duties, the scope and parameters of the duty to follow-up may be challenged in RPM. We will nonetheless postulate which types of factors

[274] See e.g. Vivian Hsao et al, "Disparities in Telemedicine Access: A Cross-Sectional Study of a Newly Established Infrastructure during the COVID-19 Pandemic" (2021) 12:3 Applied Clinical Informatics 445 at 446.
[275] See e.g. *McLintock v Alidina*, 2011 ONSC 137 at para 92.
[276] See e.g. *Act respecting health services and social services,* CQLR c S-4.2, s 5*; Code of Ethics of Physicians, supra* note 207, art 35.

courts may consider in determining whether the physician was negligent (or committed a contractual fault) in failing to follow-up with their patient.

In their treatise on medical liability under Quebec law, authors Philips-Nootens and Kouri classify the duty to follow-up ("*l'obligation de suivre*") as a distinct, independent legal duty.[277] Authors Robertson and Picard, however, include considerations related to follow-up as a subset of the duty to treat at common law, and discuss it specifically in the context of post-operative care.[278] Given that post-operative care is one of the key applications of RPM, we will consider the duty to follow-up and how it is implicated in the context of RPM separately from the duty to treat. Nonetheless, we will also consider the duty to follow-up in its more general civil law conception.[279]

Physicians have a duty to exercise reasonable care during the post-operative period.[280] They must anticipate and respond to post-surgical complications in a timely manner.[281] They are required to be vigilant of any possible post-surgical complications and have been found liable, for instance, for failure to monitor the patient's condition following surgery[282] and for failure to respond in a timely manner to post-operative symptoms.[283] The duty to follow-up also includes

[277] See Philips-Nootens & Kouri, *supra* note 30 at Title II, Chapter III.
[278] See Robertson & Picard, *supra* note 130 at 417—19. Common law courts have recognized a distinct duty to follow-up with their patients in the context of post-operative care. See e.g. *Burke-Pietramala v Samad*, 2004 BCSC 470 at paras 18—22 [*Burke*]; *Ibrahim v Hum,* 2004 ABQB 420 at para 78.
[279] Nonetheless, in medical liability cases in Quebec, the duty to follow-up has most often been raised in the post-operative context. See Philips-Nootens & Kouri, *supra* note 30 at para 373.
[280] See e.g. *Burke*, *supra* note 278 at para 18.
[281] See Robertson & Picard, *supra* note 130 at 417.
[282] See *ibid*.
[283] See *ibid.*

the disclosure of important and time sensitive information to the patient, such as foreseeable complications and symptoms of warning signs.[284]

Under the broader civil law conception of the duty to follow-up, physicians have a duty to be reasonably available to their patients and be present at the patient's bedside where required.[285] Authors Philips-Nootens and Kouri note that the duty to follow-up is especially important in the hospital setting, where physicians must respond to urgent situations and must be easily reachable by nursing staff.[286]

Whether in the specific context of post-operative care or in the broader conception of the duty to follow-up, the judicial evaluation of reasonableness may depend on the types of systems the physician has put in place to manage the situations where follow-up with patients is necessary. In many cases, patient follow-up can involve the use of a follow-up system, such as the use of patient management software.[287] Follow-up systems have primarily been used for diagnostic testing result follow-up.[288] They can play a critical role in identifying patients who require follow-up based on abnormal test results or trends, and help ensure that appropriate action is taken in a timely

[284] See *Rupert v Toth,* [2006] OJ No 882, 38 CCLT (3d) 261 (SC) at para 117 [*Rupert*]; Philips-Nootens & Kouri, supra note 30 at para 376.
[285] See *Laurendeau c Centre hospitalier de LaSalle,* 2015 QCCS 1923 at para 86 [*Laurendeau*]. See also *Code of Ethics of Physicians*, *supra* note 207, art 37: "physician must be diligent and display reasonable availability with respect to his patient and the patients for whom he accepts responsibility when he is on call".
[286] See Philips-Nootens & Kouri, *supra* note 30 at para 372.
[287] See e.g. Welkin, "Patient Management Software: What Your Care Team Needs to Know" (6 October 2020), online: <https://welkinhealth.com/patient-management-software/>.
[288] See e.g. *Kahlon (Litigation guardian of) v Vancouver Coastal Health Authority*, 2009 BCSC 922; *Rupert, supra* note 284.

manner.[289] Furthermore, they are increasingly being used to manage post-surgical follow-ups, through the remote monitoring and identification of post-operative complications.[290]

In *Braun Estate v Vaughan*, the Manitoba Court of Appeal asserted that physicians have a duty to ensure that "reasonably effective" follow-up systems are in place to review test results and manage patient follow-up treatments accordingly.[291] This case, however, concerned follow-up upon reception of laboratory testing results. What then becomes of the duty to follow up in the context of RPM, where there are higher volumes of patient data that must be managed and analyzed? Where the patient is monitored remotely, do the parameters of the duty to follow-up change? Determining the temporal limitations of the scope of this duty in the context of RPM will likely be challenging for courts.

For the duty to treat, we posited that courts would look at data workflows to ensure patient data is monitored and addressed consistently. For the duty to follow-up, we theorize that courts will focus on two factors: the frequency of follow-up, the occasions at which the physician must follow-up with the patient, and the implementation of systems to manage patient follow-ups. These factors correspond to concerns raised in the literature over physician follow-up with patients in RPM. For instance, some authors question how often physicians must follow-up with patients and whether they are only required to do so in urgent or necessary situations.[292]

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[289] These systems can detect abnormal test results, which necessitate patient follow-up. For example, if a patient's test results fall outside of a normal range, the system can automatically generate an alert that triggers follow-up by the healthcare provider. See e.g. Sureyya Tarkan et al, "Reducing Missed Laboratory Results: Defining Temporal Responsibility, Generating User Interfaces for Test Process Tracking, and Retrospective Analyses to Identify Problems" (2011) AMIA Annual Symposium Proceedings 1382 at 1382.
[290] See e.g. JL Semple & KA Armstrong, "Mobile applications for postoperative monitoring after discharge" (2017) 189:1 Can Med Assn J 22 at 22.
[291] See [2000] MJ No 63, 145 Man R (2d) 35 (CA) at para 33 [*Braun Estate*].
[292] See e.g. Atreja, *supra* note 44 at 8; Wallace et al, *supra* note 171 at 1013.

In the post-operative RPM context, where the patients generally require greater follow-up, the physician will likely have to follow-up on a more frequent basis. We do not expect, however, that courts will require physicians to follow-up with patients as frequently as would be expected in a hospital setting. It would not be feasible, in our opinion, to impose the same standards of follow-up as in the hospital setting, where the physician can readily be at the patient's bedside. Concerning follow-up frequency, it is clear from existing case law that physicians must respond to post-operative complications in a timely manner.[293] In the event that a post-surgical complication that requires physician intervention is signaled by the patient's RPM system and communicated to the physician by a nurse or technician, we anticipate that courts will look at whether the timeframe between the alert and the physician's follow-up is reasonable, so that timely treatment can be initiated. The reasonability of the timeframe will, evidently, need to be evaluated on a case-by-case basis, depending on the severity of the situation and the patient's condition.

Courts are likely to consider whether reasonably effective systems are in place to ensure that potential alerts which require prompt medical attention are addressed within a reasonable timeframe taking into account the particular facts of the case. The use of patient follow-up systems, such as the post-operative use of mobile health applications,[294] to monitor and identify complications, can be an example of the use of reasonable care in the post-operative context. Where the patient's transmitted data indicates a potential post-surgical complication, the physician or clinical care team will be alerted to follow-up with the patient and take appropriate action. In

[293] See e.g. *Wilson Estate v Byrne,* [2004] OJ No 2360, 131 ACWS (3d) 962 (SC).
[294] See Semple & Armstrong, *supra* note 290 at 22.

this manner, physicians can monitor patients' post-operative condition and respond to complications in reasonably timely manners.

4. The Role of Professional Standards and Clinical Guidelines in the Determination of Medical Liability

Determining the scope and content of many of the legal duties of physician duties will likely a challenge for courts in the RPM context when the first cases start to be litigated. Judges encountering RPM-related medical liability claims for the first time will need to define the appropriate standard of care for each of these duties and determine whether physician breached these standards in their use of RPM. To help clarify the application of medical liability rules to RPM, we have proposed factors in this chapter which courts may consider in medical liability cases involving RPM. We conclude this chapter with a discussion of the role that professional standards and clinical guidelines may play in determining the appropriate standards of medical practice in RPM.

In both the common law and civil law, it is usual (and, indeed, in most cases indispensable) for expert evidence to assist courts in the determination of the appropriate standards of medical practice and the assessment of whether physicians have met these standards.[295] Expert evidence includes not only expert witnesses' opinions, but also reliance on professional standards or clinical

[295] See e.g. *Hasan v Trillium Health Centre Mississauga*, 2022 ONSC 3988 at para 67 [*Hasan*]; Deslauriers & Préville-Ratelle, *supra* note 223 at 8.

guidelines, which can be indicative of the standard of care required of physicians.[296] Aside from guidelines on the use of mobile health technologies, guidelines specifically applicable to other RPM technologies described in our typology have yet to be adopted by professional associations or colleges in Canada,[297] though guidelines exist in the United States.[298] As a first step towards clarifying the liability-related issues surrounding RPM in Canada, guidelines should be adopted to provide courts with a barometer with which to measure physician reasonable conduct when using RPM. Importantly, these standards and guidelines should address the issues we have raised in this chapter, including the disclosure of risks, patient follow-up, data management, and the delegation of responsibilities to other personnel. They should furthermore highlight the importance of providing clear and detailed instructions to patients.

The legal standard of prudent and diligent physician conduct may not necessarily correspond to professional or clinical standards, however. In *Kern v Forest,* for instance, the Supreme Court of British Columbia affirmed that clinical guidelines are not substitutes for the determination of the standard of care, but rather flexible, non-binding documents that, though indicative of the standards by which physicians can abide, are not intended to replace the physician's clinical judgment.[299] Generally, though, conformity with standard professional practices will exonerate physicians of liability.[300] As previously mentioned, there may, however, be very exceptional cases where standard practice itself may considered be negligent and conformity thereto will not exculpate the physician of liability.[301] Nonetheless, the adoption of appropriate standards and

[296] See Campbell & Glass, *supra* note 34 at 5.
[297] Some professional associations and professional colleges have adopted guidelines on telehealth and the use of mobile health applications. See e.g. *Collège des médecins du Québec, supra* note 35.
[298] See American Medical Association, *supra* note 33.
[299] See 2010 BCSC 938 at para 162.
[300] See *ter Neuzen, supra* note 193 at para 41.
[301] See *ibid* at para 43.

guidelines will play an important role in determining standards of reasonable conduct related to the clinical use of RPM.

In summary, whether a physician breached the standard of care or contractual obligation of means may present courts with certain challenges in RPM-related liability claims. Even if a physician is found to have committed such a breach, this does not automatically mean the physician is liable for the patient's injury. It must also be proven, on a balance of probabilities, that the breach caused the patient's injury. The issues of causation and of apportionment of liability, will be the subject of discussion of our next chapter.

CHAPTER IV
ISSUES OF CAUSATION AND APPORTIONMENT OF LIABILITY IN REMOTE PATIENT MONITORING

The final element that must be proven in a medical liability action is causation. At common law, causation requires demonstrating, on a balance of probabilities, that the defendant's breach of the standard of care caused the plaintiff's injury both in fact (factual causation) and in law (legal causation. Quebec civil law, however, does not distinguish between factual and legal causation, instead requiring that the plaintiff's injury be the certain, direct and immediate consequence of the defendant's fault.[302] In both legal traditions, proving causation can often be a difficult exercise in medical liability actions.[303] The use of novel health care technologies can further complexify the determination of causation. The difficulties of proving causation in the clinical use of AI, for instance, have been raised in the literature.[304]

Despite the current absence of litigation on RPM, we anticipate that several causal issues will arise should the risks of patient injury previously discussed materialize or should physicians breach their legal duties in ways we have previously described. Three key potential causal issues in medical liability cases involving RPM are likely to present themselves due to: (1) delays in treatment; (2) the involvement of multiple defendants; and (3) the increased clinical reliance on patients.

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[302] See art 1607 CCQ; Baudouin et al, *supra* note 139 at para 1-683.
[303] See e.g. Baudouin et al, *supra* note 139 at para 2-113: "Le lien entre la faute professionnelle et le préjudice subi par la victime est particulièrement difficile à établir en responsabilité médicale". See also *Wilson v Beck*, 2013 ONCA 316 at para 45, leave to appeal to SCC refused, 2013 CanLII 69866 (SCC).
[304] See e.g. Frank Griffin, "Artificial Intelligence in Liability and Health Care" (2021) 31:1 Health Matrix: The Journal of Law-Medicine 65 at 100.

Our analysis will begin with an overview of the basic causal principle in both the common law and civil law traditions. Based on our analyses in preceding chapters and discussions in the literature, we will next examine how the above causal issues may arise in RPM. We will then analyze how courts may deal with our identified causal issues.

1. Basic Causal Principles

1.1 *Common Law Causation*

In medical negligence actions, the plaintiff must prove, on a balance of probabilities, that the defendant's breach of the standard of care caused the patient's injury both *in fact* (factual causation) and *in law* (legal causation or proximate cause).[305]

The primary test for determining factual causation in medical negligence claims is the "but for" test.[306] The plaintiff must prove, on a balance of probabilities, that, but for the defendant's negligence, they would not have suffered the injury complained of.[307] In other words, it must be shown that the defendant's negligence was necessary in bringing about the plaintiff's injury and that there was a "substantial connection" between the defendant's negligence and the injury.[308] The defendant's negligence need not, however, be the sole, independent cause of the patient's injury, as there may be other tortious and non-tortious factors responsible for bringing about the patient's injury.[309]

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[305] See *Mustapha*, *supra* note 144 at para 11.
[306] See *Clements v Clements,* 2012 SCC 32 at para 8 [*Clements*].
[307] See *ibid*.
[308] See *Ediger v Johnston*, 2013 SCC 18 at para 28 [*Ediger*]; *Resurfice Corp v Hanke*, 2007 SCC 7 at para 23.
[309] See *Athey v Leonati*, [1996] 3 SCR 458, 140 DLR (4th) 235 at para 17 [*Athey*].

The Supreme Court of Canada has cautioned that the "but for" test need not be applied to rigidly or with scientific precision.[310] Rather, courts should adopt a "robust and pragmatic approach to the facts" of a case.[311] Depending on the circumstances and the evidence before them, courts may make common sense inferences of causation.[312]

Legal causation, also referred to as proximate cause or remoteness, differs from factual causation in that it is not a factual inquiry into the cause of the plaintiff's injury, but rather a liability-limiting mechanism.[313] To prove that the defendant's negligence was the proximate cause of the plaintiff's injury, the plaintiff must prove, on a balance of probabilities, that the type of injury complained of was foreseeable to a reasonable person in the position of the defendant.[314] It is not the exact manner in which the injury occurred which must be foreseeable, but rather the general type of consequences that may result from the defendant's negligence.[315] The issues identified as being particular to RPM are either factual causation challenges or a defence and, therefore, legal causation will not be addressed in this thesis.

1.2 *Civil Law Causation*

Under Quebec law, the plaintiff must prove, on a balance of probabilities, that there was a causal relationship between their injury and the fault committed by the defendant.[316] Defendants

[310] See *Clements, supra* note 306 at para 46.
[311] See *Snell v Farrell,* [1990] 2 SCR 311, 72 DLR (4th) 289 at 330 [*Snell*].
[312] See *Clements, supra* note 306 at para 10; *Ediger, supra* note 308 at para 36.
[313] See Robertson & Picard, *supra* note 130 at 362.
[314] See *Overseas Tankship (UK) Ltd v Mort's Dock and Engineering Co, The Wagon Mound (No. 1)*, [1961] AC 388, [1961] 1 All ER 404 (PC).
[315] See *Hughes v Lord Advocate*, [1963] AC 837, [1963] 1 All ER 705 at 857 (HL).
[316] See arts 1457 (extracontractual liability), 1458 (contractual liability), 2804 CCQ (standard of proof).

are liable for any bodily, moral or material injuries suffered by the plaintiff which are the logical, direct, and immediate consequence of their faulty conduct.[317] In assessing causation, civil law courts generally employ the theory of adequate causation ("*causalité adéquate*"), whereby they seek to isolate the immediate cause of an event and to eliminate mere circumstance in the occurrence of an injury.[318] The determination of causation is a question of fact, left entirely to the appreciation of the trier of fact.[319]

In certain cases, plaintiffs may indirectly prove causation using presumptions of fact.[320] In order to be accepted, presumptions of fact must be "serious, precise and concordant",[321] allowing the court to conclude, on a balance of probabilities, that the defendant's fault caused the patient's injury.[322] Overall, courts generally have little difficulty in determining causation.[323] Where there are difficulties, they will generally arise in cases where from multiple factors have contributed to the plaintiff's injury.[324]

2. Analysis of Causal Issues in Remote Patient Monitoring

2.1 *Delays in Treatment*

[317] See art 1607 CCQ; *Imperial Tobacco Canada ltée c Conseil québécois sur le tabac et la santé*, 2019 QCCA 358 at para 666 [*Imperial Tobacco*]; Baudouin et al, *supra* note 139 at para 1-683.
[318] See *Imperial Tobacco, supra* note 317 at para 840; Baudouin et al, *supra* note 139 at para 1-672.
[319] See Baudouin et al, *supra* note 139 at para 1-679.
[320] See arts 2846, 2849 CCQ. Legal presumptions against physicians do not exist under Quebec law. See Philips-Nootens & Kouri, *supra* note 30 at para 72.
[321] See art 2849 CCQ.
[322] Some authors have argued that the application of presumptions of fact should be done with circumspection. See Deslauriers & Préville-Ratelle, *supra* note 223 at 2. For further information on the application of presumptions of fact in medical liability cases, see Baudouin et al, *supra* note 139 at para 2-115.
[323] See Baudouin et al, *supra* note 139 at para 1-667: "Dans la plupart des cas, les tribunaux ne soulèvent pas le problème du lien de causalité, parce que la relation entre la faute et le préjudice est évidente".
[324] See *ibid.*

Our discussion of the risks of patient injury in Chapter II highlighted the potential risks that could result from delays in treatment where an RPM system malfunctions or where the patient's data is improperly managed.[325] As RPM can allow for the earlier detection and management of health deteriorations,[326] it is likely treatment delays will be the focus of much judicial attention in medical liability cases involving RPM. Medical liability cases involving delays in diagnosis or treatment are "among the most complex to assess from the perspective of causation".[327] Though not unique to RPM, we anticipate that the use of RPM will lead to situations of causal uncertainty in delayed treatment cases.

Consider, for example, a case where a patient with a heart condition is prescribed an RPM device which is supposed to automatically transmit their vital signs to the treating physician's hospital office twice daily. For the first few weeks, the device functions properly and the patient's condition is stable, with no signs of deterioration. One day, however, there is a technical malfunction with the device and it fails to transmit the patient's vital signs for several days. The physician and the nurse hospital staff responsible for helping monitor the patient's data both fail to notice that they have not received the patient's vital signs and do not follow up with the patient. Meanwhile, the patient's condition begins to deteriorate and their heart rate becomes dangerously high, causing them to suffer a heart attack.

[325] See Chapter II, Section 3.
[326] See e.g. Taylor et al, *supra* note 21 at 2.
[327] See *LR v Semenjuk*, 2020 ABQB 350 at para 92. See also *Sacks v Ross,* 2017 ONCA 773 at para 51, leave to appeal to SCC refused, [2017] SCCA No 491, [2017] CSCR no 491 [*Sacks*].

In order to prove that the delay in treatment caused their heart attack, the patient must prove, on a balance of probabilities, that their injury could have been avoided with prompt treatment.[328] It is not enough to prove that prompt treatment would have led to a chance of avoiding the injury.[329] In some cases, it will be difficult to determine whether the patient's condition was treatable and whether prompt treatment would have led to a favourable prognosis.[330] This may be particularly so in the case of the many RPM patients who have health conditions which can quickly deteriorate.[331] The patient would have to prove that, more likely than not, their injury was due to the delay in treatment rather than the occurrence of an injury that would have happened in any event due to their health condition, regardless of medical intervention.

There will nearly always be multiple potential causes for a patient's injury.[332] In our factual scenario, there are two alternative possible causes of the patient's injury – one tortious (fault-related) and one non-tortious (non-fault-related). On the one hand, had the patient's vital signs been properly monitored, they may have allowed the clinical team to predict the impending heart attack, allowing them to intervene in time to prevent its occurrence. On the other hand, had the medical team noticed the device's malfunction and addressed it, and had the device shown signs of a possible heart attack and the team had observed and reacted appropriately to these indicators, it is possible that it might have already been too late and that the patient would nonetheless have had the heart attack. It is noteworthy that because of the malfunction, there might also be

[328] See *Beldycki Estate v Jaipargas*, 2012 ONCA 537 at para 44.
[329] See *Cottrelle v Gerrard*, [2003] OJ No 4194, 67 OR (3d) 737 (Ont CA), at paras 25—6 [*Cottrelle*]; *Hasan, supra* note 295 at para 145; *Laferrière v Lawson*, [1991] 1 SCR 541, 78 DLR (4th) 609 at 608 [*Laferrière*].
[330] See e.g. Forcier et al, *supra* note 26 at 8; Robertson & Picard, *supra* note 130 at 340—41.
[331] See e.g. Edward Itelman et al, "Assessing the Usability of a Novel Wearable Remote Patient Monitoring Device for the Early Detection of In-Hospital Patient Deterioration: Observational Study" (2022) 6:6 JMIR Formative Research 1 at 2.
[332] See Erik S Knutsen, "Clarifying Causation in Tort" (2010) 33:1 Dal LJ 153 at 168.

uncertainty as to what signs the device would have transmitted and, therefore, whether anyone would have been able to predict the heart attack.

In cases where there are multiple potential causes of the patient's injury, Professor Knutsen writes that answering the "but for" question "most often rests not on causation but on evidentiary sufficiency and the plaintiff's ability to prove causation on a balance of probabilities".[333] Many delayed treatment cases have failed due to lack of evidence of causation.[334] While not unique to RPM, delayed treatment cases are likely to raise many difficulties for plaintiffs in proving causation, as exemplified in our factual scenario, where many elements of unknown surround the causality of the patient's injury.

2.2 *Multiple Defendants*

Health care is becoming an increasingly collaborative or team-based venture.[335] It is more common today for a patient's care to be handled by multiple health care providers. With RPM, this trend is expected to proliferate due to frequency of transmission and volume of patient data which must be addressed.[336] The CHUM's CareSimple-Covid system[337] and the NewYork-Presbyterian Hospital's COVID-19 Hypoxia Monitoring program,[338] both of which involve teams of physicians, nurses, physician assistants, and medical and nursing students, are two examples of this "shared care approach". Furthermore, because RPM entails the use of a technological device,

[333] See *ibid* at 168.
[334] See e.g. *Aristorenas v Comcare Health Services*, [2006] OJ No 4039, 83 OR (3d) 282 (CA); *Barker v Montfort Hospital*, 2007 ONCA 282; *Cottrelle, supra* note 329.
[335] See Robertson & Picard, *supra* note 130 at 441.
[336] See Anton Vedder et al, "The Law as a 'Catalyst and Facilitator' for Trust in E-Health: Challenges and Opportunities" (2014) 6:2 L Inn Tech 305 at 311.
[337] See Bouabida et al, *supra* note 8 at 2.
[338] See Paul N Casale et al, "The Promise of Remote Patient Monitoring: Lessons Learned During the COVID-19 Surge in New York City" (2021) 36:3 Am J Med Quality 139 at 141.

it introduces potential technology wrongdoers, who, though not directly involved in the treatment of the patient, are responsible for the development and manufacturing of the devices used in the patient's treatment and care.

In instances where RPM is used, it is therefore likely that there will be multiple parties susceptible of owing duties to the patient, the breaches of which may cause injury to the patient. The involvement of multiple actors in the patient's care creates the possibility of a multiple defendant scenario, whereby the negligent or faulty conduct of multiple parties may combine to cause the patient's injury. Moreover, breaches of duties of actors other than the physician may combine with those of the physician in causing a patient's injury. At common law, this would correspond to a situation of cumulative causes,[339] whereas under civil law, this would correspond to a situation of contributory faults ("*fautes contributoires"*).[340] Our above fact pattern illustrates this causal scenario, whereby breaches by the product manufacturer, physician, and the hospital (both directly and vicariously for the nursing staff) combine to create the patient's injury.

At common law, the Ontario Court of Appeal has set out three basic steps in determining "but for" causation in multiple defendant scenarios.[341] First, the court must determine whether the defendants' negligence, treated globally as a team, caused the plaintiff's injury.[342] Second, the court will examine whether each defendant's negligence was necessary to bring about the patient's injury.[343] If multiple defendants are found to have caused the patient's injury, courts will hold

[339] See Lara Khoury, *Uncertain Causation in Medical Liability* (Oxford: Hart Publishing, 2006) at 233.
[340] See Baudouin, *supra* note 139 at para 1-171.
[341] See *Sacks, supra* note 327 at para 47. Linden et al describe the merit of using such an approach in multiple defendant cases. See Allen M Linden et al, *Canadian Tort Law* (Toronto: LexisNexis Canada, 2022) at 4.03.
[342] See *Sacks, supra* note 327 at para 98; Linden et al, *supra* note 341 at 4.03.
[343] See *Sacks, supra* note 327 at para 98.

them jointly and severally liable to the plaintiff, in accordance with provincial contributory negligence legislation.[344] Finally, the third step is to apportion liability among the negligent defendants in accordance with their relative degree of fault or blameworthiness.[345]

Similarly, under civil law, if the faults of multiple defendants contributed to the patient's injury, courts may hold them solidarily liable if their obligation to the plaintiff was extracontractual[346] or liable *in solidum* if the plaintiff's injury is caused by both contractual and extracontractual faults.[347] Liability is then apportioned in accordance with the seriousness of the fault of each defendant.[348]

In our factual scenario, we envisage that there may be breaches of the standard of care or faults on the part of the manufacturer of the device, the physician, and the hospital (both directly and vicariously for the acts of its employees), each of which was a cause of the patient's injury. Though we will not provide detailed analyses of the negligence or fault of each of these actors but rather cursory overviews of these factors, we nonetheless will illustrate how the implication of multiple actors in the patient's care using RPM can raise causal challenges for courts.

Under both legal traditions, product manufacturers may be found liable for safety defects in their products. At common law, manufacturers have a duty to exercise reasonable care in the

[344] See e.g. *Negligence Act*, RSBC 1996, c 333, s 4(2); *Negligence Act*, RSO 1990, c N.1, s 1.
[345] See *Sacks, supra* note 327 at para 47. See e.g. the British Columbia Court of Appeal's discussion of the apportionment of liability under the provincial statutory scheme in *Alberta Wheat Pool v Northwest Pile Driving Ltd*., 2000 BCCA 505 at paras 45—46 [*Alberta Wheat Pool*]. See also *Cempel v Harrison Hot Springs Hotel Ltd* (1997), 43 BCLR (3d) 219, 76 ACWS (3d) 680 (CA) at para 19.
[346] See art 1526 CCQ.
[347] See *Montréal (Ville) v Lonardi*, 2018 SCC 29 at para 85.
[348] See art 1478 para 1 CCQ.

manufacture of their products, including their component parts.[349] If the product defect results from negligent manufacturing, i.e. the manufacturer did not take reasonable care in the manufacturing of the device, the manufacturer could be held liable if the defect is both the factual and legal cause of the patient's injury. The court would have to determine whether, but for the defect, there would not have been a delay in the transmission of the data and, hence, injury to the patient.

Quebec law imposes strict liability on manufacturers,[350] who may be found liable for safety defects where the product does not "afford the safety which a person is normally entitled to expect, particularly by reason of a defect in design or manufacture, poor preservation or presentation, or the lack of sufficient indications as to the risks and dangers it involves or as to the means to avoid them."[351] It is not necessary for the plaintiff to prove the manufacturer's fault, but rather that there was a safety defect, the plaintiff suffered an injury, and the safety defect caused the injury.[352] As long as a safety defect is demonstrated, the exact source of the problem does not need to be identified.[353] A safety defect exists where the product does not afford the expected level of safety, thereby posing an unexpected danger and risk.[354] If such danger materializes and is directly connected to the injury, causation is established.[355]

Concerning the liability of the physician, we hypothesized in Chapter III that physicians could have a duty to periodically assess the efficacy and efficiency of the system, whether by themselves

[349] See e.g. *Farro v Nutone Electrical Ltd*., [1990] OJ No 492, 68 DLR (4th) 268 (CA) at para 11.
[350] See art 1468 CCQ.
[351] See art 1469 CCQ.
[352] See *Imperial Tobacco, supra* note 317 at para 365.
[353] See *ibid* at para 379.
[354] See art 1469 CCQ; *Imperial Tobacco, supra* note 317 at para 398.
[355] See *ibid* at paras 398, 401.

or by delegation to other personnel.[356] The physician's breach of these duties could, in addition to the device malfunction, be considered causative of the patient's injury. Indeed, while the device malfunction was the triggering event in the chain of occurrences leading up to the patient's injury, earlier detection of the technical issue and disruption of the transmission of the patient's data through proper follow-up and earlier medical intervention could have prevented the patient's injury. It is likely that courts would consider the absence of data transmission for several days to be a circumstance necessitating patient follow-up and, consequently, find it within the scope of the aforementioned duties for the physician to follow-up with the patient. Accordingly, in our factual scenario, the product manufacturer may be held liable for the technical defect and the physician for the failure to follow-up with the patient where circumstances indicated a need for follow-up.

Breaches of the standard of care or faults on the part of the hospital may also be considered causal factors in our factual scenario, both through vicarious and direct liability. Vicarious liability is a legal doctrine that holds one party responsible for the actions or omissions of another party, even if the responsible party did not directly cause the harm, based on the relationship between the two parties, most commonly an employer-employee relationship.[357] Hospitals could be held vicariously liable for the acts of its employees, including nurses.[358]

[356] Even where these tasks are delegated, the physician is ultimately responsible for their proper execution. See e.g. *R v Ashkani*, 2017 ONSC 7345 at para 7.
[357] See Linden et al, *supra* note 341 at 12.01.
[358] See Robertson & Picard, *supra* note 130 at 610. Generally, physicians are considered to be independent contractors and not employees of the hospital (*ibid* at 599). See also *Act respecting health services and social services*, *supra* note 276, s 236.

Nurses, for instance, are an integral component of many RPM systems in hospitals, as they are responsible for monitoring the influx of patient data.[359] Courts have recognized that nurses are responsible for monitoring patients and informing physicians of issues that require medical attention.[360] In a hospital setting, the hospital can be held vicariously liable for the negligent or faulty acts of the nurse which caused the patient's injury. In our factual scenario, the nurses' failure to ascertain the absence of data transmission and notify the physician could be considered within the scope of their duty to monitor the patient, the breach of which was necessary to bring about the patient's injury. Though the physician, as described above, will be liable for failing to follow-up with the patient where necessary, the nurse's failure to bring the data transmission disruption to the physician's attention is also a necessary causal factor, as the nurse would be responsible for discerning the technical issue and relaying the message to the physician for follow-up. The hospital, as the employer of the nurse, would consequently be held liable for the injury.

Additionally, hospitals directly owe a number of direct duties to patients, the breaches of which could be causal factors in the patient's injury in our factual scenario. At common law, courts have recognized that hospitals have duty to provide proper instruction and supervision to staff, as well as to provide and maintain proper facilities and equipment.[361] Under Quebec law,

[359] See e.g. Khayreddine Bouabida et al, "Healthcare Professional Perspectives on the Use of Remote Patient-Monitoring Platforms during the COVID-19 Pandemic: A Cross-Sectional Study" (2022) 12:4 J Personalized Med 1 at 2.

[360] See e.g. *Laurendeau, supra* note 285 at paras 128—29. The conduct of the nurse is evaluated against that of a prudent and diligent nurse placed in the same circumstances. At common law, enhanced standards of care are also applied to non-physician health care professionals, such as nurses, who are held to the standards of the normal, prudent practitioners of their respective professions. See e.g. Robertson & Picard, *supra* note 130 at 300; *Brodeur v Provincial Health Services Authority*, 2016 BCSC 968 at para 98.

[361] See Robertson & Picard, *supra* note 130 at 593.

hospitals have a duty to provide attentive and conscientious care ("*des soins attentifs et consciencieux*") to patients.[362]

Though existing cases have largely focused on the provision of basic necessary facilities, such as bed rails,[363] we argue that, where a hospital implements an RPM program, as did the CHUM and NewYork-Presbyterian Hospital, courts may consider it part of a hospital's duty to ensure the proper functioning and maintenance of the system.[364] Let us consider, for example, that in the above factual scenario, the delay in data transmission is not due to negligent or faulty manufacturing, but rather the hospital's failure to ensure that the RPM apparatus is installed, used and maintained as per the manufacturer's instructions, which the hospital has a duty to ensure.[365] The hospital's breach of this duty could be a causal factor, the occurrence of which was necessary to bring about the patient's injury.

In multiple defendant cases, apportioning liability among negligent (or faulty) defendants may pose difficulty for courts, as apportionment will require an assessment of the degree of relative blameworthiness or seriousness of fault of each defendant. Fault or blameworthiness refers to the parties' conduct in the circumstances of the case and the degree to which their conduct departed from the standard of care.[366] This can vary from "extremely careless conduct" to a "minor lapse of care" which nonetheless entails a risk of foreseeable harm.[367]

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[362] See Deslauriers & Préville-Ratelle, *supra* note 223 at 12.
[363] See Robertson & Picard, *supra* note 130 at 593—94.
[364] Indeed, "the issue in negligence cases brought against hospitals normally concerns the scope of the duty rather than its existence". See *Braun Estate*, *supra* note 291 at para 38.
[365] See e.g. *Stockford v Johnston*, 2008 NBQB 118 at paras 92—93.
[366] See *Alberta Wheat Pool, supra* note 345 at para 46.
[367] See *ibid; Cipllaka v Albert-Moore,* 2023 BCSC 457 at para 28.

RPM is still a burgeoning health care modality and much uncertainty surrounds its clinical use. Clinicians and health care institutions alike are still very much navigating the novelties and complexities of RPM, including the unclear content and scope of their duties, how to familiarize themselves with these new technologies, and how to allocate roles and responsibilities among members of the clinical care team. Courts may consider these factors in the assessment of the parties' relative blameworthiness or fault in medical liability actions involving RPM.

2.3 *Patient Contributory Negligence*

The final issue in our analysis flows from one of the most significant changes that patient care technologies, including RPM, will bring to the health care system: the increasingly active and important role the patient will play in their own care and treatment.[368] As we previously described, with the use of telehealth technologies, where the physician is not able to physically examine the patient, there is an increased clinical reliance on patients.[369]

With greater patient responsibility and increased clinical reliance on patients arises the possibility that the patient's own acts or omissions may be considered contributory factors to their injuries if they fail to act prudently. Though this thesis focuses on the duties that physicians owe toward their patients, both parties in the physician-patient relationship owe each other obligations. If the patient's acts or omissions are found to be contributory factors to their injury, they may be

[368] Vedder et al, *supra* note 336 at 310.
[369] See e.g. Elaine C Koong et al, "The Abrupt Expansion of Ambulatory Telemedicine: Implications for Patient Safety" (2022) 37:5 J Gen Internal Med 1270 at 1271.

held contributorily negligent and, consequently, their recovery of damages of damages will be affected.

At common law, for historical reasons, contributory negligence, which refers to "unreasonable conduct on the part of a victim which […] has in law contributed to [their] own injuries"[370] constitutes a defence to the tort of negligence.[371] Contributory negligence has been applied in relatively few medical negligence actions in Canada to date.[372] Under Quebec law, contributory negligence is not a defence in civil liability actions, but rather a causal issue whereby the plaintiff is included in the apportionment of liability if their injury is "partly the effect" of their own fault.[373] For the purposes of our analysis, we deal with patient contributory negligence within our section on causation.

Within the physician-patient relationship, patients' duties include providing information to the physician which is complete, transparent, pertinent and exact,[374] following the physician's instructions,[375] and generally acting in their own best interests.[376] If a patient breaches these duties and their breach is found to be a contributing factor to the cause of their injury, they will be found contributorily negligent and their recovery of damages will be reduced.[377]

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[370] See e.g. *Taylor v Morrison*, [2006] OJ No 2978, 149 ACWS (3d) 1149 at para 147.
[371] See Linden et al, *supra* note 341 at 10.01. The burden of establishing contributory negligence is on the defendant. See e.g. *Province of New Brunswick v Malsen et al*., 2022 NBCA 8 at para 22.
[372] See Robertson & Picard, *supra* note 130 at 468.
[373] See art 1478 para 2 CCQ.
[374] See e.g. *Rose v Dujon* (1990), 108 AR 352 (AB KB), 22 ACWS (3d) 1175 at para 148; *Ross Estate v Hiscock,* 2006 NLTD 47, 254 Nfld & PEIR 319 at para 118, aff'd 2007 NLCA 2; *Therrien, supra* note 129 at para 591.
[375] See e.g. *Crossman, supra* note 129 at 686; *Polera v Wade*, 2015 ONSC 821 at para 23 [*Polera*]. At common law, patients must uphold these duties to the standard of care of a reasonable patient, which is measured objectively, considering all the facts and circumstances of the case. See also Robertson & Picard, *supra* note 130 at 467.
[376] See e.g. *Polera, supra* note 375 at para 23; Robertson & Picard, *supra* note 130 at 467.
[377] See e.g. *Polera, supra* note 375 at para 23.

As authors Robertson and Picard note, as patients achieve a "more equal role in their medical care", it is likely that "there will be more patients found to be contributorily negligent".[378] As patients generally have a higher degree of responsibility in RPM and play a more active role in their care, contributory negligence may play an important role in medical liability cases involving RPM, especially where the patient is required to actively collect and transmit their own data. In such cases, there is a greater onus of responsibility on the patient to report their data in a timely manner according to physician instructions compared to passive collection technologies, whereby the data is automatically collected and transmitted.

In evaluating medical liability claims involving RPM, we anticipate the courts will place much attention on how the patient used the device and the degree to which they followed the physician's instructions. As previously mentioned, patient participation is crucial to the successful clinical use of RPM and the patient's failure to follow the physician's instructions may lead to a finding of contributory negligence. Consider the example of a patient with diabetes to whom their physician recommends an RPM device to track their blood glucose levels. The patient is instructed to input their blood glucose readings into the device twice daily. Despite these instructions, the patient neglects to input their data into the device regularly. The physician, however, does not follow up with the patient concerning their neglect to use the device as instructed. Eventually, the patient's blood glucose levels become dangerously high, and they suffer a diabetic coma. In this factual scenario, the physician's failure to follow-up will likely constitute a breach of the standard of

[378] See *ibid.*

care[379] and be considered a causal factor in the patient's injury. However, the patient's failure to follow the physician's instructions and provide their data through the RPM device will also be a contributing factor to their injury, which will lead to a decrease in their award of damages.

In determining whether the patient was contributorily negligent in a medical liability claim involving RPM, courts will likely assess the level of accuracy, detail, and clarity in the physician's instructions, especially considering the issue of digital literacy previously discussed in this thesis.[380] In general, it is considered reasonable for patients to rely on the professional opinion of their physicians.[381] If the physician's instructions were found to be incomplete, inadequate, or the physician did not take reasonable steps to ensure the patient completely understood the provided instructions or information, it is unlikely courts would find the patient to be contributorily negligent. Findings of contributory negligence will ultimately depend on the specific facts and circumstances of the case.

The above scenarios illustrate some of the causal issues that may arise from the clinical use of RPM. The determination of causation is ultimately a fact-specific exercise. In the absence of recorded cases of patient injuries resulting from the clinical use of RPM, we can only hypothesize on the types of causal issues that may emerge. Our causal analysis nonetheless highlights the challenges courts may face in determining causation in liability medical liability cases involving RPM and postulates how courts may resolve these causal issues.

[379] See our analysis of the duty to follow-up in Chapter III.
[380] See Chapter I.
[381] See Robertson & Picard, *supra* note 130 at 474.

CONCLUSION

Health care is a rapidly evolving and developing field, with scientific and medical advancements having introduced numerous technologies into the provision of clinical care services. Social and public health crises have also spurred changes in the health care sector. The widespread use of telehealth, the use of information and communication technologies to provide health care services remotely, is such an example. As a subset of telehealth, RPM comprises the use of information technologies and telecommunication tools to collect health data from patients in their own environment, outside of traditional health care settings, such as hospitals and clinics, and electronically transmit the data to health care providers for monitoring and evaluation purposes. The clinical implementation of RPM can be beneficial for many patients and clinical applications, including chronic diseases, the elderly, and patients who live in rural or remote regions. The use of RPM has increased significantly since the onset of the COVID-19 pandemic and is expected to continue in the coming years.

Despite these promising signs, concerns over uncertain medical liability have been raised by clinicians and have been identified as a significant barrier to the greater adoption of RPM.[382] Indeed, lack of clarity surrounding medical liability for the use of novel technologies can often have a chilling effect on physicians. Uncertainties over medico-legal liability risks in RPM are further compounded by the absence of case law concerning medical liability involving RPM in Canada and by the paucity of relevant professional guidelines and clinical standards. Through attempting to clarify the application of medical liability rules under both the Anglo-Canadian

[382] See e.g. Davis et al, *supra* note 25 at 436; Ritu Thamman & Rajesh Janardhanan, "Cardiac rehabilitation using telemedicine: the need for tele cardiac rehabilitation" (2020) 21:4 Rev Cardiovascular Medicine 497 at 499.

common law and Quebec civil law traditions, our thesis aims to address some of the liability concerns which may hinder the greater adoption of RPM in Canadian clinical care.

In Chapter I, we provided an overview of the different clinical applications of RPM and a typology of the different RPM technologies used in clinical care. We found that there are many types of technologies which make up the RPM ecosystem, with different benefits, risks, and clinical applications. In Chapter II, we began our analysis of the medical liability issues in RPM with a discussion of the risks of patient injury that could result from the clinical use of RPM technologies. In particular, we highlighted the lack of clarity surrounding the scope and content of the traditional legal duties of physicians in the RPM context.

In Chapter III, we attempted to address this lack of clarity by postulating how courts may address issues surrounding physician breaches of the standard of care (common law) or of the contractual obligation of means (civil law) when using RPM, focusing specifically the duties to inform, to treat, to instruct, and to follow-up. We also insisted on the importance of adopting RPM-specific professional guidelines and clinical standards, which can be indicative of accepted standards of medical practice and provide guidance to physicians who use RPM. Finally, in Chapter IV, we discussed the key causal issues that could arise in medical liability actions involving RPM: delays in treatment, multiple defendants, and patient contributory negligence.

In their essay on the clinical adoption of electronic (or e-health) technologies, authors Vedder *et al* describe the law as a "catalyst and facilitator" for trust in e-health, stating that "the law may be able to create necessary conditions for health-care providers and patients to trust e-

health and to adopt it voluntarily".[383] From our analysis of the medical liability issues related to RPM, we are able to propose certain factors which physicians should consider in their use of RPM to mitigate patient risks and the potential for legal liability.

Our discussion of the physician's duty to inform in the context of RPM highlights the importance of the informed consent process in RPM, particularly as it pertains to the disclosure of its risks and limitations. As a burgeoning health care modality, patients may be unaware of these risks and limitations as well their implications for their care and treatment. Disclosure of this information will be critical, as will be ensuring patient comprehension of this information, especially when considering the digital literacy levels of many population groups.

In our first causal scenario, which involved a device malfunction, we addressed the issue of clinical overreliance on technologies, which can constitute a breach of the physician's duty to treat.[384] In the context of health care technologies, physicians should be cognizant that these technologies do not replace human activity or judgment.[385] We previously highlighted the caution with which physicians should use RPM, so that they do not over rely on these technologies or consider them as replacing the use of professional clinical judgment.[386] Technologies are not infallible and the consequences of a technical malfunction can be prejudicial to the patient whose care is entrusted with the device.[387]

[383] See Vedder et al, *supra* note 336 at 307—08.
[384] See e.g. Grissinger, *supra* note 257 at 320 for a discussion of human overreliance on technology.
[385] See *ibid.*
[386] See Terry & Wiley, *supra* note 173.
[387] See Gerke et al, *supra* note 158 at 1181.

Our second factual scenario on patient contributory negligence illustrates the importance of providing accurate, precise and comprehensible instructions to patients on how to use the device and when to contact the physician should the patient encounter any issues using the RPM system. The duty to instruct the patient is likely to become more important with the increasing clinical reliance on patients in telehealth. While patient contributory negligence is likely to become more prominent in medical liability claims in the telehealth era, so too will the physician's duty to instruct. Physicians should therefore provide patients clear, patient-friendly instructions and take reasonable steps to ensure that the patient has properly understood these instructions.[388]

Finally, our analysis illustrates the importance for physicians and other health care providers involved in the use of RPM to document all relevant information concerning the use of the RPM system, including informed consent with the patient, data flows, delegation of tasks to other personnel, patient follow-ups, including when and how often the patient was followed-up with, and the instructions that were provided to the patient. Should there a liability claim be brought against the physician or institution, these notes may be adduced as evidence that reasonable care was exercised in the use of the RPM system.

Ultimately, using RPM in a safe and efficient manner with patients will require additional effort that may not otherwise be necessary in in-person care. Despite its clinical benefits, RPM raises a number of risks of patient injury. Appropriate measures should be implemented by clinicians to mitigate both risks of patient injury and the potential for legal liability. In this way, patients who may benefit from RPM can reap the benefits of this novel health care modality. While

[388] For further information on patient comprehension, see e.g. Suzanne Graham & John Brookey, "Do Patients Understand?" (2008) 12:3 Permanente J 67.

our thesis focused specifically on the clarification of medical liability rules as a facilitator for clinical adoption the clinical adoption of RPM, Vedder *et al*'s statement above also emphasizes the importance of patient trust and acceptance of health care technologies. While much has been written about clinician concerns over the adoption RPM, there is a paucity of scholarship on patient's views and perspectives of RPM. The future success of RPM will not only be contingent upon clinician adoption of these technologies, but upon patient trust and acceptance as well.

As a future direction, studies on patient perspectives can provide clinicians, policy-makers and health care institutions with valuable empirical data, which can inform how RPM technologies are used and ensure that future guidelines and standards on RPM adequately consider patient concerns and viewpoints. Furthermore, research on the risks of patient harm in RPM will also be critical to better inform the clinical implementation of RPM to mitigate these risks, ensuring safer and more efficient patient care. In the meantime, clarifying medical liability issues can serve as a first step in addressing some of the barriers currently facing RPM.

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