## THE VIRTUAL PHYSICIAN: Clarifying Medical Liability Issues in the Use of Remote Patient Monitoring

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More than ever before, information and communication technologies are playing an important role in the provision of health care services. 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. There are many challenges to RPM's greater implementation in health care, including the potential for risk of harm for patients, and uncertainty regarding the liability of physicians utilizing RPM. 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. This article attempts to clarify some of the liability issues raised by RPM. To help guide physicians in their use of RPM, I propose the adoption of professional guidelines specific to RPM that courts can use in determining whether physicians have breached relevant standards of practice. Furthermore, by providing evidence-based standards, guidelines can mitigate risks of patient injury and reduce physicians' reticence to adopt RPM.

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### I. INTRODUCTION

Historically, health care was primarily provided in patients' homes, either by family members or by physicians who made house calls.<sup>1</sup> By the late nineteenth century, however, the provision of health care had been largely institutionalized, mainly spurred by socioeconomic changes and advances in modern medicine and science.<sup>2</sup> 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 toward home-based care, facilitated by scientific and technological innovations that now allow health care providers to reach patients outside of institutional settings, such as hospitals or clinics.<sup>3</sup> 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,"<sup>4</sup> 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 of traditional health care institutional settings. The patient's data is then electronically transmitted to health care providers for monitoring, assessment, and treatment purposes.5

RPM allows health care providers to assess and evaluate their patients' medical conditions more regularly. This allows them to make more accurate and interactive treatment decisions, which is more challenging under episodic care models.<sup>6</sup> Indeed, one of the unique features

2 Ibid.

<sup>1</sup> See e.g. Thomas S Nesbitt & Jana Katz-Bell, "History of Telehealth" in Karen Schulder Rheuban & Elizabeth A Krupinski, eds, Understanding Telehealth (New York: McGraw-Hill Education, 2018) 3 at 3.

<sup>3</sup> 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 Open 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. The terms "telehealth" and "telemedicine" are often used interchangeably to refer to the remote

<sup>4</sup> provision of health care services using 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 Medicine 183 at 183. See e.g. Zineb Jeddi & Adam Bohr, "Remote Patient Monitoring Using Artificial Intelligence" in Adam

<sup>5</sup> Bohr & Kaveh Memarzadeh, eds, Artificial Intelligence in Healthcare (London, UK: 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. 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.

and advantages of RPM is that it is tailored to the patient's specific condition and health needs.<sup>7</sup> 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.<sup>8</sup> All this can occur without the need for regular in-person medical consultations.

Furthermore, the use of RPM (and telehealth more generally) can help improve access to care, especially for underserved populations, such as the socioeconomically disadvantaged or populations who live in rural or remote regions.<sup>9</sup> 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.<sup>10</sup> 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, both federal and provincial governments have been paying increased attention to the policy aspects of telehealth.<sup>11</sup>

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 also report high use of acute hospital care.<sup>12</sup> 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.<sup>13</sup> Reductions in the number of hospital admissions not only benefit patients, but are also beneficial to health care systems. Unplanned acute hospital use is a major financial burden on health care systems, which have become increasingly overburdened since the onset of the COVID-19 pandemic, which created delays in services like inpatient care, surgeries, and emergency care.<sup>14</sup> The benefits provided by RPM can result in significant cost savings for health care systems, which can then be allocated to other resources.

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 D Cole & Robert M 7 Hughes, "Remote Patient Monitoring During COVID-19: An Unexpected Patient Safety Benefit" (2022) 227:12 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. See e.g. Lakmini P Malasinghe, Naeem Ramzan & Keshav Dahal, "Remote Patient Monitoring: A

<sup>8</sup> Comprehensive Study" (2019) 10:1 J Ambient Intelligence & Humanized Computing 57 at 58.

See e.g. Abigail Baldwin-Medsker, Jessie Holand & Elizabeth S Rodriguez, "Access to Care: Using Health 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 Medical Internet Research 1 at 2. See e.g. David Blumenthal et al, "Covid-19: Implications for the Health Care System" (2020) 383:15

<sup>10</sup> 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 Lancet 1243 at 1243. See e.g. Government of Canada, "British Columbia Virtual Care Action Plan" (26 July 2022), online: [perma.cc/SY9A-LEVD]; Health Canada, Virtual Care: Policy Framework: A Product of the Federal, Provincial and Territorial Virtual Care / Digital Table, Catalogue No H22-4/27-2021E-PDF (Ottawa:

Health Canada, 7 July 2021), online: [perma.cc/W4XE-MRUJ]. See e.g. Monica L Taylor et al, "Does Remote Patient Monitoring Reduce Acute Care Use? A Systematic Review" (2021) 11:3 BMJ Open 1 at 4. 12

*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. 13

<sup>14</sup> Taylor et al, ibid. For further information on the impacts of COVID-19 on Canadian health care systems: Canadian Institute for Health Information, "Overview: COVID-19's Impact on Health Care Systems" (9 December 2021), online: [perma.cc/D9UE-RHRC].

One key driver in the increasing adoption of RPM and other forms of telehealth has been the COVID-19 pandemic, during which public health measures and restrictions significantly limited the number of in-person interactions in health care settings.<sup>15</sup> While telehealth was already playing a growing role prior to the pandemic, it experienced an exponential surge after the onset of the pandemic.<sup>16</sup> 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.<sup>17</sup> 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.<sup>18</sup> This expansion presents an opportunity to not only tackle these growing health issues, but to harness the potential benefits of RPM in other health care contexts and address many of the infrastructural and systemic issues currently facing health care systems.

Despite the projected expansion of the RPM and its purported benefits to patients and health care systems alike, there are many challenges and barriers that may hinder its greater adoption. For one, structural barriers may exacerbate inequities in remote care accessibility. There are significant disparities concerning access to technology and digital 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.<sup>19</sup> Additionally, 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.20

From a legal perspective, one significant challenge to the wider adoption of RPM is that of uncertain medical liability. As is often the case when new technologies are introduced into clinical care, uncertainty regarding the legal liability that may result from adverse events related to technology uptake may have a chilling effect on the adoption of RPM by clinicians. This issue has been raised, for instance, in the case of the integration of artificial intelligence (AI) in health care.<sup>21</sup> The literature has highlighted the effects uncertain liability

Khayreddine Bouabida et al, "Remote Patient Monitoring Program for COVID-19 Patients Following Hospital Discharge: A Cross-Sectional Study" (2021) 3:721044 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 102703-15 1.

<sup>16</sup> According to Canada Health Infoway's Digital Health Survey, 73 percent of Canadians had at least one virtual interaction with a health care provider in 2021, an increase from 67 percent in 2020, the first year of the COVID-19 pandemic. Canada Health Infoway, "Canadian Digital Health Survey 2021: What Canadians Think" (November 2021) at 14, online (pdf): [perma.cc/4TJ3-VZJW]. Kat Jercich, "RPM Market Will Double in Next Five Years, Predict Stakeholders," *Healthcare IT News* 

<sup>17</sup> (5 August 2020), online: [perma.cc/8E42-NC8E].

<sup>18</sup> Jercich, ibid.

<sup>19</sup> See e.g. Yohualli Balderas-Medina Anaya et al, "Post-Pandemic Telehealth Policy for Primary Care: An Equity Perspective" (2022) 35:3 J Am Board Family Medicine 588. Melinda M Davis et al, "A Systematic Review of Clinician and Staff Views on the Acceptability of

<sup>20</sup> Incorporating Remote Monitoring Technology into Primary Care" (2014) 20:5 Telemedicine & e-Health 428 at 430; Ariane M Fraiche et al, "Patient and Provider Perspectives on Remote Monitoring of Pacemakers and Implantable Cardioverter-Defibrillators" (2021) 149 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. Mélanie Bourassa Forcier, Lara Khoury & Nathalie Vézina, "Liability Issues for the Use of Artificial

<sup>21</sup> Intelligence in Health Care in Canada: AI and Medical Decision-Making" (2020) 46:2 Dalhousie Medical J 7 at 7.

may have on the greater adoption of RPM by health care professionals.<sup>22</sup> Despite the mainly positive clinician views reported in a systemic review of clinician and staff views of RPM published by Meline Davis et al, the authors reported clinicians' concerns over uncertain medico-legal liability in six different studies.<sup>23</sup>

Concerns over potential liability may make health care providers hesitant to adopt RPM, despite their overall favourable views of these technologies.<sup>24</sup> Without adequate clinician buy-in and support, the potential benefits of RPM will remain unrealized, and patients who may benefit from these technologies may be deprived of their advantages. An analysis of the medical liability issues raised by RPM technologies is therefore timely and relevant, especially as there is a paucity of legal scholarship on RPM.<sup>25</sup> Furthermore, medical liability issues related to RPM have vet to be addressed by courts in Canada<sup>26</sup> and internationally.<sup>27</sup> With its anticipated exponential growth in the coming years, however, it is likely that medical liability issues related to RPM could eventually be litigated.

Uncertainty over medical liability is further compounded by the paucity of professional standards and guidelines specific to the use of RPM in clinical care in Canada.<sup>28</sup> Though not legally binding, soft law instruments such as professional guidelines may be indicative of the professional norms required of health care practitioners and may be used by courts when assessing whether practitioners have met accepted standards of practice in liability lawsuits.<sup>29</sup> While some professional associations and colleges have adopted guidelines on telehealth,<sup>30</sup> there are currently no RPM-specific standards and guidelines in Canada.<sup>31</sup> 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 therefore makes it more difficult to predict legal standards for medical professionals.

<sup>22</sup> 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, the authors reported clinicians' concerns over uncertain medico-legal liability in six different studies: Davis et al, supra note 20 at 436.

<sup>23</sup> Ibid.

<sup>24</sup> Ibid.

<sup>25</sup> In Canadian legal scholarship, Dylan 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 my knowledge, yet to be explored in legal scholarship, Canadian or international.

A search conducted on 16 November 2023, on Lexis Advance Quicklaw using the primary search terms "remote patient monitoring" and "liability" yielded zero cases. Telehealth, specifically the use of virtual consultations, has begun to be addressed by professional disciplinary tribunals, though there have been very few cases to date: Suzame Philips-Nootens & Robert P Kouri, *Éléments de responsabilité civile* 26 médicale: Le droit dans le quotidien de la médecine, 5th ed (Cowansville, QC: Yvon Blais, 2021) at para 360.

<sup>27</sup> 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. Though, in the United States, the American Medical Association (AMA) has adopted guidelines on

<sup>28</sup> RPM: American Medical Association, "Remote Patient Monitoring Playbook" (2022), online (pdf): [perma.cc/2C4T-AKTW]

Angela Campbell & Kathleen Cranley Glass, "The Legal Status of Clinical and Ethics Policies, Codes, and Guidelines in Medical Practice and Research" (2014) 46:2 McGill LJ 473 at 480. See e.g. Canadian Medical Association "Guiding Principles for Physicians Recommending Mobile 29

<sup>30</sup> Health Applications to Patients" (2015), online (pdf): [perma.cc/7AXG-3FJY]; Collège des médecins du Québec, "Télémédecine" (13 June 2022), online: [perma.cc/G5JR-8WQX]. Though guidelines on the use of mobile health applications may be applicable to RPM, as will be

<sup>31</sup> discussed later in this article.

Accordingly, in this article, I aim to clarify some of the medical liability issues surrounding the use of RPM in clinical care by identifying risks of patient injury in RPM and postulating the types of factors courts might consider in determining whether physicians have breached the appropriate standards of medical practice when using RPM. Having identified these risks and factors, I propose the adoption of professional guidelines specific to RPM, which can help mitigate risks of patient injury and the concomitant liability of physicians who use RPM. These guidelines can then help practitioners navigate the complexities of RPM, ensuring safer and better care for their patients.

This article will be presented in four parts. First, I will provide an overview of the different types of technologies that make up the RPM landscape and their clinical applications. As will be demonstrated, the RPM landscape is highly heterogeneous, encompassing a wide array of technologies. Second, I will examine the conditions for imposing medical liability under Anglo-Canadian common law and Quebec civil law and identify risks of patient injury that may be created by the clinical use of RPM. Third, I will postulate, based on existing medical liability rules, the types of factors courts might consider in determining whether physicians have breached appropriate standards of medical practice (the standard of care at common law and the contractual obligation of means under civil law). Finally, I will examine the role professional guidelines can play in establishing standards of medical practice and propose the adoption of RPM-specific guidelines as a first step toward clarifying the liability issues raised by RPM. Based on my analyses, I propose factors that can be included in professional guidelines to address some of the liability issues identified in this article.

## **II. OVERVIEW OF REMOTE PATIENT** MONITORING TECHNOLOGIES

Given its clinical utility, RPM will likely soon be used in many clinical applications, as many patients have health conditions that require ongoing monitoring and personalized care. Indeed, RPM can be beneficial in many clinical applications, including when treating patients with mobility issues, the elderly, and patients in post-surgical recovery.<sup>32</sup> 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.<sup>33</sup> In this section, I will provide an overview of the fundamental components of RPM technologies and provide a typology of the different types of RPM technologies that are used in clinical care.

#### A. FUNDAMENTAL COMPONENTS OF REMOTE PATIENT MONITORING TECHNOLOGIES

RPM relies on the ability to electronically acquire and transmit health data from the patient's location to the health care provider's location.<sup>34</sup> Technological devices or

<sup>32</sup> 

See e.g. Malasinghe, Ramzan & Dahal, *supra* note 8 at 58. Sandra Mierdel & Kirk Owen, "Telehomecare Reduces ER Use and Hospitalizations at William Osler 33 Health System" (2015) 209 Studies in Health Technology & Informatics 102 at 102; Tomasz Szydło & Marek Konieczny, "Mobile and Wearable Devices in an Open and Universal System for Patient Monitoring" (2016) 46 Microprocessors & Microsystems 44 at 44. Bobby Gheorghiu & Fraser Ratchford, "Scaling up the Use of Remote Patient Monitoring in Canada"

<sup>34</sup> (2015) 209 Studies in Health Technology & Informatics 23 at 23.

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.<sup>35</sup>

RPM technologies can range from mobile health applications on smartphones to wearable body sensors and wireless enabled implanted devices.<sup>36</sup> Clinical applications can range from chronic disease management to cardiac monitoring and post-surgical monitoring. Generally, most RPM systems entail the use of a single type of technology and target a single disease or health condition.<sup>37</sup> 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.<sup>38</sup> 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.<sup>39</sup>

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 constitutes an RPM system.<sup>40</sup> This variability is not only acknowledged by scholars but also by professional organizations, such as the American College of Physicians, which notes these variabilities in their online telehealth practice resources.<sup>41</sup> 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.42

Irrespective of the types of technologies that are employed or how they are implemented, RPM systems 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.<sup>43</sup> 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.<sup>44</sup>

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

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Jeddi & Bohr, *supra* note 5 at 204. See e.g. Ashish Atreja et al, "Remote Patient Monitoring in IBD: Current State and Future Directions" 36 (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 & Hepatology 1697 at 1697; Roskams-Edris, supra note 25 at 61.

<sup>37</sup> Jeddi & Bohr, supra note 5 at 208.

<sup>38</sup> Ahmed Alboksmaty et al, "Effectiveness and Pulse Oximetry in Remote Patient Monitoring of Patients with COVID-19: A Systematic Review" (2022) 4:4 Lancet Digital Health e279 at e279; Amy L Tucker, "Remote Patient Monitoring and Care Coordination" in Rheuben & Krupinski, *supra* note 1 at 136. 39

<sup>40</sup> 

Bouabida et al, *supra* note 15 at 2; Tucker, *ibid*. Jeddi & Bohr, *supra* note 5 at 208; Malasinghe, Ramzan & Dahal, *supra* note 8 at 58. 41

American College of Physicians, "Variations Among RPM Solutions" (12 July 2022), online (pdf): [perma.cc/CU34-YETD]. 42

Ibid.

<sup>43</sup> Jeddi & Bohr, supra note 5 at 204; Malasinghe, Ramzan & Dahal, supra note 8 at 59. 44

Tucker, supra note 38 at 136.

that collect health data from the patient.<sup>45</sup> 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 their team of health care providers.<sup>46</sup> 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.<sup>47</sup>

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 (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 on the health condition of the patient, the type(s) of data that are collected, and the complexity of the data.<sup>48</sup>

## B. TYPES OF REMOTE PATIENT MONITORING TECHNOLOGIES

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. My typology systematically classifies RPM technologies first into two broad categories described in the literature, 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.

## 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.<sup>49</sup> Within this general category, we find the following types of technologies: (1) wearable devices that use passive data collection modalities; (2) implantable devices; and (3) contactless devices, such as image-based and radar-based technologies. I will describe each of these technologies in turn.

<sup>&</sup>lt;sup>45</sup> Ibid.

<sup>&</sup>lt;sup>46</sup> Jeddi & Bohr, *supra* note 5 at 204.

<sup>&</sup>lt;sup>47</sup> *Ibid*; Malasinghe, Ramzan & Dahal, *supra* note 8 at 58.

<sup>&</sup>lt;sup>48</sup> Jeddi & Bohr, *ibid*.

<sup>&</sup>lt;sup>49</sup> 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.

#### Wearable Devices with Passive Data Collection Modalities а

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."50 Wearable devices can be worn directly on the user's body or on an article of clothing or other type of worn accessory.<sup>51</sup> While wearable devices can be employed for personal use by individuals for self-diagnosis and self-monitoring,<sup>52</sup> they can also be employed by physicians for integration within an RPM system.53

In addition to consumer wearables, such as smartwatches and fitness trackers, wearable devices include blood pressure monitors, glucometers, electrocardiograms (ECGs), and other types of body sensors.<sup>54</sup> 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.55

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 heartbeat rate.<sup>56</sup> Wearable sensors can be used in blood oxygen saturation monitoring systems, with built-in pulse oximeters that can measure levels of oxygenated hemoglobin in the patient's bloodstream.57 These devices connect to Bluetooth and transfer collected data to the patient's health care provider via the Internet.58

#### b. Implantable Devices

Implantable devices refer to those devices that 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.<sup>59</sup> Examples of such devices include pacemakers, which are used to regulate abnormal cardiac rhythms, and 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.<sup>60</sup>

<sup>50</sup> Jesse V Jacobs et al, "Employee Acceptance of Wearable Technology in the Workplace" (2019) 78 Applied Ergonomics 148 at 148.

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. 51

<sup>52</sup> 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. Roblyer, *supra* note 15 at 102703-2; Szydło & Konieczny, *supra* note 33 at 44.

<sup>53</sup> 

<sup>54</sup> Roblyer, ibid.

<sup>55</sup> Mirza Mansoor Baig et al, "A Systematic Review of Wearable Patient Monitoring Systems: Current Challenges and Opportunities for Clinical Adoption" (2017) 41:115 J Medical Systems 1 at 2.

<sup>56</sup> T Sivani & Sushruta Mishra, "Wearable Devices: Evolution and Usage in Remote Patient Monitoring System" in Sushruta Mishra et al, eds, Connected e-Health: Integrated IoT and Cloud Computing (Cham, Switzerland: Springer, 2022) 311 at 314. 57

*Ìbid* at 318. 58

Ibid at 325. 59

Taylor et al, supra note 12 at 1. 60

Malasinghe, Ramzan & Dahal, supra note 8 at 60.

Overall, implantable devices have been shown to play an important role in the management of cardiac disease.<sup>61</sup> 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 ICD patients.<sup>62</sup> Data was collected 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.<sup>63</sup> A similar multi-centre study based in the Netherlands tested an RPM system for remote follow-up of patients with ICD and cardiac resynchronization therapy devices.<sup>64</sup> 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.<sup>65</sup>

#### c. Contactless Devices

As RPM technologies that 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.<sup>66</sup> Contactless RPM technologies include ambient technologies and sensors that require the patient to be present within a certain distance of the sensor.<sup>67</sup> Contactless technologies are generally classified into two categories: image-based methods, which have been more fully explored to date, and radar-based methods.<sup>68</sup> Moreover, they are often more cost-efficient than other types of technologies.<sup>69</sup>

Image-based methods include video cameras, infrared sensors, and time-of-flight cameras.<sup>70</sup> They can detect a number of visual cues, such as facial expressions or physical movements.<sup>71</sup> These functionalities are especially relevant in fall detection, sleep monitoring, epilepsy monitoring, as well as respiration and apnea monitoring.<sup>72</sup> Radar-based methods include respiration sensing technologies and Impulse Radio Ultra-Wideband devices for measuring heart rate.<sup>73</sup> 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 novel and innovative domain within the larger RPM ecosystem, further research will be required to test their efficiency and feasibility.<sup>74</sup>

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.

S Perl et al, "Socio-Economic Effects and Cost saving Potential of Remote Patient Monitoring (SAVE-HM Trial)" (2013) 169:6 Intl J Cardiology 402 at 402.
 Ibid at 402.

 $<sup>^{63}</sup>$  *Ibid* at 403.

 <sup>&</sup>lt;sup>64</sup> H Versteeg et al, "Patient Perspective on Remote Monitoring of Cardiovascular Implantable Electronic Devices: Design of the REMOTE-CIED Study" (2014) 22:10 Netherlands Heart J 423 at 423.
 <sup>65</sup> *Ibid* at 425

 $<sup>\</sup>frac{15}{100}$  Ibid at 425.

Malasinghe, Ramzan & Dahal, *supra* note 8 at 59.

<sup>67</sup> *Ibid.* 

Ibid at 60.

 <sup>&</sup>lt;sup>69</sup> Ibid.
 <sup>70</sup> Source

<sup>&</sup>lt;sup>70</sup> Supriya Sathyanarayana et al, "Vision-Based Patient Monitoring: A Comprehensive Review of Algorithms and Technologies" (2018) 9:2 J Ambient Intelligence & Human Computing 225 at 226.

<sup>&</sup>lt;sup>71</sup> Ibid.

<sup>&</sup>lt;sup>72</sup> *Ibid*; Malasinghe, Ramzan & Dahal, *supra* note 8 at 59.

<sup>&</sup>lt;sup>73</sup> 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 2479 at 2486.

<sup>&</sup>lt;sup>74</sup> Malasinghe, Ramzan & Dahal, *supra* note 8 at 72.

#### 2. ACTIVE DATA COLLECTION MODALITIES

Active data collection modalities encompass technologies in which the patient plays a role within the RPM data acquisition system.<sup>75</sup> 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 that may fall into this category include: (1) wearable devices that use active data collection modalities; and (2) mobile health applications.

Wearable Devices with a. Active Data Collection Modalities

While the functionalities of wearable devices are especially conducive to continuous monitoring of patients through passive data collection, some have active data collection modalities that 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 for thoracic surgery patients.<sup>76</sup> After hospital discharge, surgical patients were provided with a tablet, a blood pressure monitor, a heart rate monitor, a weight scale, and a pulse oximeter.<sup>77</sup> 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.<sup>78</sup> Additionally, they were required to complete a daily questionnaire on their tablet, including questions related to their pain and post-operative symptoms.<sup>79</sup>

#### b. Mobile Health Applications

Like 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."80 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.<sup>81</sup> While mobile health applications are not all intended for use by physicians with their patients,<sup>82</sup> they can fit 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).

<sup>75</sup> Kourtis et al, supra note 49 at 1.

Stesha Selsky & Sean M Reed, "Non-Invasive Remote Monitoring to Decrease 30-Day Unplanned 76 Readmissions in Thoracic Surgery Patients" (2022) 7:2 J Informatics Nursing 43.

<sup>77</sup> Ibid at 44.

<sup>78</sup> Ibid at 45. 79

Ibid.

<sup>80</sup> See e.g. Chen Wang & Huiying Qi, "Influencing Factors of Acceptance and Use Behavior of Mobile 81

Health Application Users: Systematic Review" (2021) 9:3 Healthcare 357 at 357. 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. 82

Ibid at 145, 153.

The Centre of Network Flow Optimization 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."83 The implementation of the program also served to evaluate the user-friendliness of the program and identify patient perspectives on the program.84 Patients can 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. The 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.

In summary, the RPM ecosystem comprises a diverse array of technologies, which can be broadly classified into two categories, based on their data collection modalities. Despite their differences, these technologies share fundamental components that enable data transmission from the patient's location to the physicians or clinical care teams. This method of data transmission allows patients to be remotely monitored outside of health care institutional settings, presenting new and innovative opportunities for patient care. With opportunity and innovation, however, comes the potential for risk. RPM is relatively recent and is not standard of care in general medical practice. The introduction of new technologies can indeed pose challenges for clinicians, and unfamiliarity with these technologies may contribute to the potential for patient injury. I will explore some of these risks in the next section.

### **III. RISKS OF PATIENT INJURY IN REMOTE PATIENT MONITORING**

Patients cannot succeed in a medical liability action unless they have demonstrated that they have suffered a legally cognizable injury. In this section, I will identify risks of patient injury that may arise from the use of RPM. While many of these risks are associated with the development and manufacturing of the RPM technologies themselves, there may also be risks of patient injury raised by their usage by health care providers. Before examining these risks, I will first provide an overview of the basic conditions required for the determination of medical liability under the Anglo-Canadian common law and Quebec civil law systems.

<sup>83</sup> Bouabida et al, supra note 15 at 3. Ibid.

<sup>84</sup> 

# A. CONDITIONS FOR IMPOSING MEDICAL LIABILITY

Proof of patient injury<sup>85</sup> is central to the determination of physician liability, in both civil law and common law.<sup>86</sup> As authors Gerald Robertson and Ellen Picard note in their treatise on the liability of physicians and hospitals at common law, proof of the other elements in a legal 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."<sup>87</sup> Under both legal traditions, patient injuries may comprise both physical and psychological or mental injuries.<sup>88</sup>

In both legal systems, the primary objective of liability is compensation, that is, to indemnify those who have suffered injury through the fault or negligence of another.<sup>89</sup> At common law, medical liability is generally determined through the tort of negligence.<sup>90</sup> 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. 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;
- 3. The patient suffered a legally cognizable injury; and
- 4. The physician's negligence was the factual and legal cause of the patient's injury.<sup>91</sup>

Under Quebec civil law, there is no special regime for the treatment of medical liability claims, which instead fall under the civil liability regime of the *Civil Code of Québec*.<sup>92</sup> In a medical liability action, the patient must prove, on a balance of probabilities,<sup>93</sup> that:

- 1. The physician committed a fault ("faute");
- 2. The patient suffered an injury ("préjudice"); and

 <sup>&</sup>lt;sup>85</sup> Injury may also be referred to as "loss" or "damage": Gerald B Robertson & Ellen I Picard, *Legal Liability of Doctors and Hospitals in Canada*, 5th ed (Toronto: Thomson Reuters, 2017) at 325.
 <sup>86</sup> Ibid.

<sup>&</sup>lt;sup>87</sup> Ibid. Ibid.

<sup>&</sup>lt;sup>88</sup> For common law: Mustapha v Culligan of Canada Ltd, 2008 SCC 27 at para 8 [Mustapha]. Compensable mental injuries must be "serious and prolonged and rise above the ordinary annoyances, anxieties and fears that people living in society routinely, if sometimes reluctantly, accept" (Mustapha, ibid at para 9). The Civil Code of Québec refers to bodily, moral, material injuries. This applies to both the extracontractual and contractual regimes (Arts 1457–58 CCQ).

 <sup>&</sup>lt;sup>89</sup> Allen M Linden, Lewis N Klar & Bruce Feldthusen, *Canadian Tort Law: Cases, Notes & Materials,* 16th ed (Toronto, ON: LexisNexis Canada, 2022) at 9 (for the compensation functions of tort law). For civil law, see arts 1457, 1458 CCQ (extracontractual liability and contractual liability, respectively).

 <sup>&</sup>lt;sup>90</sup> 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: Robertson & Picard, *supra* note 85 at 543.

 $<sup>^{91}</sup>$  Mustapha, supra note 88 at para 3.

<sup>&</sup>lt;sup>92</sup> Under Quebec law, the physician-patient relationship is generally characterized as an *intuitu personae* contractual relationship: see e.g. X v Mellen, [1957] BR 389 at 408 (CQ). There are circumstances, however, in which a patient may not be capable of entering into a medical contract. This may occur, for instance, when 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): Philips-Nootens & Kouri, *supra* note 26 at para 42.

<sup>&</sup>lt;sup>93</sup> Art 2804 CCQ.

- 3. There is a causal relationship between the fault and the injury. That is, that the physician's fault caused the patient's injury ("lien causal" or "lien de causalité").<sup>94</sup>
- 4. Additionally, in contractual claims, the patient must prove that the damages suffered were "foreseen or foreseeable at the time the obligation was contracted."<sup>95</sup>

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 medical liability where novel medical technologies or models of patient care are utilized, such as the use of AI.<sup>96</sup> Some commentators have even suggested modifications to existing liability regimes for novel health care technologies.<sup>97</sup> Nonetheless, the basic conditions for imposing medical liability described above apply to RPM, despite being challenged by its novel aspects.<sup>98</sup> Given the centrality of proof of patient injury in medical liability claims, I will now examine the risks of injury raised by RPM.

## **B.** Types of Risks of Patient Injury

While the clinical use of RPM may be beneficial to some patients, it may also create risks of injury. Some of these risks are associated with the RPM technologies themselves, which raises product liability issues. 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 manufacture of their products, including their component parts.<sup>99</sup> If the product defect results from negligent manufacturing, namely, 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. Quebec law imposes strict liability on manufacturers,<sup>100</sup> 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."<sup>101</sup>

<sup>&</sup>lt;sup>94</sup> Art 1457 CCQ (extracontractual liability); Art 1458 CCQ (contractual liability).

<sup>&</sup>lt;sup>95</sup> Art 1613 CCQ.

<sup>&</sup>lt;sup>96</sup> See e.g. Forcier, Khoury & Vézina, *supra* note 21 at 7; Michael Lang, Alexander Bernier & Bartha Maria Knoppers, "Artificial Intelligence in Cardiovascular Imaging: 'Unexplainable' Legal and Ethical Challenges?" (2022) 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.

<sup>&</sup>lt;sup>97</sup> See e.g. Iria Giuffrida, "Liability for AI Decision-Making: Some Legal and Ethical Considerations" (2019) 88:2 Fordham L Rev 439 at 443; Sullivan & Schweikart, *ibid* at 164.

<sup>&</sup>lt;sup>98</sup> 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." In English: "At a time when telemedicine is becoming increasingly important, and particularly in the context of the COVID-19 crisis, physicians must realize that all their ethical and legal obligations apply when using this technology." [emphasis added; translated by author]. 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.

<sup>&</sup>lt;sup>99</sup> See e.g. *Farro v Nutone Electrical Ltd* (1990), 72 OR (2d) 637 at para 11 (CA).

<sup>&</sup>lt;sup>100</sup> Art 1468 CCQ.

<sup>&</sup>lt;sup>101</sup> Art 1469 CCQ.

Indeed, poorly designed or negligently manufactured devices can cause injury and, in extreme cases, death.<sup>102</sup> Consider, for instance, the case of a manufacturing defect affecting RPM for cardiac monitoring that causes a delay in the transmission of data or the data to not be transmitted altogether.<sup>103</sup> A delay in treatment due to the device's failure to indicate a "cardiac arrhythmia [or irregular heartbeat] may have disastrous consequences for a patient's health."<sup>104</sup> 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.<sup>105</sup> These false results may result, for instance, from battery issues or calibration problems with the RPM device.<sup>106</sup>

In addition to technical issues, inaccurate data transmission can result from improper device usage by patients.<sup>107</sup> The improper placement of continuous glucose monitoring wearable devices by the patient on their body, for example, may lead to inaccurate data collection.<sup>108</sup> The use of body sensors, as another example, may create patient discomfort, which in turn may influence their device's reading of their physiological data.<sup>109</sup> 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. I will return to this issue in Part IV when I examine the duty of physicians to provide proper instructions to their patients.

A 2019 French study on the use of ICDs illustrates the types of challenges related to inaccurate diagnoses and inappropriate clinical responses.<sup>110</sup> ICDs, which are implanted into the chest, detect irregular heartbeats and, where necessary, use electrical shocks to restore the patient's regular heart rhythm.<sup>111</sup> 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 15-month period.<sup>112</sup> The study found that inappropriate diagnoses occurred in 9 percent of patients, 36 percent of whom suffered at least one inappropriate electrical shock.<sup>113</sup> Though the overall rate of inappropriate shock in patients was found to

<sup>&</sup>lt;sup>102</sup> Angela Ryan et al, "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, Switzerland: Springer, 2021) 201 at 202.

Workforce: Current and Future Developments (Cham, Switzerland: Springer, 2021) 201 at 202.
 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 Medical Engineering & Technology 623 at 626.

<sup>&</sup>lt;sup>104</sup> See e.g. Sara Gerke et al, "Regulatory, Safety, and Privacy Concerns of Monitoring Technologies during COVID-19" (2020) 26:8 Nature Medicine 1176 at 1178.

 <sup>&</sup>lt;sup>105</sup> See e.g. Neil Charness et al, "Metrics for Assessing the Reliability of a Telemedicine Remote Monitoring System" (2013) 19:6 Telemedicine & e-Health 487 at 487.
 <sup>106</sup> See e.g. Publicia NK Trianthi, & Pagerage Kitigayung "A Pagel Time Health Manitoring

 <sup>&</sup>lt;sup>106</sup> 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) Intl J Telemedicine & Applications 1 at 2.
 <sup>107</sup> Official Cardiac Patients (2017) 100 (2017

<sup>&</sup>lt;sup>107</sup> Charness et al, *supra* note 105 at 487.

<sup>&</sup>lt;sup>108</sup> Robab Abdolkhani et al, "Patient-Generated Health Data Management and Quality Challenges in Remote Patient Monitoring" (2019) 2:4 JAMIA Open 471 at 474.

<sup>&</sup>lt;sup>109</sup> Malasinghe, Ramzan & Dahal, *supra* note 8 at 59.

<sup>&</sup>lt;sup>110</sup> 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 Europace 607.

<sup>&</sup>lt;sup>1111</sup> National Heart, Lung and Blood Institute, "What are Defibrillators?" (24 March 2022), online: [perma.cc/F35L-LPMN].

<sup>&</sup>lt;sup>112</sup> Perrin et al, *supra* note 110 at 608.

<sup>&</sup>lt;sup>113</sup> *Ibid* at 610.

be low (3 percent), this study demonstrates the potential for inappropriate treatments or clinical responses in RPM, which may be prejudicial to patients.<sup>114</sup>

The management of the patient's data by the physician and clinical care team may also raise risks of patient injury. For instance, depending on the type of RPM technology and how it is used, numerous types of data can be transmitted, making data management and patient surveillance difficult.<sup>115</sup> 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.<sup>116</sup> 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.<sup>117</sup>

The management of large volumes of patient data leads to a further challenge connected to possible clinician fatigue or cognitive overload.<sup>118</sup> Clinicians may become distracted or desensitized to these large volumes of data, which could potentially lead to clinical errors that could harm patients.<sup>119</sup> Conversely, there may be clinician overreliance on RPM technologies, whereby the data transmission and detection features of these technologies are overestimated.<sup>120</sup> Overreliance could potentially create a "false sense of complacency should the technology not detect a problem."<sup>121</sup> Indeed, the 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 to use the RPM technologies, a common concern when novel technologies are introduced into clinical care.<sup>122</sup> Sufficient training and clinicians' consequent preparedness to use novel health technologies have been highlighted as key factors in ensuring a well-skilled and competent health workforce.<sup>123</sup> I will return to the question of overreliance when I address the duty of physicians to treat their patients.

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.<sup>124</sup> Data breaches could occur, for instance, if the patient's data is not properly encrypted when transmitted.<sup>125</sup> Given that RPM involves

<sup>&</sup>lt;sup>114</sup> *Ibid* at 612.

 <sup>&</sup>lt;sup>115</sup> See e.g. Eric L Wallace et al, "Remote Patient Management for Home Dialysis Patients" (2017) 2:6
 Kidney Intl Reports 1009 at 1013.
 <sup>116</sup> *I*<sub>1</sub>: *J*

<sup>&</sup>lt;sup>116</sup> *Ibid*.

Ibid. See also Sarah Cook et al, *Citizen Generated Data: The Ethics of Remote Monitoring* (Cambridge, UK: PHG Foundation, May 2019), online: [perma.cc/48G9-XJTR]; Davis et al, *supra* note 20 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 103 at 623.

<sup>&</sup>lt;sup>118</sup> Wallace et al, *supra* note 115 at 1013.

ECRI Institute, Top 10 Health Technology Hazards for 2020: Expert Insights from Health Devices (ECRI Institute, 2019), online: [perma.cc/T2WC-CY9S].
 Contextual 127

<sup>120</sup> Cook et al, *supra* note 117.

<sup>&</sup>lt;sup>121</sup> *Ibid*.

MiOk 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 JAMIA 246 at 248.
 Ryan et al, *supra* note 102 at 202.

See e.g. Adil Hussain Seh et al, "Healthcare Data Breaches: Insights and Implications" (2020) 8:2 Healthcare 1 at 3.

<sup>&</sup>lt;sup>125</sup> 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.

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.<sup>126</sup>

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.<sup>127</sup> 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 confidentiality of the information stored on the platform, such as interception of data during transmission and denial-of-service attacks.<sup>128</sup> The implementation of robust data encryption techniques and privacy safeguards is therefore critical in helping to mitigate these privacy risks.<sup>129</sup> Nonetheless, risks to patient privacy are inherent in all digital health technologies, and the confidentiality of patients' information can never be fully safeguarded, even with the implementation of robust protective measures.<sup>130</sup> As will be discussed in Part IV, the disclosure of privacy risks will be a key component of the disclosure of risks related to RPM by physicians to patients.

In short, RPM may create risks of patient injury, which could potentially expose physicians to legal liability. While the occurrence of patient injury is essential to a finding of legal liability, it is not, on its own, sufficient.<sup>131</sup> The injury must be linked to the physician's breach of the standard of care (common law) or of the contractual obligation of means (civil law). While courts have yet to address medical liability claims involving RPM, I will, based on analogy with existing legal principles, postulate the types of factors courts may consider in determining whether physicians have breached these standards when using RPM.

### IV. BREACHES OF THE STANDARD OF CARE AND 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.<sup>132</sup> 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).<sup>133</sup> Despite its increased clinical uptake in recent years, RPM is still very

<sup>&</sup>lt;sup>126</sup> See e.g. Gerke et al, *supra* note 104 at 1180; Timothy M Hale & Joseph C Kvedar, "Privacy and Security Concerns in Telehealth" (2014) 16:12 Am Medical Assoc J Ethics 981 at 981.

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 & Decision Making 1.
 Built and Construction Security Risks in a Technology Platform for Home-Based Chronic Disease Rehabilitation and Education" (2013) 13:85 BMC Medical Informatics & Decision

<sup>&</sup>lt;sup>128</sup> *Ibid* at 6-8.

<sup>&</sup>lt;sup>129</sup> Malasinghe, Ramzan & Dahal, *supra* note 8 at 59.

See e.g. Liang Hong et al, "Big Data in Health Care: Applications and Challenges" (2018) 2:3 Data & Information Management 175 at 191.
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<sup>&</sup>lt;sup>131</sup> Robertson & Picard, *supra* note 85 at 259.

 <sup>&</sup>lt;sup>132</sup> See e.g. *Bafaro v Dowd*, 2008 CanLII 45000 at para 24 (ONSC), aff'd 2010 ONCA 188: "An unfortunate outcome does not constitute proof of negligence."
 <sup>133</sup> By its very nature, the clinical use of RPM implies that there is an ongoing physician-patient

<sup>&</sup>lt;sup>133</sup> 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 (Art 1458 CCQ).

much a burgeoning health care modality and has yet to become standard medical practice, though pacemakers and other cardiac devices with some remote monitoring features have become more common in recent years. 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.<sup>134</sup> This, in turn, creates challenges in defining the applicable professional standards for physicians who adopt these technologies.<sup>135</sup> In this section, I will briefly introduce the concepts of standard of care and contractual obligation of means, following which I will postulate factors that courts might consider in determining whether physicians have breached these standards.

#### A. **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.<sup>136</sup> 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.<sup>137</sup> Failure to meet the applicable standard of care may arise from both negligent actions and omissions.<sup>138</sup>

The identification of the applicable standard of care in a medical negligence action is a question of law.<sup>139</sup> 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).<sup>140</sup> This is mainly an objective 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.<sup>141</sup> 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.<sup>142</sup> Physicians are not liable for errors in judgment if their judgment was exercised honestly and intelligently.<sup>143</sup>

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."<sup>144</sup> Whether a practice is considered an "approved

<sup>134</sup> 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. 135

Ibid at 13.

<sup>136</sup> Mustapha, supra note 88 at para 7.

<sup>137</sup> This is known as the "reasonable physician" standard: Ter Neuzen v Korn, 1995 CanLII 72 at para 33 (SCC) [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: Wilson v Swanson, 1956 CanLII 1 at 119 (SCC) [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 CanLII 5 at 614–15 (SCC). See e.g. Gemoto v Calgary Regional Health Authority, 2006 ABQB 740 at para 474.

<sup>138</sup> 

<sup>139</sup> See e.g. Kent v MacDonald, 2021 ABCA 196 at para 26.

<sup>140</sup> Ibid. See also Robertson & Picard, supra note 85 at 287.

<sup>141</sup> Robertson & Picard, ibid at 288.

<sup>142</sup> The standard of care is not a gold standard: see e.g. Hillis v Meineri, 2017 ONSC 2845 at para 54 [Hillis].

<sup>143</sup> Wilson, supra note 137 at 119. If the physician applied appropriate clinical judgment, an error of judgment will generally not amount to negligence: see e.g. Leckie v Chaiton, 2021 ONSC 7770 at para 18 144

Ter Neuzen, supra note 137 at para 41.

practice" is assessed at the relevant time and circumstances of the alleged act of negligence.<sup>145</sup> 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.<sup>146</sup>

## B. BREACH OF THE CONTRACTUAL OBLIGATION OF MEANS (CIVIL LAW)

Under Quebec law, physicians have a duty to honour their contractual undertakings to their patients.<sup>147</sup> Where the physician fails in this duty, they are liable for any bodily, moral, or material injury they cause to the patient and are bound to make reparations for the injury.<sup>148</sup> In order to assess the physician's discharge of their contractual undertakings, the nature and intensity of their obligations must be ascertained.<sup>149</sup> 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).<sup>150</sup>

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 for their patients.<sup>151</sup> The obligation of physicians is therefore usually one of means.<sup>152</sup> Accordingly, they must use reasonable and practicable means to attain the desired result.<sup>153</sup> 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.<sup>154</sup> The burden is on the plaintiff to prove, on a balance of probabilities, that the physician breached the contractual obligation of means.<sup>155</sup> The determination of whether the physician breached this obligation is a mixed question of law and fact.<sup>156</sup>

## C. REMOTE PATIENT MONITORING: RELEVANT DUTIES AND ATTENDANT STANDARDS OF CARE

Having introduced the above general concepts, I will now consider how they may be applied to RPM through an examination of some of the legal duties of physicians implicated

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].
 Hilling guarge acts 142 at page 57.

Hillis, supra note 142 at para 57.

<sup>&</sup>lt;sup>147</sup> Art 1458 CCQ.

<sup>&</sup>lt;sup>148</sup> Arts 1458, 1607 CCQ.

 <sup>&</sup>lt;sup>149</sup> 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.
 <sup>150</sup> Jean-Louis Baudouin, Patrice Declouring, & Denoît Magne, La magneticité civile vol 1, 0th ed

Jean-Louis Baudouin, Patrice Deslauriers & Benoît Moore, *La responsabilité civile*, vol 1, 9th ed (Cowansville, QC: Yvon Blais, 2021) at para 21-190.
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<sup>&</sup>lt;sup>151</sup> Indeed, the Quebec *Code of ethics of physicians* affirms that physicians must "must refrain from guaranteeing, explicitly or implicitly, the effectiveness of an examination, investigation or treatment, or the cure of a disease": *Code of ethics of physicians*, CQLR c M-9, r 17, art 83.

<sup>&</sup>lt;sup>153</sup> Philips-Nootens & Kouri, *supra* note 26 at para 55. However, if the physician guarantees a specific result, they may be found liable if the result is not attained (see e.g. *Fiset c St-Hilaire* (1976), EYB 1976-183027 (QCCS)).

See e.g. Lapointe v Hôpital Le Gardeur, [1992] 1 SCR 351 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.

Art 2804 CCQ. The physician's breach of the contractual obligation of means may either be directly proven or established using presumptions of fact (Arts 2846, 2849 CCQ).

<sup>&</sup>lt;sup>156</sup> See e.g. *St-Jean*, *supra* note 154 at para 60.

in the clinical use of RPM: the duties to inform, to treat, and to instruct.<sup>157</sup> For each duty, I will describe their attendant standards of care<sup>158</sup> and consider how courts may address whether physicians have breached these standards when using RPM. Where relevant, I will use examples of RPM technologies from the literature to illustrate how physician liability may be incurred, as well as examples of patient injuries from Part II. Though many other duties will be implicated in the use of RPM, such as the duties to follow up, to attend, and to maintain patient confidentiality, the selected duties illustrate the types of issues that could lead to potential liability claims.

#### 1. THE DUTY TO INFORM

I begin my analysis with the duty to inform for two key reasons. Firstly, the duty to inform (also referred to as the duty of disclosure) is paramount to the physician-patient relationship and the recognition of patient autonomy.<sup>159</sup> 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.<sup>160</sup> This information must include, inter alia, the nature and objectives of the proposed treatment, alternative treatment options, expected benefits, and potential risks.<sup>161</sup> Risk disclosure in particular has been emphasized by scholars as being necessary for patients to make "rational and balanced" medical decisions.162

In therapeutic settings, physicians are not required to inform patients of all possible risks engendered by the proposed treatment.<sup>163</sup> At common law, the physician's duty of disclosure encompasses risks that are considered material, special, or unusual.<sup>164</sup> Material risks are defined as those that 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 the potential injury.<sup>165</sup> Common law courts have generally

<sup>157</sup> Though the duty to maintain confidentiality (professional secrecy) will not be discussed in this article, considerations related to privacy and confidentiality will be treated at length in my discussion of the duty to inform.

<sup>158</sup> I use the term "attendant standard of care" here to encompass the standards by which physician conduct is assessed under both legal traditions.

<sup>159</sup> 160

Philips-Nootens & Kouri, *supra* note 26 at para 181; Robertson & Picard, *supra* note 85 at 155. See e.g. *Vaillancourt c Bishop*, 2016 QCCA 316 at para 13; Robertson & Picard, *ibid* at 162. See e.g. *Hopp v Lepp*, 1980 CanLII 14 (SCC) [Hopp]; Reibl v Hughes, 1980 CanLII 23 [Reibl]; Philips-161 Nootens & Kouri, supra note 26 at para 185. 162

Maximilian Kiener, "Artificial Intelligence in Medicine and the Disclosure of Risks" (2021) 36:3 AI & Society 705 at 706. See also Nadia N Sawicki, "Modernizing Informed Consent: Expanding the Boundaries of Materiality" [2016]:3 U III L Rev 821 at 828.

Baudouin, Deslauriers & Moore, *Responsabilité*, vol 2, *supra* note 152 at para 2-57; Philips-Nootens & Kouri, *supra* note 26 at para 193; Robertson & Picard, *supra* note 85 at 166. 163 164

Hopp, supra note 161 at 210.

<sup>165</sup> See e.g. Dyke v Grey Bruce Regional Health Centre, 2005 CanLII 18841 at para 63, leave to appeal to SCC refused, 31030 (9 August 2005); *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).

taken "liberal and expansive" views in interpreting the scope of physician disclosure of risks.166

Under Quebec law, physicians are required to disclose material risks that a reasonably prudent and diligent physician would have disclosed.<sup>167</sup> To determine specifically which risks are material, courts will consider the statistical probability of the materialization of the risks and the severity of their consequences.<sup>168</sup> 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.169

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."<sup>170</sup> The Collège des médecins du Québec's guidelines on telemedicine also underscore the importance of disclosing the limitations and risks of telemedicine.171

As outlined in Part III, RPM raises several risks of patient injury. 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,<sup>172</sup> RPM technologies present appreciable risks that 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 the occurrence of the risk and the severity of the 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 one in ten patients received an inappropriate diagnosis, and more than one-third of these patients received an inappropriate electrical shock.<sup>173</sup> 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

<sup>166</sup> Robertson & Picard, supra note 85 at 166.

<sup>167</sup> Patrice Deslauriers & Emmanuel Préville-Ratelle, "La responsabilité médicale et hospitalière" in 168

Responsabilité: Collection de droit 2022-2023, École du Barreau du Québec, vol 5 (2022) 165 at 178. Parenteau v Drolet, [1994] RJQ 689 at 706 (CA), rev'g in part [1991] RJQ 2956 (SC), Baudouin JA [Drolet]; Ferland c Ghosn, 2008 QCCA 797 at para 45; Frenette c Clément, 2023 QCCA 109 at para 11; Baudouin, Deslauriers & Moore, Responsabilité, vol 2, supra note 152 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. Philips-Nootens & Kouri, supra note 26 at para 193.

<sup>169</sup> See e.g. Videto v Kennedy (1981), 125 DLR (3d) 127 at 133-34 (ONCA); Deslauriers & Préville-Ratelle, supra note 167 at 170. 170

American Medical Association, supra note 28 at 95. 171

Collège des médecins du Québec, supra note 30.

<sup>172</sup> Though general risks, such as limitations due to absence of physical examinations, are inherent to all RPM technologies.

<sup>173</sup> Supra note 110 at 610. Specifically, 9 percent of patients enrolled in the study received an inappropriate diagnosis, 36 percent of whom suffered at least one inappropriate electrical shock.

mortality.<sup>174</sup> 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 occurrence and severity of injury in this example are sufficiently significant to warrant disclosure.<sup>175</sup>

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."<sup>176</sup> Furthermore, the study found that the majority of app users are "largely unaware" of the security and privacy risks raised by these apps.<sup>177</sup> Though the level of risk will depend on the type of RPM technology used, this study provides us with some indication of the types of risks that 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 of 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,<sup>178</sup> these guidelines are nonetheless indicative of the types of information physicians should disclose.<sup>179</sup> As patients may be largely unaware of the 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 information disclosure, the physician's duty to inform also includes the obligation to ensure that the information is understood by the patient.<sup>180</sup> Physicians are required to take reasonable steps to ensure that patients have understood the provided information.<sup>181</sup> In the context of RPM, the issue of digital literacy is important, as many groups, including some older adults and low socioeconomic groups, have limited proficiency in using digital technologies and a limited understanding of their risks and limitations.<sup>182</sup>

<sup>174</sup> Ibid at 608, 611.

<sup>175</sup> Indeed, as the Supreme Court of Canada indicated in Reibl, supra note 161 at 884-85: "[E]ven 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.3

<sup>176</sup> Gioacchino Tangari et al, "Analyzing Security Issues of Android Mobile Health and Medical Applications" (2021) 28:10 J Am Medical Informatics Assoc 2074 at 2074 (specifically, the study found that 1.8 percent of packaged suspicious codes, 45 percent relied on unencrypted communication, and 23 percent of personal data was sent on unsecured traffic). *Ibid* at 2074, 2082. 177

<sup>178</sup> Robertson & Picard, supra note 85 at 165.

<sup>179</sup> Compare the common law standard of disclosure with the civil law standard, which focuses on the risks that a reasonable physician would disclose: Deslauriers & Préville-Ratelle, supra note 167 at 178. 180

Ciarlariello v Schacter, [1993] 2 SCR 119 at 140; Provost c L'Abbée, 2015 QCCQ 2024 at para 39; Philips-Nootens & Kouri, supra note 26 at para 199.

<sup>181</sup> Philips-Nootens & Kouri, ibid; Robertson & Picard, supra note 85 at 202.

<sup>182</sup> See e.g. Anaya et al, supra note 19 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 & e-Health 1118 at 1118.

Physicians should therefore disclose the limitations and risks of RPM, especially those related to technological issues. They should also disclose this information 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 my 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.<sup>183</sup> It is likely that many patients, especially those for whom digital literacy is low, may not understand the significance of these terms or their privacy implications. In addition to disclosing these risks, courts would likely require that physicians explain these risks and their implications in simple, comprehensible language.

## 2. The DUTY TO TREAT

One of the main objectives of RPM is to improve patient treatment by monitoring their health status on a frequent basis, gathering relevant health data, and making adjustments to the patient's treatment plan where necessary.<sup>184</sup> Whether data is collected actively by the patient or passively by the RPM device, access to data in RPM can help physicians optimize and tailor treatment options for patients.<sup>185</sup> Nevertheless, the use of RPM can raise multiple challenges that 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.<sup>186</sup> Under Quebec law, physicians must use reasonable means at their disposal to treat the patient.<sup>187</sup> They must provide patients with conscientious and attentive care in accordance with accepted standards of medical science ("les règles de l'art").<sup>188</sup> In both legal traditions, the treatment provided must be appropriate for the patient.<sup>189</sup>

Under Quebec law, the duty to treat is often considered to encompass the duty to diagnose,<sup>190</sup> whereas the common law generally treats them as distinct duties.<sup>191</sup> Physicians have a duty to take reasonable steps to detect a patient's signs and symptoms to arrive at a diagnosis.<sup>192</sup> This includes examining the patient, taking their medical history, using

<sup>&</sup>lt;sup>183</sup> Tangari et al, *supra* note 176 at 2074.

<sup>&</sup>lt;sup>184</sup> See e.g. Jeddi & Bohr, *supra* note 5 at 203.

<sup>&</sup>lt;sup>185</sup> Pronovost, Cole & Hughes, *supra* note 7 at 1125; Spinsante & Gambi, *supra* note 7 at 57.

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.
 Division Neuropean 26 at para 202

<sup>&</sup>lt;sup>187</sup> Philips-Nootens & Kouri, *supra* note 26 at para 303.

<sup>&</sup>lt;sup>188</sup> Deslauriers & Préville-Ratelle, *supra* note 167 at 170. See also *Code of Ethics of Physicians, supra* note 151, s 44.

<sup>&</sup>lt;sup>189</sup> See e.g. *Thibert v Zaw-Tun*, 2006 ABQB 423 at para 118 [*Thibert*]; Deslauriers & Préville-Ratelle, *supra* note 167 at 174.

<sup>&</sup>lt;sup>190</sup> 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. Furthermore, Baudouin, Deslauriers, and Moore do not consider the duty to follow-up ("1'obligation de suivi") to be an independent duty, but rather a component of the duty to treat: Baudouin, Deslauriers & Moore, *Responsabilité*, vol 2, *supra* note 152 at paras 2-45, 2-80; Philips-Nootens & Kouri, *supra* note 26 at Title II.

<sup>&</sup>lt;sup>191</sup> Ibid; Robertson & Picard, supra note 85 at 377. For the purposes of this article, the duty to diagnose will be addressed as part of the duty to treat for both legal traditions.

<sup>&</sup>lt;sup>192</sup> Brough, *supra* note 145 at para 126.

appropriate tests, and employing available scientific equipment facilities.<sup>193</sup> Physicians must also collect the best factual data to arrive at their diagnosis and treat their patients.<sup>194</sup>

Patient treatment and diagnosis using RPM are predicated on the collection and analysis of a patient's data. One critical factor in the future clinical utility of RPM will be its promotion of data-driven clinical decision-making.<sup>195</sup> Clinical data are crucial to the management and operation of modern health care systems.<sup>196</sup> 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.<sup>197</sup> Given the data-centric nature of RPM and the necessity of analyzing patients' data to treat them, it is likely that courts will focus on how physicians manage their patients' data when using RPM and whether this management was reasonable in the given circumstances.

For a new and bourgeoning technology like RPM, it is not yet clear what would be considered reasonable in the circumstances. As discussed in Part III, managing a patient's data over time can be quite challenging for physicians. For instance, there may be cases where potential deteriorations in a 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.<sup>198</sup> If physicians do not pay proper attention to these patterns, they may be held liable for any patient injuries that ensue. 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 treatment or the use of clinical judgment.<sup>199</sup> 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. Studies have also shown that, where health care technologies are employed, clinicians will sometimes override their own correct decisions in favour of erroneous advice from these technologies.<sup>200</sup> It is therefore necessary that physicians develop and implement data management plans to ensure that patients' data are consistently monitored to provide them with the best possible treatment.

How physicians achieve this goal is something I anticipate courts will consider in determining whether the physician discharged their duty to treat according to the appropriate standards of practice. One option available to them is to implement measures to manage the

<sup>&</sup>lt;sup>193</sup> Peppler, supra note 186 at 207; Waters v Wong, 2019 ABQB 51 at para 59.

<sup>&</sup>lt;sup>194</sup> Boyd v Edington, 2014 ONSC 1130 at para 11; Wade v Sisters of Saint Joseph of the Diocese of London, [1978] OJ No 413 at para 22 (SC).

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 Intl 202 at 204.
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<sup>&</sup>lt;sup>996</sup> See e.g. Francesco Sanmarchi et al, "Distributed Solutions for a Reliable Data-Driven Transformation of Healthcare Management and Research" (2021) 9:710462 Frontiers in Pub Health 1 at 1.

<sup>&</sup>lt;sup>197</sup> Walker et al, *supra* note 195 at 204.

<sup>&</sup>lt;sup>198</sup> Atreja et al, *supra* note 36 at 8.

<sup>&</sup>lt;sup>199</sup> See e.g. Matthew Grissinger, "Understanding Human Over-Reliance on Technology" (2019) 44:6 Pharmacy & Therapeutics 320 at 320.

<sup>&</sup>lt;sup>200</sup> *Ibid*.

patient's data, monitor trends in the evolution of the patient's health, and address issues that 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.<sup>201</sup> 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.<sup>202</sup> This shared care approach, which is becoming increasingly common in health care,<sup>203</sup> allows for the allocation of roles and tasks among multiple providers.<sup>204</sup> Physicians are, by law, entitled to delegate certain tasks to other health care providers and even to entrust the care of their patients to others when they are absent or unavailable to treat them.<sup>205</sup> A significant portion of the monitoring responsibilities can therefore be delegated to other personnel.<sup>206</sup>

Delegating monitoring tasks to nurses and technicians can help to decrease overreliance on RPM by ensuring consistent human oversight of duties that 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.

Courts do not hold physicians to unreasonable standards. It is not possible for, nor do I expect courts to require, physicians to consistently monitor patient data flows and respond to all potential alerts themselves. In determining the applicable standard of care for treatment involving RPM, courts are therefore likely to evaluate the steps that are taken to ensure that the patient's data are addressed in a timely and accurate manner to ensure they receive their required level of treatment.<sup>207</sup> For instance, they may evaluate whether the personnel to whom monitoring tasks were delegated were adequately trained and competent to perform the delegated tasks. Courts could also look at the level of communication between the physician and the delegated personnel. They may consider whether there were clear lines of communication for reporting and responding to any issues that require medical attention. Courts may also evaluate the level of supervision provided by the physician over the delegated tasks.

Indeed, while physicians are entitled to rely on other personnel in the performance of their delegated tasks, they remain responsible for the ultimate care and treatment of their patients.<sup>208</sup> The objective of delegating tasks in RPM is to reduce physician workload and improve clinical efficiency.<sup>209</sup> Issues that require medical attention, such as deteriorations in

<sup>201</sup> Emma E Thomas et al, "Factors Influencing the Effectiveness of Remote Patient Monitoring Interventions: A 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). 202

See e.g. Bouabida et al, supra note 15 at 2. 203

Robertson & Picard, *supra* note 85 at 441. 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. 204

<sup>205</sup> See e.g. White v Turner, 1981 CanLII 2874 at 105 (ONSC), aff'd (1982) 47 OR (2d) 764 (CA).

<sup>206</sup> Davis et al, supra note 20 at 431.

<sup>207</sup> See e.g. Braun Estate v Vaughan, 2000 CanLII 17227 at para 33 (MBCA) (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. While the case concerned follow-up upon reception of laboratory testing results, it is likely to be relevant to the management of patients' data in RPM).

<sup>208</sup> See e.g. Bouabida et al, supra note 15 at 2.

<sup>209</sup> Davis et al, supra note 20 at 430.

the patient's health, must be communicated to the physician, who will take the appropriate course 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. THE DUTY TO INSTRUCT

The duty to instruct patients is likely to become more important in the age of telehealth. In RPM, patients play an important role in self-management, which is greater when they actively report their own data. This shift in the locus of responsibility to patients in selfmanagement 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 use their prescribed RPM system efficiently and effectively.

Active patient engagement and compliance are important factors for achieving high user retention and, consequently, improved adherence and clinical outcomes.<sup>210</sup> Studies have shown that the degree of patient compliance with their prescribed RPM system correlates with the degree of derived clinical benefit.<sup>211</sup> One major issue is that patients may lack motivation to continually adhere to RPM protocols.<sup>212</sup> 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.<sup>213</sup>

Patient engagement and adherence are especially important for RPM, as it is essential that patients act in such a manner as to aid their physician in properly treating them.<sup>214</sup> It also has important legal implications. Patients are required to collaborate with their physician, including providing information to the physician and following the given instructions.<sup>215</sup> As for physicians, they have a duty to instruct their patients, which requires them to provide patients with sufficient information to enable them to carry out the provided instructions.<sup>216</sup> The duty to instruct the patient (and the patient's corollary duty to collaborate with their physician) is likely to become more important with the rise of telehealth, as the locus of responsibility is likely to shift to the patient regarding adherence and compliance with the

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] SIEDS 136 at 138).

<sup>&</sup>lt;sup>211</sup> See e.g. Dejun 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.

<sup>&</sup>lt;sup>212</sup> Jeddi & Bohr, *supra* note 5 at 208.

<sup>&</sup>lt;sup>213</sup> See e.g. Leila S Rezai, Gerard Torenvliet & Catherine M Burns, "Increasing Patient Adherence to Home Health-Monitoring Systems" (2014) 3:1 Proceedings Intl Symposium on Human Factors & Ergonomics in Health Care 8 at 8.

<sup>&</sup>lt;sup>214</sup> Philips-Nootens & Kouri, *supra* note 26 at para 30.

 <sup>&</sup>lt;sup>215</sup> See e.g. Crossman v Stewart (1977), 82 DLR (3d) 677 (BCSC); Leadbetter v Brand (1980), 37 NSR (2d) 581, (SC); Bergeron c Faubert, [1996] RRA 820 (CS), aff'd [2000] JQ No 6184 (CA); Lamarre c Hôpital du Sacré-Coeur, [1996] RRA 496 (CS); Therrien c Launay, 2005 CanLII 5311 (QCCS).

<sup>&</sup>lt;sup>216</sup> Robertson & Picard, *supra* note 85 at 348.

physician's instructions. In the RPM context, the duty to instruct will be especially important for active collection technologies, which require patients to input their data themselves.

Courts have described the duty to instruct as a corollary of the duty to treat.<sup>217</sup> Physicians have the duty to provide sufficient instructions and adequate direction to ensure that any tasks delegated to their patients are properly discharged.<sup>218</sup> 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 ensuring that they have properly understood the provided information.<sup>219</sup> 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.220

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.<sup>221</sup> Indeed, physicians have been found negligent for failing to adequately educate patients about potential danger signs during the post-operative period.<sup>222</sup> Authors Robertson and Picard speculate that the delegation of responsibility toward patients will become an increasingly important issue as the provision of home care services increases.<sup>223</sup> 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 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 on 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.

In Part II, we saw that improper usage of RPM devices by patients may lead to injury. This underscores the importance of the duty to instruct in the RPM context. In the event of patient injury, I hypothesize that courts will examine the scope, level of detail, and comprehensibility of instructions provided to patients to determine whether they are 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.<sup>224</sup>

<sup>217</sup> See e.g. Anderson v Harari, 2019 ABQB 745 at para 194; See Peppler, supra note 186 at para 267. 218

See e.g. Rollin v Baker, 2010 ONCA 569 at paras 75-76. 219

Peppler, supra note 186 at para 270; Thibert, supra note 189 at para 122.

<sup>220</sup> Wei Estate v Dales (1998), 37 OR (3d) 54 at para 109 (CJ); Topliceanu c Bojanowski, 2018 QCCS 658 at paras 152, 161.

<sup>221</sup> Paterson c Rubinovich, 1999 CanLII 13540 (QCCA); Philips-Nootens & Kouri, supra note 26 at para 373; Robertson & Picard, *supra* note 85 at 445. See e.g. *Moore v Getahun*, 2014 ONSC 237 at paras 400–17.

<sup>223</sup> 

Robertson & Picard, supra note 85 at 445.

<sup>224</sup> See e.g. Vivian Hsiao 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 J 445 at 446.

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,<sup>225</sup> 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 that patients 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.

In sum, we see that RPM presents new challenges for physicians, which may challenge the scope and content of their legal duties. The issues of digital literacy, clinical overreliance on technology, and increased delegation of responsibility to patients are likely to present challenges to physicians in the discharge of their legal duties. Breaches of these duties may, in turn, cause patient injury, for which physicians may be held liable. While we do not have any precedent on RPM, we can see, using analogy with existing legal principles, the types of factors courts may consider in eventual liability claims. Based on these factors, in the next section, I will consider the adoption of professional guidelines for RPM to mitigate the risks of patient injury and concomitant physician liability.

## V. THE ROLE OF PROFESSIONAL GUIDELINES IN CLARIFYING LIABILITY ISSUES IN REMOTE PATIENT MONITORING

Medical liability claims involving RPM have yet to be litigated in Canada, making them a case of first impression. Courts will therefore need to define the appropriate standard of medical practice to determine whether physicians have breached their legal duties in their use of RPM. In the preceding section, I postulated the types of factors courts may consider in determining whether physicians have breached the standard of care (common law) or the contractual obligation of means (civil law) in medical liability claims involving RPM, based on analogy with existing principles. One resource to which courts may turn when adjudicating medical liability claims involving RPM is professional guidelines.

Professional guidelines comprise "soft law" instruments that contain statements or recommendations to guide the conduct and decision-making of clinicians.<sup>226</sup> They serve as "practical tools" to guide clinicians in the delivery of health care services.<sup>227</sup> Professional guidelines are generally formulated through rigorous and systematic reviews of scientific evidence as well as the input of expert opinions.<sup>228</sup> Guidelines reflect the state of current medical knowledge and must be periodically reviewed and updated as new scientific evidence becomes available.<sup>229</sup> In the medical context, professional guidelines are developed by groups of experts, including professional associations, such as the Canadian Medical Association, and professional colleges, such as the College of Physicians and Surgeons of Ontario or the Collège des médecins du Québec.

<sup>225</sup> See e.g. *McClintock v Alidina*, 2011 ONSC 137 at para 92. Campbell & Glass, *supra* note 29 at 480–81.

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<sup>227</sup> Ediger (Guardian ad litem of) v Johnston, 2009 BCSC 386 at 59, rev'd on other grounds 2013 SCC 18. 228 Tae Won Yi, Sine Donnellan & Adeera Levin, "Evidence-Based Decision Making 4: Clinical Practice Guidelines" in Patrick S Parfrey & Brendan J Barrett, eds, Clinical Epidemiology: Practice and Methods, 3rd ed (New York: Humana Press, 2021) 455 at 456.

<sup>229</sup> Ibid.

In both the common law and civil law traditions, 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.<sup>230</sup> Expert evidence includes not only expert witnesses' opinions but also reliance on professional standards or clinical guidelines, which can be indicative of the standard of care required of physicians.<sup>231</sup> Aside from guidelines on the use of mobile health technologies, guidelines specifically applicable to other RPM technologies described in my typology have yet to be adopted by professional associations or colleges in Canada,<sup>232</sup> though guidelines exist in the United States.<sup>233</sup>

As a first step toward clarifying the liability-related issues surrounding RPM in Canada, professional guidelines regarding RPM should be adopted by relevant professional associations and bodies. These guidelines can help provide courts with a barometer with which they can assess the conduct of physicians who use RPM, should litigation in this area ever arise. Furthermore, these guidelines can help guide physicians in their usage of RPM and assist them in navigating this novel way of delivering health care. This, in turn, can help mitigate the potential for patient injuries, ensuring safer and better care for patients. Providing physicians with standards and recommended courses of action can also help to alleviate some of their liability-related concerns, thus reducing their reticence to adopt RPM where it could be clinically useful. As a result, patients for whom RPM may be advantageous can benefit from its usage.

Based on my analysis of the risks of patient injury and physician liability in this article, I propose, as a starting point, certain factors that should be included in professional guidelines on RPM. My discussion of the physician's duty to inform in the context of RPM highlighted 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 as their implications for their care and treatment. Disclosure of this information will be critical, as will ensuring patient comprehension of this information, especially when considering the digital literacy levels of many population groups. Professional guidelines should underscore the importance of risk disclosure in RPM, the importance of explaining information in a comprehensible manner, and ensuring patients have adequately understood these risks and limitations. Guidelines should enumerate the types of risks raised by RPM based on the best available published research and practice experience, providing physicians with an indication of the types of risks they should disclose to patients.

<sup>&</sup>lt;sup>230</sup> See e.g. Hasan v Trillium Health Centre Mississauga, 2022 ONSC 3988 at para 67; Deslauriers & Préville-Ratelle, supra note 167 at 184.

 $<sup>^{231}</sup>$  Campbell & Glass, *supra* note 29 at 480.

<sup>&</sup>lt;sup>232</sup> Some professional associations and professional colleges have adopted guidelines on telehealth and the use of mobile health applications: see e.g. Canadian Medical Association, *supra* note 30; Collège des médecins du Québec, *supra* note 30. Content from these guidelines may be applicable to all forms of RPM, regardless of the type of technology used. For instance, the Collège des médecins du Québec's guidelines on telemedicine emphasize the importance of disclosing to patients the particular risks associated with the collection and transmission of their data via the use of telecommunication and information technologies.

<sup>&</sup>lt;sup>233</sup> American Medical Association, *supra* note 28.

In my analysis of the duty to treat, I addressed the issue of clinical overreliance on technologies, which can constitute a breach of the duty to treat.<sup>234</sup> In the context of health care technologies, physicians should be cognizant that these technologies do not replace human activity or judgment.<sup>235</sup> I previously highlighted the caution with which physicians should use RPM so that they do not overly rely on these technologies or consider them as replacements for the use of professional clinical judgment.<sup>236</sup> Technologies are not infallible, and the consequences of a technical malfunction can be prejudicial to the patient whose care is entrusted with the device.<sup>237</sup> Professional guidelines should emphasize that health care professionals must continue to apply their clinical judgment and critical thinking skills while using RPM. They should also be encouraged to implement "appropriate monitoring and verification strategies" to offset the effects of overreliance and complacency.<sup>238</sup>

Furthermore, professional guidelines should encompass the delegation of tasks to other personnel. They should emphasize the importance of developing an effective and efficient delegation plan. This plan should include proper training of personnel to ensure they are competent and proficient in the use of the RPM system. Guidelines should emphasize the importance of division of labour to ensure that patients' data are consistently monitored so that potential alerts or degradation patterns are promptly detected. They should also encapsulate the need for clear and open channels of communication between physicians and personnel, as well as frequent physician supervision and oversight. Furthermore, guidelines should provide recommended plans of action for personnel in cases where a patient may require prompt medical attention while their treating physician is unavailable to attend to them. These could include, for instance, emergency protocols and procedures or having a network of secondary physicians available to intervene when the treating physician is unavailable. This could include colleagues within the same practice or specialty or on-call physicians who are familiar with the patient's medical file. In short, systems should be implemented to ensure consistent data monitoring and continuity in the patient's treatment and care.239

My analysis of the duty to instruct highlighted the importance of providing patients with adequate instructions to carry out the tasks delegated to them. Professional guidelines should emphasize the importance of providing accurate, detailed, and clear instructions, especially considering the issue of digital literacy previously discussed in this article.<sup>240</sup> In general, it is considered reasonable for patients to rely on the professional opinion of their physicians.<sup>241</sup> If the physician's instructions were found to be incomplete or inadequate, or if the physician did not take reasonable steps to ensure the patient completely understood the provided instructions or information, it is likely that the physician would be found to have breached their duty to instruct.

<sup>&</sup>lt;sup>234</sup> See e.g. Grissinger, *supra* note 199 at 320.

<sup>&</sup>lt;sup>235</sup> *Ibid.* 

Terry & Wiley, supra note 117.

<sup>&</sup>lt;sup>237</sup> Gerke et al, *supra* note 104 at 1181.

<sup>&</sup>lt;sup>238</sup> Grissinger, *supra* note 199 at 321.

 <sup>&</sup>lt;sup>239</sup> The importance of continuity of patient treatment and care is affirmed, for example, in Quebec's *Act respecting health services and social services*, CQLR c S-4.2 ("[e]very person is entitled to receive, *with continuity* and in a personalized and safe manner, health services and social services which are scientifically, humanly and socially appropriate," s 5 [emphasis added]).

Part IV, above.

<sup>&</sup>lt;sup>241</sup> Robertson & Picard, *supra* note 85 at 474.

Overall, my proposed points represent only some of the factors that should be included in professional guidelines on RPM. Many other factors will need to be considered. RPM is a fast-evolving field, and many more issues are likely to be raised in the future that cannot be currently anticipated or addressed. It is important to note, however, that the legal standard of prudent and diligent physician conduct may not necessarily correspond to standards put forth by professional guidelines. 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.242

Generally, conformity with standard professional practices will exonerate physicians of liability.<sup>243</sup> Indeed, a physician's conformity with relevant professional guidelines constitutes "compelling evidence that their conduct did not fall below the standard of care."<sup>244</sup> Conversely, failure to act in accordance with relevant guidelines can be compelling evidence that the physician breached the standard of care.<sup>245</sup> Nonetheless, the adoption of appropriate standards and guidelines will play an important role in determining standards of reasonable conduct related to the clinical use of RPM.

These standards will not only assist courts in dealing with medical liability claims involving RPM, but they can also help guide physicians in their usage of RPM through establishing standards of practice and recommended courses of action. As professional guidelines are developed based on current scientific evidence as well as the input of relevant experts, they establish evidence-based standards.<sup>246</sup> By promoting evidence-based practice, professional guidelines can help ensure that clinicians adopt methods and treatments that have been proven effective, mitigating the risks of patient injury.<sup>247</sup>

#### VI. 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 remote health care, is one such 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

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<sup>242</sup> 2010 BCSC 938 at para 162.

<sup>243</sup> Ter Neuzen, supra note 137 at para 41. Nonetheless, as previously mentioned, there may be very exceptional cases where standard practice itself may be considered to be negligent and conformity thereto will not exculpate the physician of liability. *Medina v Wong*, 2018 BCSC 292 at para 108. 244

Ibid. 246

Yi, Donnellan & Levin, supra note 228 at 456.

See e.g. Walter Ricciardi & Fidelia Cascini, "Guidelines and Safety Practices for Improving Patient 247 Safety" in Liam Donaldson et al, eds, Textbook of Patient Safety and Clinical Risk Management (Cham, Switzerland: Springer, 2021) 3 at 7.

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 to expand in the future.

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.<sup>248</sup> Indeed, the lack of clarity surrounding medical liability for the use of novel technologies can often have a chilling effect on physicians. The absence of case law on medical liability involving RPM in Canada, along with the paucity of relevant professional guidelines and clinical standards, further compounds uncertainties over medico-legal liability risks in RPM.

In this article, I attempted to clarify some of the medical liability issues surrounding RPM. First, I identified some types of patient injuries that could arise from RPM. I then postulated the types of factors courts might consider in determining whether physicians have breached the appropriate standards of medical practice when using RPM. As examples, I discussed the duties to inform, to treat, and to instruct. Many other duties will, of course, be implicated in RPM, such as the duties to follow-up, to attend, and to maintain the confidentiality of patients' information. Finally, I considered how the adoption of professional guidelines could help clarify some of the liability issues I raised. These guidelines can be used by courts to determine whether physicians have breached the standard of care or the contractual obligation of means. Additionally, by establishing evidence-based standards of practice, they can help promote better patient care and mitigate the risks of injury.

Though this analysis is a first step toward clarifying medical liability issues in RPM, additional research is necessary to continue to elucidate many of the liability concerns surrounding RPM. While I raised the issues of risk disclosure, clinical overreliance on technologies, and providing patients with instructions in this article, there are many other facets of RPM that are likely to raise liability issues. Furthermore, while I focused on the risks of patient injury and breaches of the standard of care or of the contractual obligation of means, these conditions are not sufficient to make a finding of liability. It must also be proven, on a balance of probabilities, that the physician's breach *caused* the patient's injury. Though I did not address issues of causation in this article, future scholarship should consider the challenges the use of RPM raises in the determination of causation and in the apportionment of liability.

For instance, with RPM, there will likely 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. The RPM set-ups used by the CHUM's CareSimple-Covid system<sup>249</sup> and the

See e.g. Davis et al, *supra* note 20 at 436; Ritu Thamman & Rajesh Janardhanan, "Cardiac Rehabilitation Using Telemedicine: The need for Tele Cardiac Rehabilitation" (2020) 21:4 Reviews in Cardiovascular Medicine 497 at 499.

<sup>&</sup>lt;sup>249</sup> Bouabida et al, *supra* note 15 at 2.

NewYork-Presbyterian Hospital's COVID-19 Hypoxia Monitoring program<sup>250</sup> illustrate how multiple health care providers may be involved in the patient's care, including physicians, nurses, physician assistants, and medical and nursing students. Breaches of duties of actors other than the physician may combine with those of the physician in causing a patient's injury. In a hospital setting, the hospital can be held vicariously liable for the negligent or faulty acts of the nurse that caused the patient's injury.

Furthermore, because RPM entails the use of a technological device, 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. Moreover, as patients take on greater responsibility to follow physicians' instructions, their own acts or omissions could be considered contributory factors to their injuries if they fail to act prudently. RPM is therefore likely to create challenges for courts in determining causation and apportioning liability. Future scholarship will be necessary in this area.

Additionally, empirical research should be conducted on the perspectives of patients who have used RPM. While much has been written about clinician concerns over the adoption of RPM, there is a paucity of scholarship on patients' views and perspectives on RPM. With growing calls for patient-centred care,<sup>251</sup> empirical research on patients' experiences and viewpoints can provide clinicians and health care institutions with valuable evidence on how to use RPM in better ways for patients. This research should also help inform the development of professional guidelines on RPM. Since RPM is still in its early stages, there is a valuable opportunity to involve patients in its development and clinical implementation from the outset. 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 discussed in Part II, much research has been done on the risks of patient injury in RPM. However, as RPM continues to grow and expand in clinical care, more research on the risks of patient injury should be conducted. This research will be critical to better informing clinicians on how to mitigate these risks, thereby ensuring safer and more efficient patient care. As RPM technologies evolve, new types of patient injuries may arise that were previously unforeseeable. Given that health technologies are among the fastest-evolving,<sup>252</sup> up-to-date research on these risks will help ensure clinicians develop appropriate mitigatory strategies.

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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 Medical Quality 139 at 141. See e.g. Gemmae M Fix et al, "Patient Centred Care is a Way of Doing Things: How Healthcare Employees Conceptualize Patient Centred Care" (2018) 21:1 Health Expectations 300; Terrence 251 Montague et al, "Canada's Evolving Medicare: Patient-Centred Care" (2019) 22:2 Healthcare Q 27.

<sup>252</sup> Indeed, although RPM is still very much in its infancy, there have already been plans for the integration of AI into RPM systems. See e.g. Jeddi & Bohr, supra note 5.

In their essay on the clinical adoption of electronic health (or e-health) technologies, authors Anton 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."<sup>253</sup> Though further research will be needed to create these necessary conditions, clarification of medical liability issues is an important first step in fostering trust in RPM.

<sup>&</sup>lt;sup>253</sup> Anton Vedder et al, "The Law as a 'Catalyst and Facilitator' for Trust in E-Health: Challenges and Opportunities" (2014) 6:2 L Innovation & Tech 305 at 307–308.