



The app will see you now: mobile health, diagnosis, and the practice of medicine in Quebec and Ontario

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ABSTRACT

Mobile health applications are increasingly being used as tools of medicine. Outside of the clinic, some of these applications may contribute to diagnoses made absent a physician's care. We argue that this contravenes reservations of diagnosis to healthcare professionals in the law of two Canadian provinces: Quebec and Ontario. On the one hand, the law conceives of diagnosis in relatively broad terms. Drawing an association between symptoms and illness, for example, has been recognized in case law as sufficient. On the other hand, provincial law reserves diagnosis to physicians and other healthcare professionals.

We argue that a number of health applications are capable of drawing associations between symptoms and disease and, in doing so, of delivering diagnoses in contravention of the law of Quebec and Ontario. This places mobile health applications in a poorly understood legal space. While prosecution is unlikely, the increasing ubiquity and technological sophistication of health applications promises to make such diagnosis widespread. We suggest that the legal status of such mobile health apps should be given serious attention. While our analysis focuses on the state of the law in Canada's largest provinces, we suggest that our argument will have implications in other jurisdictions.

KEYWORDS: Diagnosis, mHealth, Penal Liability, Practice of Medicine

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INTRODUCTION

Mobile health apps are becoming both more popular and technologically sophisticated. As they do, interest in their use as tools for healthcare is correlatively growing. There are currently over 165,000 smartphone apps with health monitoring or data storage functions available on Apple iOS and Google Android systems.¹ The majority of these record and trend diet, fitness, and stress-related information.² These applications, and the smartphone hardware they utilize, are becoming more sophisticated, the metrics they record are becoming more accurate, and their use is becoming ever more widespread. It is predicted by some that such technologies will increasingly ‘do more of the heavy lifting in medicine’.³ To be sure, computerized medicine has played an important role in clinical practice for several decades.⁴ The increasing reliance of physicians on computer technology in recent years has raised concerns, for example, about reliability, the cost of healthcare, and the deterioration of the physician–patient relationship.⁵ It is expected that physicians and other healthcare professionals will increasingly rely on technology in their practice. These trends, in turn, will raise a number of legal and ethical questions. Our focus here, however, will be on a different, though related trend. Mobile health applications have put tools of medicine in the hands of patients and consumers. This is a relatively new phenomenon, one which, we suggest, has not yet been adequately studied.

We argue that one consequence of this trend is that a number of popular consumer health applications have functions that enable the diagnosis of disease according to Canadian law. By drawing associations between symptoms and illness, these applications contribute to a process of medical diagnosis according to legal frameworks in Canada’s two largest provinces: Ontario and Quebec.⁶ This may be a problem, for both jurisdictions reserve exclusive competence to diagnose disease and disorders to healthcare professionals.⁷ Diagnosis in the absence of a legal right to do so is a penal offense, potentially making developers susceptible to fines and imprisonment.⁸ Application developers will thus find themselves in a poorly defined legal space, one in which the potentially diagnosis-enabling functions of their products may, on a technical reading of the law, be prohibited.

Our aim is not impugn the use or development of health applications (apps), many of which have empirically demonstrated benefits.⁹ Instead, our goal is to show how

¹ The Economist, *Things are Looking App: Mobile Health Apps are Becoming More Capable and Potentially Rather Useful* (2016) [Economist].

² *Id.*

³ *Id.*

⁴ See eg Ranolph A. Miller et al., *Internist-I, an Experimental Computer-Based Diagnostic Consultant for General Internal Medicine*, 307 *NEW ENG. J. MED.* 468 (1982); Gary L. Horowitz & Howard L. Bleich, *PaperChase: A Computer Program to Search the Medical Literature*, 305 *NEW ENG. J. MED.* 924 (1981).

⁵ See generally, ROBERT WACHTER, *THE DIGITAL DOCTOR: HOPE, HYPE, AND HARM AT THE DAWN OF MEDICINE’S COMPUTER AGE* (2015).

⁶ See Regulated Health Professions Act, R.S.O. 1991, c 18, s 27(1)–27(2)1 [RHPA]; Grenier v. Collège des médecins du Québec, 2006 Q.C.C.S. 622, at para. 23 [Grenier]; Professional Code, C.Q.L.R. 1973 c C–26, art. 26 [Professional Code].

⁷ RHPA, *supra* note 6, at s 27(1); Medical Act, C.Q.L.R. 2016, c M–9, art. 31 [Medical Act].

⁸ RHPA, *supra* note 6, at s 40(1)–40(3); Professional Code, *supra* note 6, at art. 188.

⁹ See eg Alessandra Sarcona et al., *Differences in Eating Behaviour, Physical Activity, and Health-related Lifestyle Choices between Users and Nonusers of Mobile Health Apps*, 48 *AM. J. HEALTH EDUC.* 298 (2017)

these apps exist in a poorly understood legal space, one which might challenge our understanding of the law of professional obligations of healthcare providers and complicate the widespread adoption of these technologies.¹⁰ To be sure, this argument does not directly imply that legislation or oversight is necessary; on balance, it may be that the benefits of mobile health apps outweigh their dangers. Nevertheless, it may be that the argument we present here will complicate the relationship of healthcare professions to these broadly available consumer technologies. At the very least, mobile health apps promise to change the way many of us interact with and monitor our health.¹¹ Indeed, recently developed artificially intelligent apps have led some media commentators to suggest that health apps will soon be a substitute for visiting a doctor.¹² Beyond that, it is likely that the diagnostic and other healthcare functions of these applications will become ever more routine and precise. In general, smartphones will almost certainly continue to play an increasingly central role in healthcare,¹³ thereby situating them within a broader trend toward medical automation.¹⁴ Health apps could also be used for conducting clinical trials, with smartphones used to ‘measure disease progression’, thereby contributing, for example, to determinations about drug efficacy and treatment success.¹⁵

In addition, the legal implications of the increased adoption of mobile health apps are worth considering in light of the growing ubiquity and functionality of smartphones and health (apps).¹⁶ The health app industry, for example, is rapidly growing. By some estimates, the global mobile health market will be valued in excess of \$100 billion USD within 5 years.¹⁷ If this occurs, then we can expect that the legal status of these technologies will take on a certain degree of economic importance. For these reasons, it is incumbent upon us now to understand the legal and policy landscape in which such technology will operate. Adding to these concerns, mobile health apps are currently

(presenting evidence that the use of mobile health apps may have a positive effect on eating behaviors); J. Chen, *The Use of Smartphone Health Apps and Other Mobile Health (mHealth) Technologies in Dietetic Practice: A Three Country Study*, 30 J. HUM. NUTR. DIET. 439 (2017) (pointing to the benefits of using mHealth in dietetic practice); Jonathan S. Abelson, *Barriers and Benefits to Using Mobile Health Technology After Operation: A Qualitative Study*, 162 SURGERY 605 (2017) (examining the benefits associated with using mobile health apps in postoperative care).

¹⁰ For a thorough overview of liability issues associated with mobile health apps, see Nicolas Terry & Lindsay F. Wiley, *Liability for Mobile Health and Wearable Technologies*, 25 ANN. HEALTH L. 62 (2016).

¹¹ See eg Donna S. Eng & Joyce M. Lee, *The Promise and Peril of Mobile Health Applications for Diabetes and Endocrinology*, 14 PEDIATR. DIABETES 231 (2013); Jennifer K. Carroll et al., *Who Uses Mobile Phone Health Apps and Does it Matter? A Secondary Data Analytics Approach* 19 J. MED. INTERNET RES. 125 (2017).

¹² See eg Douglas Heaven, *An App a Day Keeps the Doctor Away*, NEW SCIENTIST (2017), <https://www.newscientist.com/article/2141247-an-app-a-day-keeps-the-doctor-away/> (accessed Sept. 15, 2017).

¹³ See eg Greg A. J. Robertson et al., *Smartphone Apps for Spinal Surgery: Is Technology Good or Evil?* 25 EUR. SPINE J. 1355 (2016).

¹⁴ See eg David R. Reuben et al., *An Automated Approach to Identifying Patients With Dementia Using Electronic Medical Records*, 65 J. AM. GERIATR. SOC. 658 (2017); Ying Wing, *Application of Novel Automated Anesthesia Cart to Improve Medication Management in a Large Tertiary Hospital*, 10 INT. J. CLIN. EXP. MED. 1522 (2016); Ken Monahan et al., *Automated Detection of Atrial Fibrillation From the Electrocardiogram Channel of Polysomnograms*, 20 SLEEP BREATH. 515 (2016).

¹⁵ Economist, *supra* note 1.

¹⁶ See eg Ray E. Dorsey et al., *The Use of Smartphones for Health Research*, 92 ACAD. MED. 157 (2017).

¹⁷ Zion Market Research, News Release, *Global mHealth Market Will Reach USD 102.43 Billion by 2022* (Dec. 20, 2016), <https://globenewswire.com/news-release/2016/12/20/899026/0/en/Global-mHealth-Market-will-reach-USD-102-43-Billion-by-2022-Zion-Market-Research.html> (accessed May 30, 2017).

unregulated in Canada. This contributes to the sense that mobile health apps exist in a poorly understood legal space: one in which app developers could conceptually become subject to penal prosecution.

We hope to contribute to understanding some of the legal and policy implications of the use of mobile health technologies in this paper. Our claim that consumer health apps may have diagnostic functions turns on a comparative analysis of the provinces of Quebec and Ontario. As we will show, the legal conception of diagnosis and medical practice more generally differs markedly in these jurisdictions. At the same time, our argument that health apps may be subject to penal liability applies with equal strength in both provinces. Our decision to focus on Quebec and Ontario allows us to compare a civilian jurisdiction (Quebec) with one of common law heritage (Ontario). Despite foundational philosophical differences between these traditions, on the regulation of the practice of medicine, their approaches end up aligning more than might be expected. This comparative analysis, we hope, will help frame similar analyses in other jurisdictions and provide a general overview of the legal frameworks that may be applied in a range of settings. The diagnostic functions we identify, after all, will persist irrespective of the jurisdiction in which the applications in question are used. Beyond that, given that the regulatory landscape in Canada and the USA with respect to mobile health apps is largely consistent, many of the policy implications will, likewise, be quite similar.

Our argument will be presented in four parts. First, we will compare the law surrounding diagnosis in Quebec and Ontario and examine their respective approaches to penal liability for diagnoses that are not performed by medical professionals. Second, we will outline the various functions of mobile health apps we see as potentially delivering diagnoses. In the third section of the paper, we will contemplate applying the diagnostic regime to mobile health devices and consider the extent to which app and device developers may be subject to penal liability for violations of Quebec's *Professional Code* and Ontario's *Regulated Health Professions Act*. Finally, we will introduce several qualifications and respond to several objections against our view. Importantly, this paper does not suggest that application developers *will* or *should* be subject to penal liability for performing diagnoses in the law of either Quebec or Ontario. In our final section, we will outline some of the normative considerations that should weigh against or in favor of increased regulatory or professional oversight.

DIAGNOSIS IN QUEBEC AND ONTARIO

In this section, we will describe the penal liability regimes for the illegal practice of medicine that exist in Quebec and Ontario by outlining the definition of diagnosis expressed in statute and jurisprudence. Our approach will be to highlight the ways in which the law of these distinct jurisdictions conceives of the issues, drawing particular attention to the similarities in their approaches. Preliminarily, it is worth briefly touching on the divisions of power relevant in the regulation of healthcare in Canada. The power to enact legislation regulating the provision of healthcare is shared by the federal and provincial governments.¹⁸ The *Constitution Act 1867* provides the federal

¹⁸ *Schneider v. The Queen* [1982] 2 S.C.R. 112 at 142, 139 D.L.R. (3d) 417.

government with broad taxation and spending power.¹⁹ This is the foundation of the federal Parliament's power to fund Canada's Medicare system under the *Canada Health Act*.²⁰ Under the federal government's criminal law power, Parliament is empowered to protect public health through the regulation of drugs, food, and medical devices.²¹ The criminal law power, along with the federal Parliament's jurisdiction over emerging issues not otherwise contemplated in the 1867 Constitution,²² grounds the federal government's power to regulate health applications. The provinces, contrastingly, are responsible for the bulk of the administration of the healthcare system, including regulation of the healthcare professions.²³ Our discussion below will touch primarily on the provincial power to oversee the practice of medicine, though we will, of course, also outline the federal government's regulatory authority over smartphone apps.

Both of the provincial jurisdictions we will contemplate here demand that we assess both statutes and case law. In fact, in contrast with the reputation of civilian jurisdictions as intrinsically dependent on enacted codes, much of Quebec's approach to medical diagnosis is found in a vibrant case law. Ontario's approach, similarly shirking expectations, is largely contained in the relevant statute, with a somewhat lessened reliance on judicial consideration of the issue. As we will show, the primary difference in approaches to diagnosis between Quebec and Ontario is that, while Quebec law prohibits anyone who is not a member of designated health professions from diagnosing illness, Ontario prohibits the *communication* of diagnoses from anyone not a member of a set of regulated professions. We will claim that this difference, on a strict understanding of the law, ends up producing relatively identical effects. The section to come will consider two general questions. First, we will outline the legal capacity to diagnose in the two jurisdictions in question. Second, we will consider the substantive character of diagnosis, that is, how each of the provinces defines the relevant practice.

Permissions to Diagnose

In Quebec, the practice of medicine is primarily regulated by the *Medical Act*. Article 31 of that statute purports to reserve the diagnosis of disease to physicians.²⁴ This rule, however, is not absolute. The professional capacity to diagnose, to a relatively limited extent, is shared with other professions, most notably, nursing and dentistry. For example, article 26 of the *Dental Act* permits dentists to diagnose deficiencies of the teeth, mouth, maxillae, and adjacent tissue.²⁵ The *Nurses Act*, similarly, permits members of that profession to prescribe diagnostic examinations and utilize invasive

¹⁹ Constitution Act, 1867 (UK), 30 & 31 Vict, c 3, reprinted in R.S.C. 1985, App. II, No. 5 at ss 91(1A) & 91(3) (Constitution Act, 1867).

²⁰ See Library of Parliament, *The Federal Role in Health and Health Care*, Doc. No. 2008-58-E at 2 (2008), <https://lop.parl.ca/content/lop/researchpublications/prb0858-e.pdf> (accessed July 14, 2017) [Library of Parliament].

²¹ Constitution Act, 1867, *supra* note 19 at s 91(27); Library of Parliament, *supra* note 20.

²² Constitution Act, 1867, *supra* note 19, at s 91.

²³ Library of Parliament, *supra* note 20, at 2.

²⁴ Medical Act, *supra* note 7, art. 31: The following activities in the practice of medicine are reserved to physicians: (1) diagnosing illnesses; (3) using diagnostic techniques that are invasive or entail risks of injury.

²⁵ Dental Act, C.Q.L.R. 2009, c D-3, art. 26: Every act the object of which is the diagnosis or treatment of any deficiency affecting the teeth, mouth, maxillae, or adjacent tissue in human beings constitutes the practice of dentistry.

diagnostic techniques within the authority conferred by regulation.²⁶ Other professions, though not explicitly permitted to diagnose, perform somewhat closely related functions. Podiatrists, for example, are responsible for the treatment of local foot disorders²⁷ while pharmacists determine and ensure the proper use of medication, ‘particularly to identify and prevent pharmacotherapeutic problems’.²⁸ It is thus evident that, while physicians are not, strictly speaking, the only persons authorized to diagnose disease in Quebec, legal permissions for non-physician diagnosis are nevertheless fairly tightly constrained. Practically speaking, diagnosis is reserved to physicians subject to a small number of special cases.

Diagnosis in Ontario is controlled by the *Regulated Health Professions Act* (RHPA), a sweeping statute that provides a comprehensive framework for the regulation of most health services.²⁹ At s. 27, the RHPA prohibits the performance of a controlled act by anyone who is not a member of a health profession authorized to perform the act in question or who has not been delegated the power to do so by an authorized member.³⁰ Diagnosis is one such controlled act. More specifically, the RHPA reserves to health professionals the act of:

Communicating to the individual or his or her personal representative a diagnosis identifying a disease or disorder as the cause of symptoms of the individual in circumstances in which it is reasonably foreseeable that the individual or his or her personal representative will rely on the diagnosis.³¹

This reservation is relatively more complex than the analogous provisions enacted in Quebec. While the latter simply reserves the act of diagnosing a disease to physicians, the Ontario legislator has elected to describe a controlled act with at least two components. The act is described as (a) the communication of a diagnosis in (b) circumstances in which the person to whom the diagnosis is communicated could be reasonably foreseen to rely on it. We will say more about how the reserved act is defined in the following subsection.

While the RHPA reserves the communication of diagnoses to the members of certain healthcare professions, it does not explicate which professions have such permission. Professional scope of practice aligned with the RHPA is outlined in a number of statutes specifically applying to each of the health professions under its ambit. For example, the *Medicine Act*, which regulates the College of Physicians and Surgeons of Ontario, describes the practice of medicine by physicians as the capacity to assess ‘the physical or mental condition of an individual and the diagnosis, treatment and prevention of any disease, disorder or dysfunction’.³² Registered nurses with advanced training are similarly permitted to communicate diagnoses.³³ Just as in Quebec, the practice of dentistry is understood to include the diagnosis of diseases, disorders, and dysfunctions of

²⁶ Nurses Act, C.Q.L.R. 2012, c I-8, art. 36.1(1-2).

²⁷ Podiatry Act, C.Q.L.R. 2011, c P-12, art. 7.

²⁸ Pharmacy Act, C.Q.L.R. 2015, c P-10, art. 17.

²⁹ LINDA S. BOHNNEN, REGULATED HEALTH PROFESSIONS ACT: A PRACTICAL GUIDE 1 (1994).

³⁰ RHPA, *supra* note 6, at s 27(1).

³¹ *Id.* at s 27(2)1.

³² Medicine Act, R.S.O. 1991, c 30, s 3 [Medicine Act].

³³ Nursing Act, R.S.O. 1991, c 32, s 5.1(1)1.

the ‘oral-facial complex’.³⁴ Other professions permitted to diagnose at least some set of illnesses include psychologists,³⁵ podiatrists,³⁶ chiropractors,³⁷ and physiotherapists.³⁸ In all, only 7 of the more than 20 professions regulated by the RHPA have some measure of permission to diagnose.³⁹

In both Quebec and Ontario, performance of these reserved activities is prohibited. Diagnoses made by persons not authorized to deliver them is the subject of a penal offense described in article 43 of the *Medical Act* and article 188 of the *Professional Code*.⁴⁰ Individual violators of this reservation may be fined up to \$20,000, while corporations may be fined a maximum of \$40,000.⁴¹ Ontario’s approach is nearly identical; the RHPA prohibits the performance of controlled activities and supports the attendant penal offense with a possible fine of \$25,000 and up to 1 year of incarceration.⁴² Second and subsequent offenses may incur a fine up to \$50,000 and an additional year of imprisonment.⁴³ Corporations may be fined \$55,000 for first offences and up to \$200,000 for subsequent violations.⁴⁴ It is apparent that the possible punishments for non-authorized diagnosis in Quebec are substantially less serious; not only are the relevant maximum fines lower, but the possibility of imprisonment upon conviction is non-existent as well. It may be that this is explained by the greater breadth of the prohibition in Quebec. While Ontario restricts the communication of a diagnosis in only those cases that would admit of a reasonably foreseeable reliance, Quebec prohibits diagnoses by non-authorized persons whether it would be relied upon or not. We will say more about this in what follows, where we turn to the legal substance of diagnosis in Quebec and Ontario. In this subsection, we have outlined the legal requirements for engaging in diagnosis and the penalties potentially arising when diagnoses are made absent authority. In the next subsection, we will focus on what diagnosis is.

Definitions of Diagnosis

The law of Quebec and Ontario take different approaches to defining diagnosis, yet, in the end, substantively reach quite similar conclusions. Though non-authorized diagnosis is the subject of a penal prohibition supported by potentially substantial fines, it is not defined explicitly in Quebec legislation.⁴⁵ Ontario’s RHPA, in contrast, relatively

³⁴ Dentistry Act, R.S.O. 1991, c 24, s 3.

³⁵ Psychology Act, R.S.O. 1991, c 38, ss 3–4.

³⁶ Chiropody Act, R.S.O. 1991, c 20, s 5(2)1.

³⁷ Chiropractic Act, R.S.O. 1991, c 21, ss 3–4(1).

³⁸ Physiotherapy Act, R.S.O. 1991, c 37, ss 3–4(1)1.

³⁹ Health Professions Regulatory Advisory Council, *Adjusting the Balance: A Review of the Regulated Health Professions Act*, Report to the Minister of Health and Long-Term Care, Ontario (2001), http://www.hprac.org/en/reports/resources/RHPA_Review_2001_Report.pdf (accessed July 14, 2017) [Adjusting the Balance].

⁴⁰ Medical Act, *supra* note 7, art. 43: Subject to the rights and privileges expressly granted by law to other professionals, no person may engage in any activity described in the second paragraph of section 31, unless he is a physician; Professional Code, *supra* note 6, art. 32: No person shall engage in a professional activity reserved to the members of a professional order, claim to have the right to do so, or act in such a way as to lead to the belief that he is authorized to do so, unless he holds a valid, appropriate permit, and is entered on the roll of the order empowered to issue the permit, unless it is allowed by law.

⁴¹ Professional Code, *supra* note 6, art. 188.

⁴² RHPA, *supra* note 6, at s 40(1)(a).

⁴³ *Id.* at s 40(1)(b).

⁴⁴ *Id.* at s 40(3).

⁴⁵ See eg *Collège des médecins du Québec v. Labonté*, 2006 Q.C.C.Q. 6346 at para. 37 [Labonté].

clearly outlines the substance of legal diagnosis. In this section, we will describe and contrast the respective approaches taken in these two jurisdictions.

Given the absence of legislative guidance, it is necessary in Quebec to turn to academic literature and case law to understand the law's understanding of diagnosis. Respected legal commentators Baudouin, Deslauriers, and Moore write that diagnosis consists of an 'opinion given by a physician on the state of their patient'.⁴⁶ This proposal captures the level of generality typically adopted by Quebec courts, which have traditionally opted for a dictionary-inspired, 'common sense' approach to diagnosis.⁴⁷ In the leading case on the contours of diagnosis, *Collège des médecins (Québec) v Javanmardi*, decided by the Quebec Court of Appeal in 2013, the court drew on the *Petit Larousse* dictionary to inform their reasons.⁴⁸ According to that dictionary, diagnosis consists simply of the identification of an illness based on its symptoms.⁴⁹ This way of thinking about diagnosis, moreover, has been adopted in an array of lower court decisions. For example, in *Grenier v Collège des médecins du Québec*, a purported healthcare provider who was not authorized to diagnose was convicted after attempting to treat the fictitious symptoms of undercover agents of the professional association of physicians (the Collège des médecins). The accused had his patients complete a survey, inquired about their medical history, and recommended that they purchase and use a product named *Phytocure, Complexe DC*, a pseudomedical capsule treatment that allegedly 'cleans' organ systems and balances stomach acidity.⁵⁰ The accused was convicted of illegally practicing medicine and his appeal was dismissed by the Superior Court of Quebec.⁵¹ Crucially, the court grounded its decision on the view that a correct application of article 31 of the *Medical Act* requires the adoption of a common sense understanding of diagnosis, one in which the association of symptoms with disease signifies that an illness has been diagnosed.⁵² Beyond that, other lower court cases, such as the decision in *Collège des médecins du Québec v Blouin*, have disregarded disclaimers made by persons who are not authorized healthcare providers that patients are not being provided with diagnoses.⁵³ In the *Blouin* case, the accused, a self-styled naturopath, prepared documents summarizing various conditions patients were suspected of having. Among other things, the accused purported to expose deficiencies in the pancreas, liver, and kidneys present in her patients. She was convicted despite disclaimers of non-diagnosis.⁵⁴ The court was satisfied that simply drawing associations between illnesses and disease by a person not authorized to practice medicine is an illegal diagnosis. After the *Javanmardi* decision, this remains the position of the law of Quebec.

⁴⁶ Jean-Louis Baudouin et al., 2 *LA RESPONSABILITÉ CIVILE*, 2-72 (8th ed 2014), our translation [BDM].

⁴⁷ See eg *Collège des médecins (Québec) v Javanmardi*, 2013 Q.C.C.A. 306 at paras. 59–69 [Javanmardi]; Grenier, *supra* note 6, at paras. 32–35; See Labonté, *supra* note 45 (This decision was confirmed at the Quebec Court of Appeal: 2007 Q.C.C.A. 917. Leave to appeal to the Supreme Court was denied: SCC, *Demandaes d'autorisation*, N° 32230); Vézina v. Corporation Professionnelle des Médecins du Québec, 1998, R.J.Q. 2940 at 2945–2946, 1998 CanLii 12500 [Vézina].

⁴⁸ Javanmardi, *supra* note 47, at para. 60.

⁴⁹ Larousse 2009, *sub verbo* 'diagnostic': '1. Méd. Identification d'une maladie par ses symptômes' [Larousse].

⁵⁰ Grenier, *supra* note 6, at paras. 15–17.

⁵¹ *Id.* at para. 40.

⁵² *Id.* at paras. 34–36.

⁵³ *Collège des médecins du Québec v. Blouin*, 2011 Q.C.C.Q. 3429, at para. 19 [Blouin].

⁵⁴ *Id.* at para. 84.

Ontario's approach to the communication of diagnoses is somewhat more straightforward. For one thing, the legislation itself offers a relatively clear legal framework in line with the dictionary definition adopted in Quebec. The RHPA maintains that a diagnosis occurs where a 'disease or disorder' is identified as 'the cause of symptoms' of an individual.⁵⁵ Importantly, diagnosis is understood not to consist in merely labeling symptoms or performing assessments.⁵⁶ Instead, a diagnosis is a *conclusion* drawn about the underlying cause of a patient's symptoms.⁵⁷ This description bears much in common with Quebec's conception of diagnosis. In both jurisdictions, drawing an association between symptoms and their underlying cause is sufficient to qualify, legally, as diagnosis. That said, there are several important substantive differences in the penal liability regimes present in these two provinces. On one interpretation, Ontario's approach provides a conception of diagnosis that is much more constrained than Quebec's—simply making a diagnosis in Ontario does not, after all, create a space for penal liability. This view is supported by two observations. For one thing, Ontario explicitly requires that the relevant diagnosis be *communicated* to a patient. Quebec has no similar communication requirement. For another thing, the controlled act of diagnosis in Ontario requires that it can reasonably be foreseen that the person to whom the diagnosis is communicated would have relied on it in the circumstances, 'perhaps to the extent of subjecting him/herself to invasive treatment'.⁵⁸ As above, Quebec's legal conception of diagnosis contains no such analogous condition. These additional components imply that the act of diagnosis protected by Ontario law is narrower than that protected in Quebec.

By extension, it should follow that proving a violation of the prohibition against non-authorized diagnosis will be somewhat more challenging in Ontario. Indeed, it may be that the apparent lack of litigation on the issue of illicit diagnosis in Ontario can be partially attributed to the high threshold for conviction required by that province's penal offense. Nevertheless, at least one high profile decision of the Ontario Superior Court will help to provide some insight into the regulation of the communication of diagnoses. In *College of Optometrists of Ontario v SHS Optical*, the professional association of optometrists sought an order compelling a glasses store to refrain from, among other things, offering diagnoses of eye conditions.⁵⁹ Opticians employed by SHS Optical, who do not have the authority to communicate diagnoses under the RHPA,⁶⁰ administered refractometry tests and informed customers that they would need glasses to correct astigmatism.⁶¹ The Court concludes that 'where an employee of an optical outlet informs a customer, or potential customer, that he has "astigmatism," a diagnosis has been communicated' within the meaning of s. 27(2)1 of the RHPA.⁶² Informing a customer that they needed glasses, on the other hand, was found not to infringe

⁵⁵ RHPA, *supra* note 6, at s 27(2)1.

⁵⁶ *Adjusting the Balance*, *supra* note 39, at 23.

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *College of Optometrists of Ontario v. SHS Optical Ltd*, 2003, O. J. No. 3077 at paras 1–5, 124 A.C.W.S. (3d) 1169 [SHS Optical].

⁶⁰ *Id.* at para. 41.

⁶¹ *Id.* at paras. 5–14.

⁶² *Id.* at para. 67.

the controlled act of communicating a diagnosis.⁶³ While pointing to the presence of astigmatism identifies a ‘disease or disorder as the cause of symptoms’,⁶⁴ an indication that they need glasses does not. Despite the finding that employees of SHS Optical had acted in violation of s. 27(2)1 of the RHPA, the Court elected to make no order in response.⁶⁵ Instead, the Court found that determinations about what opticians should be permitted to tell their customers is best addressed by a consultative process involving the Ontario Ministry of Health, the relevant professional colleges, and the Health Professions Regulatory Advisory Council.⁶⁶ This, the Court concluded, would be the most ‘appropriate means of developing standards of practice in this regard’.⁶⁷ In later sections of the paper, we will return to such proposed consultative processes as a potential means of addressing the diagnostic capacities of mobile health apps.

For now, the *SHS Optical* decision is relevant for two reasons. Firstly, it underlines the associative quality of the controlled act of communicating a diagnosis. Just as in Quebec, the critical diagnostic element the legislator has sought to restrict is the associational act of giving a causal explanation of symptoms. Secondly, this case indicates a measured approach to the prohibition of illegal diagnoses, one that favors consultation between relevant actors over strict application of the penal liability regime. It is not clear, however, that this approach would be taken by other Ontario courts. In the context of this decision, the Court issued an order with respect to other violations of the RHPA, specifically, violations of the prohibition on issuing prescriptions. Despite an injunction to refrain from such activity, SHS Optical refused to comply. Applications for civil contempt of court were brought by the College of Optometrists in 2006 and 2007.⁶⁸ In 2010, a further civil action and criminal charges were brought against the glasses store owners.⁶⁹ Interestingly, at the time of this writing, the *Opticianry Act* still does not extend to opticians the legal authority to communicate diagnoses.⁷⁰

Other Ontario cases have contributed more pointedly to the legal context surrounding the control of diagnosis. In particular, the *Spurrell v College of Massage Therapists* decision reinforces that the test for determining if the reservation of the communication diagnoses has been infringed contains two distinct steps.⁷¹ More precisely, the Superior Court in *Spurrell*, acting as an appellate court for an administrative tribunal, held that conviction for infringement of s. 27(2)1 of the RHPA

requires establishing both that the member communicated a diagnosis identifying a disease or disorder as the cause of symptoms and that this communication occurred in circumstances where it was reasonably foreseeable that the individual to whom the communication was made would rely on the diagnosis.⁷²

⁶³ *Id.* at para. 69.

⁶⁴ *Id.* at para. 62, quoting RHPA, *supra* note 6, at s 27(2)1.

⁶⁵ *Id.* at para. 68.

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ See *College of Optometrists of Ontario v. SHS Optical Ltd*, 2010 O.N.S.C. 3786 at paras. 1–4 [SHS Optical 2010]; See also *College of Optometrists of Ontario v. SHS Optical Ltd*, 2008 O.N.C.A. 685, 93 OR (3d) 139.

⁶⁹ SHS Optical 2010, *supra* note 68, at para. 5.

⁷⁰ See *Opticianry Act*, R.S.O. 1991, c 34.

⁷¹ *Spurrell v. College of Massage Therapists*, 2013 O.N.S.C. 4117 at para. 22, 229 A.C.W.S. (3d) 887 [Spurrell].

⁷² *Id.*

The accused's defense against the allegation that he had communicated a diagnosis in this case was that he had not identified a disease or disorder. Spurrell, a massage therapist, had informed his client that she was likely suffering from a 'muscle spasm'.⁷³ In doing so, the Court concluded, the accused had offered an explanation of his client's symptoms and had implicitly ruled out alternative explanations, thereby giving 'a clinical impression he was not competent to give'.⁷⁴ Just as in *SHS Optical*, the *Spurrell* decision underscores the associational nature of diagnosis in Ontario law. Beyond that, it reinforces that the controlled act of communicating a diagnosis incorporates two distinct elements: the communication of an explanation of presented symptoms in terms of a disease or disorder and the foreseeable reliance of the person to whom the diagnosis is given. But what is perhaps more important, *Spurrell* stands for the view that the reality of diagnosis is such that drawing associations between symptoms and disease implicitly dismisses alternative explanations and thereby gives a clinical impression. In what follows, we will point to the clinical impression in greater depth, arguing that mobile health applications may reasonably be suspected of providing their users the impression that they are providing clinical insight.

Conclusion

In this section, we have outlined and compared the law surrounding diagnosis in Quebec and Ontario. While Quebec reserves diagnosis to certain health professions, Ontario reserves the *communication* of diagnoses where it is reasonably foreseeable that such diagnoses will be relied upon. Despite these important differences in the scope of diagnostic activities reserved to health professionals in either jurisdiction, some crucial similarities persist. Most notably, the law of both provinces understands diagnosis to consist of explaining symptoms in terms of disease or disorders. Both jurisdictions thus understand diagnosis as associational in nature: the core of the reserved act in either province is the drawing of associations between symptoms and illness. This, we maintain, is a general legal principle that may be applied in the context of mobile health applications. The work of the following sections will be to outline how popular consumer health apps draw associations between symptoms and disease, thereby performing diagnostic functions that may be in violation of the reservations of diagnosis in Quebec and Ontario. First, we will describe and categorize the kinds of health we predict may have diagnostic functions. Following this, we will connect such technologies to the concepts presented in the current section, and defend the view that certain mobile health technologies should be understood to be capable of diagnosing disease in contravention of the law of Quebec and Ontario.

MOBILE HEALTH APPS CATEGORIZED

In this section, we begin outlining the set of mobile health apps that we argue provide diagnostic information according to the law of the jurisdictions under contemplation. We will also briefly comment on standalone devices that may be conceptually incorporated into the framework we propose. It is important to note that our focus in this section is on mobile health applications that are expressly targeted to consumers, that is, to members of the general public for purposes of monitoring illness, recording

⁷³ *Id.* at para. 10.

⁷⁴ *Id.* at para. 29.

symptoms, or simply for tracking health statistics such as running speed or calorie intake. Following from the comparative legal analysis we gave in the previous section, our argument specifically focuses on devices that are not typically used by physicians (or other healthcare professionals) in the course of treating patients. Devices of that nature, such as computer-assisted detection software (for example, those used in radiology), would likely not fall under the ambit of provisions that limit diagnosis by non-physicians. This is so simply because these tools are most often used by persons who are legally permitted to use them, for the explicit purpose of providing diagnosis. For this reason, we will focus on applications intended for, and available to, the general public.

In doing so, we will present a categorization of health applications organized in terms of classifications proposed by the federal Food and Drug Administration in the USA. In particular, we will focus on examples of mobile applications for which the FDA has decided to exercise its enforcement discretion *not* to regulate. Such applications are listed in Appendix B of the FDA's *Guidance for Industry and Food and Drug Administration Staff on Mobile Medical Applications*, which specifically lists applications not subject to FDA regulation, but which may nevertheless qualify as medical devices under the *Federal Food, Drug, and Cosmetic Act*.⁷⁵ Medical devices, importantly, are defined in that statute as any implement, machine, or apparatus 'intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease'.⁷⁶ The FDA is of the view that applications listed in Appendix B, despite their status as potential medical devices, pose a relatively low risk to the public.⁷⁷ Of course, given their potential status as medical devices, many such applications may be capable of performing diagnoses in the according to the law of Quebec and Ontario.

It is important to point out that the FDA is currently undertaking a review of its approach to mobile health app oversight in response to the *21st Century Cures Act*.⁷⁸ For our purposes here, however, the 2015 FDA guidance document will be used primarily to help categorize the applications we discuss. In that function, the FDA's 2015 guidance remains a helpful guidepost. Beyond that, there are two principal reasons for appealing to classification regimes proposed by the FDA. First, in summer 2016, Health Canada explicitly directed medical device and technology developers in this country to FDA guidance documents on topics where analogous regimes do not yet exist in Canada.⁷⁹ To our knowledge, Health Canada has not yet issued specific guidance on mobile health applications. FDA guidance documents may provide a useful guide to app developers trying to understand Canada's regulatory landscape (though it should be said that ongoing adjustments to FDA guidance may have the effect of introducing greater uncertainty into the Canadian regulatory landscape). Secondly, FDA guidance

⁷⁵ Federal Food and Drug Administration, *Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff* (US Department of Health and Human Services Food and Drug Administration: 2015), at 21 <http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf> (accessed Dec. 7, 2017) at 21 [FDA Guidance].

⁷⁶ Federal Food, Drug, and Cosmetic Act, U.S.C. tit 21 at § 201(h).

⁷⁷ FDA Guidance, *supra* note 75.

⁷⁸ FDA, *Digital Health* (updated Sept. 6, 2017), <https://www.fda.gov/medicaldevices/digitalhealth/> (accessed Dec. 7, 2017).

⁷⁹ Health Canada, *Notice: Use of United States Food and Drug Administration (FDA) Guidance Materials to Support Canadian Medical Devices Licence Applications*, (2016), <http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/notice-fda-ref-avis-eng.php> (accessed July 14, 2017).

on mobile health apps offers generally clear and thorough descriptions of mobile application functionality. Such descriptions will be indispensable in understanding which of the categories they propose may admit of diagnosis.

The FDA describes 28 categories of applications that may qualify as medical devices, but which are not subject to the administration's regulatory authority. Several such categories are defined in terms of their interaction with medical health professionals, for example, 'mobile apps for providers that help track or manage patient immunizations'.⁸⁰ Considering that our concern in this article are those applications the purpose of which is *not* to mediate interactions with healthcare professionals, we have chosen not to assess the diagnostic potential of those whose primary purpose is to facilitate patient–healthcare provider interactions. In all, 9 of the FDA's 28 categories appear to have such functions. We have included a list of the FDA categories, organized in terms of this classification, in the appendix to this article.

The 19 classifications that remain are each targeted to independent users not typically interacting with the services of healthcare providers. From these, several more encompassing categories can be discerned. First, five FDA classifications are of apps that provide users with general health and wellness information, for example, those that provide smokers with educational information or guidance on strategies for quitting.⁸¹ This classification would also include apps that record health information, but which do not analyse or trend user input.⁸² These are again noted in the appendix to this article. Second, a number of FDA classifications share the characteristic of assisting their users in the management or prevention of a specific disease. Such applications include those that 'use video and video games to motivate patients to do their physical therapy exercises' or 'apps that help asthmatics track inhaler usage'.⁸³ In general, these apps allow users to record their treatments, predict episodes of illness, or motivate programmes of recovery. There is an underlying assumption in each of these application classifications that users will be seeking treatment assistance for an illness with which they have already been diagnosed. Third, the FDA points to a set of applications that may be used to track, log, and trend health information, such as physical activity or general health statistics. Both applications designed to facilitate the recording of general health and wellness data and those designed to track more targeted such as blood glucose statistics are included in this category. This variety of application includes perhaps the broadest classification cited by the FDA, in which a number of distinct functions are subsumed into the more general tracking category.⁸⁴ Among other things, it includes apps that provide tools 'to promote and encourage healthy eating', apps that 'provide dietary logs', and apps that 'monitor and trend exercise activity'.⁸⁵ Finally, a single FDA classification contemplates applications for which users interact with checklists of symptoms, select those relevant to their case, and are provided with a list of possible medical conditions that may be responsible.⁸⁶ This classification is paradigmatically represented by

⁸⁰ FDA Guidance, *supra* note 75, at 25.

⁸¹ *Id.* at 23.

⁸² *Id.* at 23.

⁸³ *Id.* at 23.

⁸⁴ *Id.* at 25.

⁸⁵ *Id.* at 25.

⁸⁶ *Id.* at 24.

the *WebMD* and *Ada* applications, both of which we will discuss at length in the section that follows.

Essentially all of the app classifications predicted by the FDA may be subsumed into one of the five general categories, including those for which healthcare provider interaction is presupposed, which we have described above. To be sure, there are cases in which the FDA's classifications do not clearly match any of these encompassing categories. For example, apps that 'transfer, store, convert formats, and display medical device data without modifying the data' do not clearly perform any of the generalized functions we have discussed.⁸⁷ Obviously, much of what we have said simplifies the trends exhibited by the health applications described in Appendix B of the FDA's mobile health guidance. Our object here is simply to highlight categories of applications that are not generally thought to pose a danger to the public, but which may nevertheless be engaged in the diagnosis of disease in contravention of the *Professional Code*. In the following table, we summarize what we have said here, synthesizing the FDA's 28 classifications into four broad categories pertinent to our work in this article. Accompanying each of these categories are examples of applications we see satisfying the relevant descriptions present in the FDA guidance.

At this stage, it is worth noting that two distinct and important mobile health technologies have not been present in the discussion we have had in this section. For one thing, applications for the facilitation of scientific research projects have not been explicitly contemplated. This is so because the FDA guidance document with which we have outlined this framework does not consider them. For another, standalone consumer devices, that is, technologies other than smartphone applications, have been excluded. This, obviously, has been for an identical reason. For the purposes of this article, we will discuss research applications as their own unique category defined in terms of their availability through Apple's ResearchKit open source framework in which independent and institution-affiliated researchers develop medical research apps for distribution on Apple's App Store.⁸⁸ These applications are relatively novel innovations, with the primary objective of collecting data for use in organized research projects. Currently, there are more than 30 applications offered on the ResearchKit platform, with developers including the American Sleep Apnea Association, Stanford University, and the Boston Children's Hospital.⁸⁹ Users are participants who, through a typically electronic interface, consent to the use of data overtly provided for the study of a disease or condition. In some cases, though not all, these applications require that medical diagnosis be obtained prior to enrollment in the study. It is important to note that most research applications are not yet available in Quebec or Ontario. Even where they are, enrollment in attendant research projects is restricted to residents of the USA. Obviously, this places a firm limit on the extent to which penal liability will be possible for this app category. That said, it is likely that the geographic reach of such technologies will continue to expand. Apart from that, contemplating the bounds of their potential

⁸⁷ *Id.* at 25.

⁸⁸ Apple Inc, *ResearchKit and CareKit* (2016), <http://www.apple.com/researchkit/> (accessed July 14, 2017) [ResearchKit].

⁸⁹ App Store (United States). See also, Vincent Tourraine, *List of all ResearchKit Apps*, SHAZINO BLOG (Feb. 1, 2016), <http://blog.shazino.com/articles/science/researchkit-list-apps/> (accessed July 14, 2017) [Tourraine].

to diagnose disease may be of some benefit to application developers and researchers with Canadian-based practices.

Standalone devices, contrastingly, may generally be subsumed under Tracking, Logging, and Trending Application category. Personal devices, such as the *Fitbit*, perform many of the same functions as, for example, the *Nike + Run Club* application. The *Fitbit*, of course, is a brand of wearable fitness device that, among other things, typically track the number of footsteps taken by a user, map their movements, monitor their sleep, and, in some models, record their heart rate.⁹⁰ In that sense, they are essentially somewhat more sophisticated smartphone applications. We will discuss their capability in greater detail in the next section of the paper. For now, we want only to suggest that relevant self-tracking devices, though not contemplated by the FDA, have functions sufficiently similar to tracking applications for our purposes, to be effectively discussed in tandem.

Our purpose in this section has been to introduce the kinds of technologies we believe will have diagnostic functions according to the law of Quebec and Ontario. We have examined the application landscape through the lens of FDA guidance on mobile health, and have proposed a small number of meta-categories that draw together the various functions such applications perform. Those that we have identified in Table 1 are those which we suspect will have some degree of diagnostic capability. As we will outline in the section that follows, the extent to which this is the case is fairly variable. Our work in the next portion of this article will be to draw connections between diagnosis in law and the mobile health technologies we have singled out in this section. To do so, we will more concretely describe the relevant functions of suspect applications and devices.

LIABILITY

In this section, we will argue that the applications we have described above have diagnostic functions according to the law of Quebec and Ontario. To the extent that this is so, such applications may contravene the *Professional Code* and *Regulated Health Professions Act*, thereby potentially opening their developers to penal prosecution. To be sure, such prosecution is unlikely; our aim is simply to suggest that, on a plain reading of the law, a range of consumer health applications are engaged in diagnosis and, conceptually speaking, may be doing so in violation of the law.

General Health and Wellness Information Applications

Applications that provide only general health information not targeted to individual patients are, generally speaking, unlikely to have diagnostic functions in the meaning of the *Professional Code* and *Regulated Health Professions Act*. Recall that the applications we have in mind here are those that, for example, ‘provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women’ or ‘prompt a user to enter which herb and drug they would like to take concurrently and provide information about whether interactions have been seen in the literature’.⁹¹ *Smoke Free*, for example, is an application which clearly conforms to the first of these classifications. The application is designed to assist and motivate smokers who wish to quit, providing them with daily missions, a space

⁹⁰ Fitbit, <https://www.fitbit.com/en-ca/home> (accessed Feb. 21, 2018).

⁹¹ FDA Guidance, *supra* note 75, at 25.

Table 1. Health Application Categories Drawn from FDA Guidance.

<i>Technology Classification</i>	<i>Key Characteristics</i>	<i>Examples</i>
(1) General health and wellness information applications	<i>Provide general health information that is not typically targeted to individual users</i>	<i>Smoke Free, Walgreens</i>
(2) Illness prevention and management applications	<i>Provide health information or record health data tailored to a specific disease or set of diseases. Information is sometimes targeted to individual users or user input</i>	<i>Dr K's Breast Checker, Asthma MD</i>
(3) Tracking, logging, and trending applications	<i>Facilitate user input of health data, store and track such data</i>	<i>Nike + Run Club, MySugr Diabetes Logbook</i>
(4) Association applications	<i>Facilitate user interaction with checklists of common symptoms and provided lists of possible medical conditions, often organized in terms of their probable causal link to symptoms in question</i>	<i>WebMD, Ada</i>

to record cigarette cravings, and an overview of improvements health made as a result of smoking cessation.⁹² While, in this case, the FDA's prediction that such application will be of little risk to the public is surely accurate,⁹³ it is nevertheless not unjustified to worry that the application may have some interaction with the law of diagnosis in Quebec. In particular, an assessment of health outcomes may provide sufficient information about symptoms and disease to qualify as diagnosis under the very broad definition accepted by the courts. For example, *Smoke Free* provides its users with estimates about improvement in circulation and lung function calculated with reference to the period of time elapsed since the user last smoked cigarettes.⁹⁴

Of course, such estimates are rudimentary and are designed to have a motivational effect. They neither purport to qualify as medical advice nor predict an application user's future health outcomes. It would, as a result, be exceptionally unlikely that any prosecutor would attempt to secure a conviction against developers of this application. But this should not imply that it performs no diagnostic function at all. In fact, the core of

⁹² David Crane, *Smoke Free—Quit Smoking Now and Stop for Good* (Version 3.3.3), iTUNES APP STORE (2017), <https://itunes.apple.com/ca/app/smoke-free-quit-smoking-now-and-stop-for-good/id577767592?mt=8> (accessed July 20, 2017) [*Smoke Free*].

⁹³ See FDA Guidance, *supra* note 75, at 23.

⁹⁴ *Smoke Free*, *supra* note 92.

the reserved acts we have described above appears to be implicated. For example, the Quebec case law we have described maintains that simply pointing to another's organ health might be sufficient to constitute a diagnosis.⁹⁵ In Ontario, the practical approach to diagnosis taken in *Spurrell* indicates that eliminating causal explanations of symptoms in preference of others is typically part of the diagnostic process.⁹⁶ On both of these measures, it may be that something like *Smoke Free* is engaged in such activity. That said, Ontario's requirement that diagnoses be communicated in a circumstance that would reasonably generate reliance is quite unlikely to be satisfied here. As such, a much more plausible argument can be made for infringement of the reserved act in Quebec than in Ontario. In either case, we would not advocate for penal prosecution in the case of applications in this category. An argument for liability would be unlikely to succeed. More importantly, it is unclear how prosecution would serve the public interest. Nevertheless, it is important to identify that such applications sit in a poorly defined legal space. As we will suggest below, the poorly understood legal status of these applications and their capabilities is worthy of attention on its own terms.

Illness Prevention and Management Applications

Illness prevention and management applications include those that, for example, 'use video and video games to motivate patients to do their physical therapy exercises at home' or 'help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks'.⁹⁷ In general, these applications help their users to manage an illness, recover from a disease, or prevent becoming sick. In the spirit of the FDA's classifications, we have pointed to *Dr K's Breast Checker* as an application fitting this description. Available for download since 2010, this application is designed to help women learn about and prevent breast cancer.⁹⁸ One important function allows users to record breast tissue changes over time by providing visual diagrams and a symptom questionnaire.⁹⁹ Just as above, this may be interpreted as delivering a kind of association between symptoms and diseases affecting the breasts. Of course, these associations would not be explicit in nature; after all, it is not as though the application would directly tell their users that they have a malignancy. What they may do, however, is imply to an application user that any change that may be selected on a chart of symptoms would indicate disease. This is a subtle way of drawing an association between symptoms and an attendant illness, one which might qualify as a kind of *de facto* diagnosis. As in the case above, it would appear that Quebec law is more likely to admit of an argument for penal liability than Ontario law. In this case, however, it may be somewhat more appropriate to say it is reasonably foreseeable that users will rely on the information provided by the application, thereby infringing on the reserved act of communicating a diagnosis. This is so in large part because the information provided by *Dr K's Breast Checker* much more neatly identifies a disease than the information presented by *Smoke Free*.

⁹⁵ See Blouin, *supra* note 53, at para. 84.

⁹⁶ See Spurrell, *supra* note 71, at para. 29.

⁹⁷ See FDA Guidance, *supra* note 75, at 23–25.

⁹⁸ See Lingopal Holdings, *Dr K's Breast Checker (Version 1.0.1)*, iTUNES APP STORE (2010), <https://itunes.apple.com/ca/app/dr-ks-breast-checker/id385045662?mt=8> (accessed July 20, 2017) [Dr K's Breast Checker].

⁹⁹ *Id.*

To be sure, most illness treatment and prevention apps operate on the presupposition users are already undergoing treatment for the disease or condition the app is designed to address. The *Asthma MD* app, for example, invites users to record asthma attacks, note attack severity, and share electronically information with their physician.¹⁰⁰ The obvious intention is that this app would be used primarily by persons who wish to monitor asthma that has already been diagnosed. We might worry, however, that persons who have not yet been properly diagnosed would use *Asthma MD* as a way of self-administering tests for the disease. Of course, such use is speculative, but if it were to occur, it would likely offer a kind of *de facto* diagnosis in a vein similar to that produced by *Dr K's Breast Checker*. In general, applications used for illness treatment or prevention will tacitly associate symptoms and illnesses. This immediately places them in a suspect legal position, one in which the possibility of penal liability may be a real, present consideration. With that said, prosecution here is probably as unlikely as in the case of health and wellness apps.

Tracking, Logging, and Trending Applications

Applications that track, log, and trend personal health data include those that are designed to help their users in the development and maintenance of 'general fitness, health or wellness'.¹⁰¹ Included in this classification is the *Nike + Run Club* app. This application tracks user movement and distance using smartphone GPS systems.¹⁰² Records of time per unit of distance, duration of activity, and distances traveled are synchronized by the application. For outdoor activity, user movement and elevation changes are mapped.¹⁰³ These data, as innocuous as it may be on its face, may in fact reveal much about a person's health and fitness.¹⁰⁴ Trends elucidated by such data, or interpreted in concert with other information, could indicate illness. The relevant applications are silent about concrete associations between symptoms and disease but do potentially provide tools for drawing conclusions about disease in conjunction with additional data or expertise. As we have mentioned above, standalone devices such as the *Fitbit* could be understood to fall into this classification. These devices, which make use of an accelerometer to measure user movements, could theoretically be used to determine that a person has had a seizure while using their device.¹⁰⁵ The *Fitbit*, moreover, could be understood to be roughly analogous to sophisticated, networked body-worn sensors that are sometimes used in medical, psychological, and other research.¹⁰⁶ After all, they compile information that would indicate much about a person's private life, including, of course, their travel routine and inclination toward physical activity. Crucially, however, both devices such as the *Fitbit* and applications such as *Nike + Run Club* are silent

¹⁰⁰ Mobile Breeze, *Asthma MD (Version 3.32)*, iTUNES APP STORE (2017), <https://itunes.apple.com/us/app/asthmadm/id349343083?mt=8> (accessed July 20, 2017).

¹⁰¹ FDA Guidance, *supra* note 75, at 25.

¹⁰² See Nike, *Nike+ Run Club* (2016), http://www.nike.com/ca/en_gb/c/running/nike-run-club (accessed July 20, 2017) [Nike].

¹⁰³ *Id.*

¹⁰⁴ See Andrew Raij et al., *Privacy Risks Emerging from the Adoption of Innocuous Wearable Sensors in the Mobile Environment* (Paper delivered at the ACM CHI Conference on Human Factors in Computing Systems, Vancouver, 7–12 May 2011) at 13, published in the Proceedings of the International Conference on Human Factors in Computing Systems, 2011.

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

about concrete associations between symptoms and disease. Instead, merely they provide tools for drawing conclusions about disease in conjunction with additional data or expertise. It is unlikely that self-tracking devices such as the *Fitbit*, at least given how this technology works at present, will be capable of diagnosing disease by themselves. A *Fitbit* will not directly inform its owner that they have had a seizure: some person or device, interpreting such data, would need to reach that conclusion.

In contrast, a substantially more plausible case for a kind of direct, *de facto* diagnosis could be made for applications that record blood glucose levels, such as *MySugr Logbook*.¹⁰⁷ This application provides users a platform designed for recording blood glucose concentration levels as part of a treatment regime for diabetes.¹⁰⁸ Among other things, *MySugr Logbook* uses daily glucose concentration recordings to estimate glycated hemoglobin (HbA1c) levels, a measure typically used in the clinic as an identifier of average blood glucose concentration over the course of 3-month periods. In general, HbA1c levels found within a predetermined reference range of glucose concentration indicate favorable control of the disease.¹⁰⁹ Where this application is used by *diabetics*, the risk of diagnosis is obviously non-existent. Presumably, however, there is some chance that interested non-diabetics could make use of *MySugr Logbook* to draw conclusions about their HbA1c and, as a result, their diabetic status. Where their average blood glucose concentration habitually falls outside of the normal range, a positive conclusion about diabetes is not unjustified.¹¹⁰ This, of course, may be something of a stretch; very few people would likely *want* to diagnose their diabetes in this way. It would presumably be difficult and impractical to use this application as a diagnostic tool. Considering that an interested person would be required to use a blood glucose monitor and consistently test their blood glucose levels for a certain period of time, few people would be interested in this approach. Nevertheless, using the argument presented above, diagnosis of this variety remains conceptually possible. Just as *Asthma MD* and *Dr K's Breast Checker* drew subtle associations between symptoms and illness, *MySugr Logbook* could signal diabetes to users monitoring their blood glucose.

Association Applications

Of the categories of apps we have outlined, association applications are most likely to infringe the penal liability regimes of Quebec and Ontario. Association applications are described by the FDA as those that ‘use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a health care provider’.¹¹¹ The quintessential member of this classification is the *WebMD* application. With this application’s ‘symptom checker’ function, users indicate, on a diagram of the human body, areas that are causing them distress. After selecting from an extensive list of symptoms, the app will provide an overview of potentially responsible conditions.

¹⁰⁷ See FDA Guidance, *supra* note 75, at 26.

¹⁰⁸ *MySugr Diabetes Logbook* is classified as a Class 1 Medical Device in the United States: ‘MySugr’ (2016) <https://mysugr.com/> (accessed July 20, 2017) [MySugr].

¹⁰⁹ See Jinan B. Saaddine et al., *Distribution of HbA(1c) Levels for Children and Young Adults in the U.S.: Third National Health and Nutrition Examination Survey*, 25 *DIABETES CARE* 1326 (2002).

¹¹⁰ Persistently elevated blood glucose concentration is indicative of diabetes mellitus type 2: World Health Organization, *Diabetes: Fact Sheet N° 312* (2013), <https://web.archive.org/web/20130826174444/http://www.who.int/mediacentre/factsheets/fs312/en/> (accessed July 20, 2017).

¹¹¹ FDA Guidance, *supra* note 75, at 24.

For example, the selections ‘Left leg’, ‘muscle cramps or spasms (painful)’ that (a) are ‘brought on or made worse by lying down’ and (b) are ‘brought on or made worse at night’ result in the following list of candidate diseases:

Restless legs syndrome; Low potassium (hypokalemia); Exercise or physical activity; Anemia, chronic disease; Anemia, iron deficiency; Dehydration (adult); Multiple sclerosis; Anemia, hemolytic; Chagas disease; Mad cow disease; Pseudohypoparathyroidism; Pompe disease (late onset).¹¹²

These illnesses appear in a non-random order, with the list presented according to the probability that each disease is responsible for the symptoms described.¹¹³ Thus, in the example given above, restless leg syndrome is the most likely cause of the offending leg cramps and spasms. Mad cow disease, comparatively, is less likely to be the culprit.¹¹⁴ The *WebMD* application opens with a disclaimer warning users that it is not in the business of diagnosis and that nothing it provides is a substitute for professional medical advice.¹¹⁵ But its suggestions about disease intuitively appear to be unquestionably diagnostic.¹¹⁶

Ada is a similar app that uses artificial intelligence technology to perform many of these same functions.¹¹⁷ Just as *WebMD* does, *Ada* warns its users that it is purportedly not diagnosing disease and that a physician’s care should be sought in conjunction with use of the application. After creating an account with basic demographic information, users input symptoms by entering them into the application. The app then poses a series of questions and produces a report indicating which diseases may be responsible for the symptoms presented and the likelihood of each being the source of the user’s distress. For example, after entering symptoms associated with leg cramps similar to those presented to *WebMD*, *Ada* prepared a report warning of the following diseases:

Secondary hyperparathyroidism; Rhabdomyolysis; Quadriceps strain; Non-specific muscle cramps in leg; Painless lymphocytic thyroiditis.¹¹⁸

As part of the prepared report, the *Ada* application recommends seeking medical advice for secondary hyperparathyroidism and indicates that 20% of persons with the described symptoms will have this condition. In the case of rhabdomyolysis, *Ada* recommends seeking emergency care and indicates that 10% of persons with the described

¹¹² WebMD Health Tools, *WebMD App for iPhone (2016) (version 5.9.3)* [WebMD app].

¹¹³ See iTunes Preview, *WebMD* (2016), <https://itunes.apple.com/us/app/webmd-trusted-health-wellness/id295076329?mt=8> (accessed July 14, 2017).

¹¹⁴ Crucially, and this is a point we will return to, mad cow disease remains a candidate cause of leg pain according to the *WebMD* application. This is so even despite the exceptionally low odds of contacting mad cow disease. Indeed, at the height of the 1990s mad cow crisis in the United Kingdom, in which nearly 200,000 cattle died, only a total of 80 human cases were confirmed or predicted. See Michael Balter, *Tracking the Human Fallout From ‘Mad Cow Disease’*, 289 *SCIENCE* 1452 at 1452 (2000).

¹¹⁵ WebMD app, *supra* note 112.

¹¹⁶ Interestingly, a Google search for the term ‘diagnosis’ will return, as one of its top hits, a link to the WebMD homepage.

¹¹⁷ Ada Digital Health Ltd, *Ada (2017) (Version 2.6.0-v3)* [Ada].

¹¹⁸ *Id.*

symptoms are affected. As for quadriceps strain, the app informs its users that this condition can usually be treated at home. Following generation of the health report, *Ada* will periodically pose follow-up questions, including whether the user has consulted a physician about the symptoms in question.¹¹⁹

Such functions in both *Ada* and *WebMD* clearly satisfy the associational condition at the core of the reserved activities in Quebec and Ontario. In Quebec, these indications that symptoms are caused by a set of conditions is sufficient to satisfy the definition of diagnosis described in *Grenier* and *Blouin*.¹²⁰ Moreover, in *Javanmardi*, the accused provided a list of possible symptomatic causes and was found to have engaged in diagnosis.¹²¹ This seems to be exactly what *WebMD* and *Ada* do. In the Quebec context, disclaimers warning users that the application is not offering diagnoses will not shield against liability.¹²² On the Ontario framework, it appears to be the case that information produced by these applications could reasonably qualify as communicated diagnoses. Just as in Quebec, identifying the cause of symptoms in terms of diseases or conditions would be sufficient to satisfy the diagnosis portion of the test for violation of the reserved act. The critical question will be whether the information conveyed by these applications is delivered in circumstances in which it is reasonably foreseeable that app users would rely on them. On first glance, it appears that this is likely to be so. The *Ada* application, in particular, presents itself as an artificially intelligent healthcare tool, one that learns about its users and becomes increasingly precise in its health evaluations over time.¹²³ It is not unreasonable to conclude that the diagnoses delivered by a polished application offering detailed personalized assessment reports purportedly developed with physician oversight would foreseeably be relied upon. As a result, we submit that a convincing argument can be constructed in favor of these applications operating in violation of the reservations of activities present in the law of Quebec and Ontario. By associating symptoms with disease in a straightforward way, they do precisely what is at the core of the law of diagnosis. Further, because these apps are likely to be relied on, they find themselves in a murky legal position, one in which penal prosecution and liability are entirely possible.

Research Applications

As we have mentioned above, research applications are, generally speaking, tools used for data collection in organized research projects. We will briefly point out that these applications may be suspected of performing *de facto* diagnoses in a manner similar to that described above in the case of disease management apps. Users of research apps are participants who, through a typically electronic interface, consent to the use of data overtly provided for the study of a disease or condition. In many cases, these applications require that medical diagnosis be obtained prior to enrollment in the study. For example, this is the case for New York University Langone Medical Center's *Concussion Tracker*, for which study eligibility is restricted to adults who have been

¹¹⁹ *Id.*

¹²⁰ See *Grenier*, *supra* note 6, at paras. 37–38; *Blouin*, *supra* note 53, at para. 84.

¹²¹ *Collège des médecins du Québec v. Javanmardi*, 2010 QCCS 2279 at paras. 36 and 111.

¹²² *Javanmardi*, *supra* note 47, at paras. 13 and 92.

¹²³ See *Ada, Frequently Asked Questions* (2017), <https://ada.com/faq/> (accessed Dec. 7, 2017).

diagnosed with a concussion by a healthcare provider within the last 10 days.¹²⁴ This application is part of a study that aims to understand physical and cognitive function in the 6 weeks that follow a concussion.¹²⁵ Other research apps, however, are open to all adult residents of the USAs. *mPower*, for example, aims to improve understanding of the divergent symptomatic experiences of Parkinson's disease patients.¹²⁶ The application uses smartphone sensors to monitor dexterity, balance, and gait; subjects respond to surveys and complete coordination tasks.¹²⁷ Given the data produced by the application, it is conceivable that healthy persons may enroll in order to assess their level of risk for Parkinson's. *Mole Mapper*, by contrast, explicitly sets out to develop the capacity to diagnose melanoma over time.¹²⁸ Participants in this study use smartphone cameras to take photographs of their moles. The application then tracks physical changes over time and incorporates data, with participant consent, into a melanoma development database.¹²⁹ Developers hope that this database, upon growing sufficiently large, will allow remote melanoma diagnosis. In the same way that disease management applications were said to be capable of *de facto* diagnoses, these research apps may draw subtle associations between symptoms and illness. In doing so, they may fall under the ambit of the penal liability regimes we have described. More importantly, however, the aim of some of these applications to form the groundwork for future remote diagnosis is worth special attention. To the extent that they will eventually be able to do so, they will plainly be suspected of infringing the reserved acts we have described.

Conclusion

In this section, we have claimed that a number of applications may have functions that fall within the scope of the control of diagnosis under the law of Quebec and Ontario. Association applications such as *WebMD* and *Ada* have the most clearly diagnostic functions, and would be the most plausible candidates for penal prosecution. That said, we have been adamant in our suggestion that such prosecution is not especially likely to occur. Though our legal analysis indicates that these applications may fall under the ambit of prohibitions against diagnosis, these technologies certainly differ from cases in which unlicensed persons engage in regulated medical practice. Importantly, the general perception of mobile health applications is likely quite different than the practice of medical quackery. In addition, mobile health apps such as *WebMD* might often be points of entry into the healthcare system. Upon researching their symptoms on a mobile application, patients may be more likely to thereafter consult a physician. This lends itself to the consultative process supported in the *Spurrell* case in Ontario. Such

¹²⁴ Tourraine, *supra* note 89.

¹²⁵ NYU Langone Medical Center, *Concussion Tracker* (2016), <http://nyulangone.org/apps/concussion-tracker-app> (accessed July 20, 2017) [Concussion Tracker].

¹²⁶ As we mentioned earlier, many of the research applications we will describe in this article are not yet open to participation from residents of Quebec. As such, the problems we present here will be essentially theoretical. It is, however, likely that such applications (or similar applications) will at some point be available to participants in Quebec. See Sage Bionetworks, *mPower: Mobile Parkinson Disease Study* (2015), <http://parkinsonmpower.org/> (accessed July 20, 2017) [mPower].

¹²⁷ *Id.*

¹²⁸ Oregon Health & Science University, *Mole Mapper* (2016), <http://www.ohsu.edu/xd/health/services/dermatology/war-on-melanoma/mole-mapper.cfm> (accessed July 20, 2017) [Mole Mapper].

¹²⁹ *Id.*

Table 2. Diagnostic Capability of Mobile Health Technologies.

<i>Technology Classification</i>	<i>Examples</i>	<i>Proposed Diagnostic Capacity</i>
(1) General health and wellness information applications	<i>Smoke Free</i>	Diagnosis technically possible , for example, where symptom lists are suggestive of organ health
(2) Illness prevention and management applications	<i>Dr K's Breast Checker, Asthma MD.</i>	Diagnosis technically possible
(3) Tracking, logging, and trending applications	<i>Nike + Run Club, MySugr Diabetes Logbook (Fitbit)</i>	Diagnosis technically possible , especially where an application concerns a single specific disease and records measurements of symptoms associated with that disease. Diagnosis is less likely where an application simply records general fitness data, though possible after data assessment
(4) Association applications	<i>WebMD, Ada</i>	Diagnosis probable
(5) Research applications	<i>Concussion Tracker, Mole Mapper, mPower</i>	<i>De facto</i> diagnosis probable

a process, involving app developers, professional associations, and legislators, could be preferable to heavy-handed penal prosecution.

But whether or not prosecution will occur on the framework we have described, application developers should be attentive to the legal problem we have posed in this section. Apps that provide health information are becoming increasingly popular and sophisticated. They are returning more information to a greater number of users than ever before. As they do the line between innocuous health information and smartphone-enabled diagnosis becomes increasingly blurred. It will be worth attending to the diagnostic functions of health apps as the legal and policy frameworks in which they are situated continue to coalesce. In the following section, we will respond to several potential objections to the argument we have presented here. Table 2 summarizes the arguments we have presented in this section, drawing attention to the categories of application we believe can plausibly be understood to have diagnostic functions.

DISCUSSION

To be sure, the argument we have made above may not be especially intuitive. It relies on a fairly mechanical application of law and engages with a number of ongoing policy debates about the role of consumer technologies in modern healthcare. There is, in other words, an important normative dimension to the concerns we have raised

above. In this portion of the paper, we will sketch out some of these considerations, outlining several prominent concerns that might be raised in response to the diagnostic capacities of mobile health applications. Beyond that, several powerful objections to our argument may be raised. We will outline and respond to three of them.

Regulation

We have suggested above that prosecution for the development of health apps with diagnostic functions may not occur. We have nevertheless claimed that the state of the law governing the use of such applications is poorly understood, potentially introducing confusion into the use and development of these technologies in the healthcare context. Beyond that, we have made the normative claim that the use of mobile health apps may entail certain risks, especially in light of the present absence of regulation.¹³⁰ Such risks have been pointed out elsewhere in the literature and include potential dangers to safety and privacy.¹³¹ Application-facilitated diagnoses may similarly have the effect of unnecessarily increasing patient anxiety.¹³² Perhaps more directly relevant to our purposes, however, is the concern that mobile apps will communicate health information that is incomplete or is not evidence-based.¹³³ This and other concerns could potentially be addressed through directed oversight or regulation.¹³⁴ For example, the state could choose to require that mobile health applications undergo some process of formalized review before being made available to the public.¹³⁵ Such an approach, of course, would be administratively complex. As we have seen, the number of health applications currently on the market is quite high and is expected grow. The level of expenditure that would be required may outweigh the risks that these applications pose. Moreover, it may be that heavy-handed regulation will adversely affect innovation,¹³⁶ leading to a reduction in potentially useful technology development.

Adding to these considerations is the fact that many mobile health apps have *beneficial* effects. A number of apps, for example, hold promise for assisting in the management of chronic disease¹³⁷ or for facilitating interactions with the healthcare system in general.¹³⁸ It could also plausibly be said that access to mobile health applications will have generally positive effects on patient empowerment and health literacy.¹³⁹ By providing broad access to healthcare information and management tools, mobile health apps could be seen to have a positive, democratizing impact on the delivery of healthcare. Such benefits should be weighed against the dangers that these technologies pose.

¹³⁰ See Nathan G. Cortez et al., *FDA Regulation of Mobile Health Technologies*, 4 *NEW ENG. J. MED.* 371 (2014).

¹³¹ See eg Eng & Lee, *supra* note 11; Cortez et al., *supra* at 130; Emily Knight et al., *Public Health Guidelines for Physical Activity: Is There an App for that? A Review of Android and Apple App Stores*, 3 *JMIR.MHEALTH.UHEALTH* 43 (2015).

¹³² See Thomas A. Fergus, *Cyberchondria and Intolerance of Uncertainty: Examining When Individuals Experience Health* *CYBERPSYCHOL. BEHAV. & SOC. NETW.* 735 at 735 (2013). See also, Jon Stone & Michael Sharpe, *Internet Resources for Psychiatry and Neuropsychiatry*, 10 *J. NEUROL. NEUROSURG. & PSYCHIATRY* 10–12 (2003).

¹³³ Knight et al., *supra* note 131.

¹³⁴ See Cortez et al., *supra* note 130, at 377.

¹³⁵ *Id.*

¹³⁶ Terry & Wiley, *supra* note 10, at 4; Compare Cortez et al., *supra* note 130.

¹³⁷ Eng & Lee, *supra* note 11; Sarcona et al., *supra* note 9.

¹³⁸ See Chen et al., *supra* note 9.

¹³⁹ See eg Joy Goldsmith et al., *Plain Language and Health Literacy for the Oncology Family Caregiver: Examining an English/Spanish mHealth Resource*, 33 *SEMIN. ONCOL. NURS.* 498 (2017).

In the end, however, the legal indeterminacy that we have identified in this paper, and which has been identified by others,¹⁴⁰ warrants clarification. To the extent that regulation might stifle regulation, it may also be the case that legal uncertainty will have the same effect. For this reason, we argue that this issue should be addressed. Whether the legislator should choose to exempt mobile health apps from general prohibitions on non-physician diagnosis or introduce regulations that ensure the scientific validity of these applications is, in our view, open to debate. But it is beyond the scope of this paper to adequately take a position. A final determination about the most appropriate response to the legal vacuum that surrounds diagnosis and health applications demands a fulsome accounting of the numerous normative considerations we have presented above.

App Development Involving Physicians

We will now turn to several objections that could reasonably be made against the argument we have presented here. The first of these turns on the view that the applications most directly suspected of performing diagnostic functions typically have physician advisors on their staff. If the developers and researchers of health apps are medical doctors, then it becomes somewhat strained to say that diagnoses delivered by the relevant applications were delivered outside the contours of the reserved acts. This argument may face two compelling replies. For one thing, it is unclear that reservations of diagnosis (in Quebec) and reservations of the communication of diagnosis (in Ontario) may legally be applied by physicians acting through an electronic medium over which their supervision is likely to be impermanent. Put another way, physicians who assist in application development will typically have no clinical contact with patients who receive diagnoses. Even if physicians could be understood to deliver diagnoses mediated by health applications, such diagnosis would be something of a departure from the normal course of clinical practice. At minimum, smartphone-facilitated diagnosis should prompt the careful consideration of the effects such healthcare delivery would have on our usual conceptions of the practice of medicine. For another thing, the law surrounding reserved acts typically requires that physicians and other healthcare professionals be members of the professional associations of the province in which the relevant statute applies. For example, physicians must be members of the Collège des médecins du Québec in order to practice medicine in that province.¹⁴¹ Thus, while app development may involve physician input, such physicians may nevertheless not be permitted to give or communicate diagnoses in the relevant jurisdiction. The issue thus becomes one of professional *delegation*. Whether physicians and other professionals may delegate diagnosis to health apps is a question beyond the scope of this paper. For now, it may be sufficient simply to say that, far from solving the issues we have described above, the physician involvement in app development is instead a further layer of complication.

Conflating Research and the Clinic

Earlier, we argued that the breadth of the definition of diagnosis in the law of Quebec and Ontario implies that essentially all of the research applications for which diagnosis is not a prerequisite for enrollment will perform *de facto* diagnoses. This being the

¹⁴⁰ See eg Terry & Wiley, *supra* note 10.

¹⁴¹ Medical Act, *supra* note 7, at arts. 1(a), 1(c), and 1(g).

case, we may worry that the traditional divide between research and the clinic is being blurred. Put another way, technologies for conducting medical research simply cannot be performing diagnoses. Diagnosis is a clinical activity, entirely outside of the scope and mandate of research. Participants in these studies, we could say, understand that they not being provided medical counsel.¹⁴²

The research-clinic divide, however, is already quite porous.¹⁴³ For example, the longstanding demand that renewed consent be obtained for the use of medical care samples in research had, by the midpoint of the last decade, already began to fade from international normative frameworks.¹⁴⁴ Newborn bloodspot samples are an even more salient case. Blood samples are often drawn from infants shortly after birth, with a small portion dried onto filter paper for laboratory use.¹⁴⁵ These samples are then used for the pre-symptomatic detection of a variety of diseases and conditions.¹⁴⁶ A portion of the collected blood is usually residual to such testing, and is instead held in reserve for future health research.¹⁴⁷ Bloodspot sampling, while of clear clinical application, is also concurrently of notable research interest. In fact, it could plausibly be said that the practice is at once directed by *both* clinical and research aspirations. All of this is to say that a firm boundary between research and the clinic is often difficult to outline conceptually. Clinical results are of interest to health researchers just as research data may be of clinical significance. It should not, therefore, surprise us that health research applications could have implications for diagnosis.

Implausibility

A final objection to the kind of argument we have presented in this paper tries to point out that its logic, carried to its conclusion, suggests that we may be surrounded by illegal diagnoses. In this view, not only are mobile health technologies possibly subject to the penal liability regimes in Quebec and Ontario, but so too may be relatively innocuous websites and textbooks. The *WebMD* app, which we have discussed in detail, is mirrored in function by its online counterpart. The *WebMD* webpage does many of the same things as the application. Most importantly, the online ‘symptom checker’ is very nearly identical.¹⁴⁸ It is thus no great stretch to say that, to the extent that *WebMD* and applications like it diagnose disease, their web-based equivalents may be doing the same. Other websites, presumably, do similar things. In our reasoning, associations drawn between symptoms and illness will constitute diagnosis no matter where they take place, and we may worry about how far this thinking extends.

¹⁴² Importantly, this argument applies exclusively to the research application category. As such, it is the narrowest of the objections we will present in this section.

¹⁴³ Susan M. Wolf et al., *Mapping the Ethics of Translational Genomics: Situating Return of Results and Navigating the Research-Clinical Divide*, 43 J. L. MED. & ETHICS 486 at 486 (2015). See also Martin Boeckhout & Conor M. W. Douglas, *Governing the Research-Care Divide in Clinical Biobanking: Dutch Perspectives*, 11 LIFE SCI. SOC. & POL’Y (2015).

¹⁴⁴ Bartha Maria Knoppers, *Biobanking: International Norms*, 33 J. L. MED. & ETHICS 7 at 8 (2005).

¹⁴⁵ Shannon Cunningham et al., *Public Concerns Regarding the Storage and Secondary Uses of Residual Newborn Bloodspots: An Analysis of Print Media, Legal Cases, and Public Engagement Activities*, 6 J. COMMUN. GENET. 117 at 117 (2015).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ See WebMD Symptom Checker, <http://symptoms.webmd.com/default.htm#introView> (accessed July 20, 2017).

There are many websites, for example, that provide health information in some form. Medical textbooks, similarly, are relatively widely available. For some, the argument we have presented implies that such websites and books would be just as susceptible to penal charges as mobile health technologies. After all, these health resources certainly permit their users to make determinations about, and draw connections between, disease and symptoms. But this view neglects important differences between the kinds of proposed diagnoses under consideration. While many of the applications we have discussed synthesize data, prepare performance reports, and draw tacit inferences to specific illnesses, textbooks and health information websites typically do not. These resources are inherently inactive. Diagnosis, conceived as an activity, surely consists of more than simply providing impersonal data that could *accidentally* be relevant to the health of the person reading it. It is implausible to say that a textbook entry that describes the symptoms of melanoma could qualify as a diagnosis in the event that someone with those symptoms should happen to read it. But, of course, the mobile health technologies we have been describing do substantially more than this. Research applications, as an example, tend to target their results to specific persons. They take personalized data entries or test results and generate implications about disease that apply uniquely to some identifiable person. This seems to be a relevant consideration. In the definition expressed by Baudouin, Deslauriers, and Moore, for example, diagnosis is ‘the opinion given by the physician on the state of *their patient*’.¹⁴⁹ This view, crucially, suggests that diagnosis applies directly to the health status of a particular person. A similar focus is evident in the jurisprudence we have encountered above. In each of those cases, the diagnosis that led to conviction was specifically targeted to an individual person. However broad they may have been in their medical conclusions, they were broad with respect to *someone*. From this, we may conclude that the technologies we have discussed in this paper differ from certain other potential diagnostic platforms in that the health conclusions they state or imply are made with reference to a person. They offer, in other words, more than merely general, untargeted information.

But even if this reasoning applied to health resources generally, nothing we have said in this paper should suggest that mobile health technologies are somehow the *only* sources of illegal diagnosis deserving legal consideration. Surely diagnosis can happen in other ways not sanctioned by law. Both existing and emerging technologies are almost certain to interact with medicine and healthcare—some, inevitably, will be able to diagnose disease. Our concern in this article has been to explore the possibility of penal liability for mobile health technologies, not to suggest that other platforms are immune from similar worry. But this should not qualify as an argument against the view we have presented here. The illegality of diagnosis is unaffected by the theoretical scope of liability.

CONCLUSION

Mobile health technologies are becoming ever more common and sophisticated. They have also, as we argue, become increasingly capable of diagnosing disease. Such capability takes a number of forms. Certain technologies explicitly link symptoms to disease. Others are subtler, performing what we have called *de facto* diagnoses, in which mobile

¹⁴⁹ BDM, *supra* note 46, at 2–72. Emphasis and translation ours.

app users are prompted to draw conclusions about their health status from associations facilitated by the application. Given that the law of Quebec and Ontario reserves diagnosis to healthcare professionals, such activity raises the possibility of penal sanction.

To be sure, this regime will strike some as extreme. We could worry that a very expansive range of health applications and devices will become susceptible to developer liability simply, in many cases, for providing information. But, as we have stressed throughout, this is by design. The net cast by the *Professional Code* is intentionally wide. Its role as a mechanism for protecting the public requires some degree of flexibility. And for all their ubiquity, health technologies may yet pose risks to the public. In the absence of a robust regulatory framework, for example, diagnoses will likely be inaccurate at least some portion of the time. The effects of error will be various. At their worst, false diagnoses may keep sick people from seeking medical care they have been made to believe is unnecessary. In a somewhat different way, mobile technology diagnoses may become a source of profound patient anxiety. Certain applications, after all, deliver diagnoses absent context and framing, without consideration of medical or family history, and offering no opportunity for directed and personalized tangible medical counsel. These features, taken together, underscore the compelling public protection objective that could be served by the prosecution of the illegal practice of medicine.

While we have focused on the law of Quebec and Ontario in this paper, much of what we have said is relevant for developing an understanding of the diagnostic functions of mobile health apps and their attendant policy implications in other jurisdictions. After all, the applications we have described here typically function in identical ways no matter where they are used. Thus, to the extent that they provide diagnostic information in these Canadian provinces, they are likely to do so in other jurisdictions as well. To be sure, the law surrounding diagnosis and its accompanying penal regime will not be constant across borders. It may be that these statutory approaches to regulating the practice of medicine is a unique case. Nevertheless, the principles underpinning our discussion are easily translatable. For one thing, both Quebec and Ontario adopt legal conceptions of diagnosis explicitly informed by common sense. In defining diagnosis as it does, these provinces law seeks to develop a regime that tracks what we instinctively think is constitutive of diagnostic activity. Even if the diagnostic functions of applications we have identified here do not fall within the ambit of legal frameworks in other jurisdictions, such functions will nevertheless be diagnostic in the intuitive sense. More concretely, if it is the case that a number of widely available mobile health applications have diagnostic functions, then many of the policy implications we have identified here persist irrespective of the specific legal consequences of app-enabled diagnosis. For example, worries about public safety and confidence in the utility of mobile health apps are not directly consequences of the penal liability regimes we have studied. Rather, they are broader concerns elucidated by the diagnostic capacities of the apps we have described. Distinct from this, the diagnostic functions of health applications are a source of opacity no matter the legal framework in which they are situated. The path forward for app developers is unclear when, on the one hand, their products have diagnostic functions and, on the other, the applicable regulatory landscape is poorly defined. Our view that health apps have diagnostic functions is part of a more general call for increased clarity in the legal framework surrounding this novel and powerful set of technologies.

Underscoring the prescient nature of these issues, and the urgent need for greater regulatory clarity, the American Medical Association (AMA) released a set of mobile health principles in late 2016.¹⁵⁰ The AMA underscores that these technologies are being increasingly integrated in clinical practice, that unsafe health apps potentially pose a danger to patient health, and that such apps are largely unregulated at present.¹⁵¹ Among other things, the AMA calls on its members to ensure that ‘delivery of any services via [an] app be consistent with state scope of practice laws’.¹⁵² Ensuring that the use of apps in the provision of healthcare does not exceed the legal limits of the practice of medicine is, so to speak, the problem we have been pointing to understood from an opposing perspective. While we have suggested that the use of applications may interfere with legal understandings of the practice of medicine, the AMA is, in effect, calling on physicians to ensure that they not use health apps in a manner that exceeds the scope of medical care permitted by law. We have a different, though complimentary concern: to suggest that app developers may have allowed for interference with the legally provided scope of medical care reserved to physicians. The AMA’s statement of principles on health applications thus underscores worries analogous to our own. As more work is done on these issues, a deeper understanding of the relationship between novel health technologies and the practice of medicine will, we hope, begin to emerge.

If recent trends tell us anything, it is quite likely that the mobile health technologies we have considered here will only continue to grow in popularity. Their use in the practice of medicine will, correlatively, also continue to expand. Our goal in this article has not been to condemn mobile health technologies—far from it. Rather, it has been to point out that their use as medical tools, considering how fundamentally they promise to affect modern medicine, has thus far been left relatively unexamined. At present, these technologies operate in an unclear and poorly defined legal space. On the one hand, they exist without regulatory oversight and on the other hand, their potential diagnostic functions may be, on a technical reading of the law in certain jurisdictions, sufficient to constitute a penal offense. And even where penal liability is not possible, such functions interact with medical practice in ways yet to be fully grappled with either by professional associations or regulators. We suggest that this situation is untenable, both in light of the increasing centrality of these apps in modern healthcare and their growing consumer popularity and economic value.

As we have said, it is unclear what legislative or regulatory approach, if any, should be taken in response to the circumstance we have described. As we hinted at above, one regulatory response could be to approach health app regulation with an approval process that calls on healthcare professionals to review application functions before they are marketed to the public. A system in which the scientific validity of these technologies can be assured would protect public safety while, at the same time, work to increase confidence in their medical utility. But this approach would be administratively complex and would potentially stifle app innovation. An alternative solution could be legislative clarification of the law of diagnosis, most likely by amending its scope in a

¹⁵⁰ American Medical Association, News Release *AMA Adopts Principles to Promote Safe, Effective mHealth Applications* (Nov. 16, 2016), <https://www.ama-assn.org/ama-adopts-principles-promote-safe-effective-mhealth-applications> (accessed July 20, 2017) [AMA].

¹⁵¹ *Id.*

¹⁵² *Id.*

manner that eliminates the possibility of penal prosecution of application developers. In any case, it is, in our view, integral that medical associations, regulators, and developers take the potential diagnostic functions of health applications seriously. We hope that this article will contribute to a conversation that leads to a clarification of the legal and policy status of these technologies. Until then, many such technologies will continue going about their business, offering as they do, diagnoses prohibited by the law of Quebec and Ontario.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the financial support of Le Fonds de partenariat pour un Québec innovant et en santé (FPQIS) through the Quebec – Clinical Research Organization in Cancer (Q-CROC).

APPENDIX

*FDA Guidance for Industry and Food and Drug Administration Staff on Mobile Medical Applications*¹⁵³

Applications removed because of inherent interactions with healthcare professionals:

- Mobile apps that guide a user through a questionnaire of signs and symptoms to provide a recommendation for the type of healthcare facility most appropriate to their needs.
- Mobile apps that record the clinical conversation a clinician has with a patient and sends it (or a link) to the patient to access after the visit.
- Mobile apps that are intended to allow a user to initiate a pre-specified nurse call or emergency call using broadband or cellular phone technology.
- Mobile apps that enable a patient or caregiver to create and send an alert or general emergency notification to first responders.
- Mobile apps that provide patients a portal into their own health information, such as access to information captured during a previous clinical visit or historical trending and comparison of vital signs (eg body temperature, heart rate, blood pressure, or respiratory rate).
- Mobile apps that meet the definition of MDDS and connect to a nursing central station and display medical device data to a physician's mobile platform for review. Product code: OUG (21 CFR 880.6310).
- Mobile apps that are not intended for diagnostic image review such as image display for multidisciplinary patient management meetings (eg rounds) or patient consultation (and include a persistent on-screen notice, such as 'for informational purposes only and not intended for diagnostic use'). Such devices would be considered medical image communications devices under 21 CFR 892.2020, product code LMD.
- Mobile apps for providers that help track or manage patient immunizations by assessing the need for immunization, consent form, and immunization lot number.

¹⁵³ FDA Guidance, *supra* note 75.

- Mobile apps that enable, during an encounter, a healthcare provider to access their patient's personal health record (health information) that is hosted on a web-based or other platform.

Applications not otherwise categorized:

- Mobile apps that transfer, store, convert formats, and display medical device data without modifying the data and do not control or alter the functions or parameters of any connected medical device (ie mobile apps that meet the definition of MDDS under 21 CFR 880.6310).

(1) *General health and wellness information applications:*

- Mobile apps that provide periodic educational information, reminders, or motivational guidance to smokers trying to quit, patients recovering from addiction, or pregnant women.
- Mobile apps that prompt a user to enter which herb and drug they would like to take concurrently and provide information about whether interactions have been seen in the literature and a summary of what type of interaction was reported.
- Mobile apps that prompt the user to manually enter symptomatic, behavioral, or environmental information, the specifics of which are pre-defined by a healthcare provider, and store the information for later review.
- Mobile apps that use patient characteristics such as age, sex, and behavioral risk factors to provide patient-specific screening, counseling, and preventive recommendations from well-known and established authorities.
- Mobile apps that provide drug–drug interactions and relevant safety information (side effects, drug interactions, active ingredient) as a report based on demographic data (age, gender), clinical information (current diagnosis), and current medications.
- Mobile apps that aggregate and display trends in personal health incidents (eg hospitalization rates or alert notification rates).

(2) *Illness prevention and management applications:*

- Mobile apps that help patients with diagnosed psychiatric conditions (eg post-traumatic stress disorder, depression, anxiety, obsessive compulsive disorder) maintain their behavioral coping skills by providing a 'Skill of the Day' behavioral technique or audio messages that the user can access when experiencing increased anxiety.
- Mobile apps that use GPS location information to alert asthmatics of environmental conditions that may cause asthma symptoms or alert an addiction patient (substance abusers) when near a pre-identified, high-risk location.
- Mobile apps that use video and video games to motivate patients to do their physical therapy exercises at home.

- Mobile apps that help asthmatics track inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers of asthma attacks.
- Mobile apps that provide pre-diabetes patients with guidance or tools to help them develop better eating habits or increase physical activity.
- Mobile apps that display, at opportune times, images or other messages for a substance abuser who wants to stop addictive behavior.
- Mobile apps that provide oral health reminders or tracking tools for users with gum disease.
- Mobile apps that keep track of medications and provide user-configured reminders for improved medication adherence.

(3) *Tracking, logging, and trending applications:*

- Mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health, or wellness, such as those that
 - provide tools to promote or encourage healthy eating, exercise, weight loss, or other activities generally related to a healthy lifestyle or wellness;
 - provide dietary logs, calorie counters, or make dietary suggestions;
 - provide meal planners and recipes;
 - track general daily activities or make exercise or posture suggestions;
 - track a normal baby's sleeping and feeding habits;
 - actively monitor and trend exercise activity;
 - help healthy people track the quantity or quality of their normal sleep patterns;
 - provide and track scores from mind-challenging games or generic 'brain age' tests; or provide daily motivational tips (eg via text or other types of messaging) to reduce stress and promote a positive mental outlook;
 - use social gaming to encourage healthy lifestyle habits;
 - calculate calories burned in a workout.
- Mobile apps that allow a user to collect, log, track, and trend data, such as blood glucose, blood pressure, heart rate, weight, or other data from a device to eventually share with a health care provider, or upload it to an online (cloud) database, personal or electronic health record.

(4) *Association applications:*

- Mobile apps that use a checklist of common signs and symptoms to provide a list of possible medical conditions and advice on when to consult a healthcare provider.