Canadian Journal of Bioethics
Revue canadienne de bioéthique

Online Therapeutic Portals for Sharing Health Research: Comparative Guidance amid Regulatory Uncertainty

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Cite this article

Lang, M. & Zawati, M. H. (2023). Online Therapeutic Portals for Sharing Health Research: Comparative Guidance amid Regulatory Uncertainty. *Canadian Journal of Bioethics / Revue canadienne de bioéthique*, *6*(2), 66–75. https://doi.org/10.7202/1101129ar

Article abstract

Online resources offer a uniquely efficient way of sharing health research with scientists and the public. Using web portals to make results and study information available to diverse audiences could work to accelerate research translation and empower patients to play a more active role in their care. But using online tools to broadly share health information raises several challenging ethical and regulatory questions. Issues such as equity, privacy, and patient empowerment may create challenges for regulators, portal developers, as well as researchers. It is additionally unclear whether web portals designed to facilitate access to research results and general health information will be regulated as medical devices under emerging regimes that control software with medical purposes. This paper aims to comparatively address whether online therapeutic portals for sharing health research are likely to be regulated in Canada, the United States, the United Kingdom, and France. We find that though these jurisdictions have each taken recent steps to regulate software as medical devices, the applicable regimes will generally not capture online portals for sharing health research. Though online portals for sharing health research are probably unregulated in many (if not most) jurisdictions, agencies have nevertheless signalled their concerns regarding several important ethical considerations (such as equity, transparency, and safety), to which portal developers and researchers should be attentive and respond. We describe here one set of issues highlighted by regulators – that is, efficiency, equity, transparency, confidentiality, communication, empowerment, training, and safety & efficacy – and consider how to best guide the design of online portals in a context of regulatory uncertainty.

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ARTICLE (ÉVALUÉ PAR LES PAIRS / PEER-REVIEWED)

Online Therapeutic Portals for Sharing Health Research: Comparative Guidance amid Regulatory Uncertainty

Michael Lang[a], Ma'n H. Zawati[a]

Résumé

Les ressources en ligne offrent un moyen particulièrement efficace de partager la recherche en santé avec les scientifiques et le public. L'utilisation de portails web pour mettre les résultats et les informations sur les études à la disposition de divers publics pourrait accélérer l'application des résultats de la recherche et permettre aux patients de jouer un rôle plus actif dans leurs soins. Cependant, l'utilisation d'outils en ligne pour partager largement des informations sur la santé soulève plusieurs questions éthiques et réglementaires délicates. Des questions telles que l'équité, la protection de la vie privée et l'autonomisation des patients peuvent poser des problèmes aux organismes de réglementation, aux concepteurs de portails et aux chercheurs. En outre, il n'est pas certain que les portails web conçus pour faciliter l'accès aux résultats de la recherche et aux informations générales sur la santé soient réglementés en tant que dispositifs médicaux dans le cadre des régimes émergents qui contrôlent les logiciels à des fins médicales. Le présent document a pour but d'examiner de manière comparative si les portails thérapeutiques en ligne destinés au partage de la recherche en matière de santé sont susceptibles d'être réglementés au Canada, aux États-Unis, au Royaume-Uni et en France. Nous constatons que, bien que ces juridictions aient toutes pris des mesures récentes pour réglementer les logiciels en tant que dispositifs médicaux, les régimes applicables n'englobent généralement pas les portails en ligne destinés au partage de la recherche en matière de santé. Bien que les portails en ligne pour le partage de la recherche en santé ne soient probablement pas réglementés dans de nombreuses juridictions (si ce n'est la plupart), les agences ont néanmoins fait part de leurs préoccupations concernant plusieurs considérations éthiques importantes (telles que l'équité, la transparence et la sécurité), auxquelles les développeurs de portails et les chercheurs doivent être attentifs et répondre. Nous décrivons ici un ensemble de questions soulignées par les régulateurs – à savoir l'efficacité, l'équité, la transparence, la confidentialité, la communication, la responsabilisation, la formation, la sécurité et l'efficacité – et examinons comment guider au mieux la conception des portails en ligne dans un contexte d'incertitude réglementaire.

Abstract

Online resources offer a uniquely efficient way of sharing health research with scientists and the public. Using web portals to make results and study information available to diverse audiences could work to accelerate research translation and empower patients to play a more active role in their care. But using online tools to broadly share health information raises several challenging ethical and regulatory questions. Issues such as equity, privacy, and patient empowerment may create challenges for regulators, portal developers, as well as researchers. It is additionally unclear whether web portals designed to facilitate access to research results and general health information will be regulated as medical devices under emerging regimes that control software with medical purposes. This paper aims to comparatively address whether online therapeutic portals for sharing health research are likely to be regulated in Canada, the United States, the United Kingdom, and France. We find that though these jurisdictions have each taken recent steps to regulate software as medical devices, the applicable regimes will generally not capture online portals for sharing health research. Though online portals for sharing health research are probably unregulated in many (if not most) jurisdictions, agencies have nevertheless signalled their concerns regarding several important ethical considerations (such as equity, transparency, and safety), to which portal developers and researchers should be attentive and respond. We describe here one set of issues highlighted by regulators – that is, efficiency, equity, transparency, confidentiality, communication, empowerment, training, and safety & efficacy – and consider how to best guide the design of online portals in a context of regulatory uncertainty.

Mots-clés
réglementation, éthique, portails web, information sur la santé

Keywords
regulation, ethics, web portals, health information

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INTRODUCTION

Tremendous developments in medicine and health research have been prompted by the rise and proliferation of the Internet (1). Medicine is being increasingly digitized, with new technologies ranging from wearable devices to AI-powered decision models greatly affecting how healthcare is delivered. Wearable devices, for example, give patients unprecedented capacity to measure and record personal health data, some of which might have clinical utility. Artificial intelligence may revolutionize how medical care is delivered, promising more efficient and accurate diagnosis, more directly tailored treatment, and more effective resource allocation.

Online portals are one example of a potentially helpful innovation that can facilitate patient access to personal medical information and to new ways of managing care. While scholars have commented extensively on ethical and policy issues

related to patient portals – online tools designed primarily for improving hospital administration, tracking prescriptions, and engaging with clinical care staff (2) – the effects of online tools that translate health research into clinical practice have been a more minor focus. This paper contributes to an emerging dialogue on *therapeutic portals*, a class of online portal intended to facilitate access on the part of clinicians and patients to information and research results related to a specific disease or family of diseases and which promote the uptake of novel research findings in clinical care. We argue in this paper that emerging Internet-enabled medical tools raise numerous ethical challenges, from confidentiality to patient empowerment, from equity to safety. Such tools also fall into an apparent regulatory lacuna. While online portals might have significant clinical utility, they are not obviously subsumed under the ambit of software that has a medical purpose as it is conceived in regulation and guidance. At the same time, regulatory materials either do not define medical software or provide definitions broad enough to capture online portals. This could suggest that such portals *are* or *may soon be* subject to regulatory oversight. This paper examines the contours of this lacuna and highlights that, even in the absence of explicit regulation, portal developers may find ethical guidance in emerging regulatory documents.

In a recent contribution, we defined therapeutic portals as "web portals designed to aggregate health research findings and make them available to a diverse array of researchers, clinicians, and the general public." (3) The language of *therapeutic* portals, as contrasted with *patient* portals, was intended to capture the idea that the sharing of research findings via online resources in the context of complex disease may have therapeutic application in the sense that clinicians might use such tools to inform patient care and patients might use them to better understand a course of therapy to which they are subject. In this sense, the possible adoption of therapeutic portals is situated within a larger move toward learning healthcare systems, in which health research and therapy are mutually supportive. We approached this prior work in the context of a therapeutic portal within the ambit of "a biobank-based study to identify prognostic markers and therapeutic targets for Acute Myeloid Leukemia." (4) Cancer genomics research is fertile ground for thinking about the ways online tools might contribute to information sharing among diverse stakeholders (3). While researchers and clinicians likely have an obviously significant interest in easily accessing research findings (5), patients and the public at large could also draw considerable benefit from engaging with online resources that communicate emerging scientific consensus and that document relevant novel results.

Though therapeutic portals as we describe them may not appear to be medical devices or medical software in any *colloquial* sense, we suggest that regulators define these concepts quite broadly, potentially admitting these new tools into the ambit of existing regulation. We specifically engage with the normative frameworks of Canada, the United States, the United Kingdom, and France as a way of sketching out significant issues for the development and adoption of therapeutic portals. We do this by assessing guidance documents and government reports intended to guide software developers and regulatory agents. In each of the jurisdictions we review, medical devices are regulated by national agencies applying a risk-based classification model in which devices most likely to cause harm are subject to the most stringent premarket oversight and reporting requirements (6-9). These risk-based regulatory models are responsive to a range of potential harms and ethical challenges. In one vein, medical software presents the clear risk of physical harm to patients: erroneous or misleading information can lead directly to misdiagnosis, unsuitable intervention, or overtreatment. In a related vein, ethical challenges around the way internet-mediated clinical tools manage patient confidentiality, promote empowerment, and implicate health equity, demand particular attention.

Regulatory agencies in Canada, the United States, the United Kingdom, and France have in recent years contemplated whether software, including perhaps Internet-based tools, might be subject to existing regulatory regimes for medical devices, a development often referred to as "software as medical devices" or SaMD (10). Regulators have generally not implemented specific interpretive frameworks for the review and approval of medical software applications and Internet-powered tools; instead, faced with these emerging technological developments, they have outlined in non-binding guidance documents broad principles for the exercise of regulatory authority. To be more precise, in the case of therapeutic online portals, we know of no regulatory or legislative instrument that explicitly and directly contemplates these technologies. Formal law, in other words, leaves unanswered the question of how medical software will be regulated – from standalone computer programs to integrated applications and online platforms that may be used for clinical function. This is left to regulatory guidance and government reports, which to varying degrees clarify how agencies have been thinking about the regulation of medical software. Though not properly binding, these instruments help to structure and constrain medical software and online platform development and implementation. Until more targeted guidance or regulation is developed, this kind of agency commentary effectively operates as the most authoritative indication of the manner in which recently developed medical technologies will be regulated.

METHODS & MATERIALS

We set out to understand in broad terms how therapeutic portals might be influenced by the regulation of software as medical devices in Canada, the United States, the United Kingdom, and France. Our research question was the following: *what are the principal regulatory issues and considerations likely to be generated by the development and use of therapeutic web portals as expressed in regulatory agency guidance?* In addressing this question, we reviewed 20 documents prepared by regulatory agencies and related government entities on the oversight of software as medical devices. We first consulted the websites of each of the principal regulators responsible for the enforcement of medical device regulations in Canada (Health Canada: HC), the United States (Food & Drug Administration: FDA), the United Kingdom (Medicines and Healthcare products Regulatory Agency: MHRA), and France (Haute Autorité de Santé: HAS) to identify guidance documents related to the regulation of software as medical devices.

From there, we identified additional sources by consulting the websites of related government agencies for commentary on digital health. Finally, we used PubMed and WestLaw to identify academic sources discussing the regulation of software as

medical devices. We consulted references to regulatory guidance in these sources to identify additional government materials. A preliminary review included 41 documents that appeared to be responsive to the question of how online portals for the sharing of health research data may be regulated. Applying broadly flexible inclusion criteria, we selected 20 documents for review that 1) are issued by or on behalf of state agencies engaged in the regulation of medical devices and 2) that apply to the clinical use of Internet or software-based technologies. In interpreting these inclusion criteria, agency documents were understood to include reports and stakeholder consultation documents that may be instructive in understanding how therapeutic portals could ultimately be regulated. We found that regulators have not *directly* addressed the kinds of therapeutic portals we described above. But because these documents define medical software quite expansively, as we will describe in greater detail below, there may nevertheless be important lessons for the developers of Internet-powered resources for sharing medical information. Our present methodology is intended only to provide a preliminary overview of the regulatory landscape into which portal developers are likely to find themselves as they develop new kinds of approaches to data sharing.

We selected four Canadian documents, five documents from the United States, five documents from the United Kingdom, and four documents from France. Two of the documents included in our analysis are multilateral guidance documents, one of which is jointly agreed to by HC, FDA, and the MHRA. Though this particular document applies to the development of medical devices applying machine learning techniques, likely somewhat beyond our present focus on therapeutic portals, we have included this guidance for review due to the significance of multijurisdictional coordination on best practices for medical device development. Another is a definitional document issued by the International Medical Device Regulators Forum (IMDRF), a voluntary association of medical device regulators that includes HC, FDA, and the European Union's Directorate-General for Internal Market, Industry, Entrepreneurship, and SMEs (11). The IMDRF definitional guidance represents a major source of influence on the regulatory approaches taken in Europe, Canada, and the United States. The FDA, in fact, has adopted the IMDRF's clinical evaluation guidance in its entirety (12). Understanding how the IMDRF conceives of SaMD regulation is thus critical for understanding how therapeutic portals might be regulated in at least three of the jurisdictions under review. We excluded documents that were not responsive to both of the above criteria, namely that apply only to a specific set of medical practices, that are prepared by non-government entities, or that apply only to a specific set of medical professionals. We made this decision because such documents are unlikely to give an immediate sense of how therapeutic portals, as a broad category of Internet-based tools, may be regulated in the short-to-medium term. Documents prepared by thinktanks or non-profit organizations, for example, did not respond to our primary aim to understand whether and how therapeutic portals would be subject to direct regulatory oversight (sources are outlined in Table 1).

Table 1: Surveyed regulatory documents

Country	Document title	Issuing body	Document classification	Year
Canada	*Guidance Document: Software as a Medical Device (SaMD): Definition and Classification*	Health Canada	Regulatory guidance	2019
	What we heard: A summary of scanning and consultations on what's next for health product regulation	Health Canada	Consultation summary	2019
	Report from Canada's Economic Strategy Tables: The Innovation and Competitiveness Imperative: Health & Science	Innovation, Science and Economic Development Canada	Government report	2018
	Notice: Health Canada's Approach to Digital Health Technologies	Health Canada	Regulatory guidance	2018
United States	*Multiple Function Device Products: Policy and Considerations*	Food & Drug Administration	Regulatory guidance	2020
	Digital Health Innovation Plan	Food & Drug Administration	Government report	2020
	Clinical Decision Support Software	Food & Drug Administration	Draft regulatory guidance	2019
	Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics	Food & Drug Administration	Regulatory guidance	2018
	Software as a Medical Device (SaMD), Guidance for Industry and Food and Drug Administration Staff	Food & Drug Administration	Regulatory guidance	2017
United Kingdom	*A guide to good practice for digital and data-driven health technologies*	Department of Health & Social Care	Regulatory guidance	2021
	Consultation on the future regulation of medical devices in the United Kingdom	Medicines & Healthcare products Regulatory Agency	Government report	2021
	Guidance: Medical device stand-alone software including apps (including IVDMDs)	Medicines & Healthcare products Regulatory Agency	Regulatory guidance	2014, rev. 2021
	The future of healthcare: our vision for digital, data and technology in health and care	Department of Health & Social Care	Government report	2018
	What will new technology mean for the NHS and its patients?	Health Foundation, Institute for Fiscal Studies	Government report	2018
France	*Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care*	Haute Autorité de Santé	Regulatory guidance	2021
	Numérique: Quelle (R)évolution	Haute Autorité de Santé	Government report	2019
	National Health Strategy 2018–2022	Ministère des Solidarités et de la Santé	Government report	2018
	Stratégie nationale e-santé 2020	Ministère des Solidarités et de la Santé	Government report	2016
	Good Machine Learning Practice for Medical Device Development: Guiding Principles	Food & Drug Administration, Health Canada, and Medicines & Healthcare products Regulatory Agency	Multilateral guidance document	2021
	Software as a Medical Device (SaMD): Key Definitions	International Medical Device Regulators Forum	Multilateral guidance document	2013

In consideration of the research question posed above, our aim was not to fully define rules surrounding the regulation of software as medical devices, but rather to provide a preliminary snapshot of the ways regulators might be thinking of the issues this kind of regulation raises and to apply that snapshot to the case of therapeutic portals.

FINDINGS

Our principal findings revolve around the notion that regulators and agencies have enumerated a number of ethical considerations and issues to which the attention of software developers, patients, and the regulators themselves is drawn. We found eight issues that might have particular resonance for therapeutic portals (outlined in Table 2).

Table 2: Considerations for therapeutic portal regulation

Issue	Example treatment	Documents featuring discussion
Efficiency	"The regulatory system must be modernized, with the objective of ensuring that it serves as a catalyst for new products. A high-performing regulatory system should be predictable, efficient, consistent and transparent, so as not to present barriers to business investment, innovation and ultimately, economic growth and improved patient outcomes" (ISEDC, *Economic Tables*).	Canada (n=1): ISEDC, *Economic Tables*.
		United States (n=2): FDA, *Digital Health Innovation*; FDA, *Clinical Decision Support Software*.
		United Kingdom (n=3): DHSC, *Guide to good practice for digital and data-driven health technologies*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Numérique*; MSS, *National Health Strategy*; MSS, *Stratégie nationale e-santé*.
Equity	"[Digital health] technologies can improve access to health care information, facilitate more timely diagnoses and treatments, and improve access to care for patients at home, at health care facilities, as well as in rural and remote communities" (HC, *Notice*).	Canada (n=2): HC, *SaMD Guidance*; HC, *Notice*.
		United States (n=1): FDA, *Digital Health Innovation*.
		United Kingdom (n=2): DHSC, *guide to good practice for digital and data-driven health technologies*; DHSC, *Future of healthcare*.
Transparency	"Consultations revealed the importance of providing transparency around how classification decisions are made" (HC, *What we Heard*).	Canada (n=3): HC, *What we Heard*; ISEDC, *Economic Tables*; DHSC, *guide to good practice for digital and data-driven health technologies*.
		United States (n=2): FDA, *Multiple Function Device Products*; FDA, *Digital Health Innovation*.
		United Kingdom (n=2): DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Numérique*; MSS, *National Health Strategy*; MSS, *Stratégie nationale e-santé*.
Confidentiality	"We need to maintain a safe and secure data infrastructure that protects health and care services, patients and the public. The digital architecture of the health and care system needs to be underpinned by clear and commonly understood data and cyber security standards, mandated across the NHS, to ensure we are secure by default and that the penalties for data breaches are effective in protecting patients' privacy" (DHSC, *Future of healthcare*).	Canada (n=1): HC, *What we Heard*.
		United States (n=1): FDA, *Use of Public Human Genetic Variant Databases*.
		United Kingdom (n=4): ISEDC, *Economic Tables*; DHSC, *guide to good practice for digital and data-driven health technologies*; MHRA, *Guidance: Medical device stand-alone software*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=2): HAS, *Functional classification*; HAS, *Numérique*.
Communication	"If a technology needs to communicate with clinical systems to share data, it must comply with the relevant clinical, professional and technical standards. There are standards that create a common 'language' in the recording of healthcare data and digital health technologies must use these" (DHSC, *guide to good practice for digital and data-driven health technologies*).	United Kingdom (n=3): DHSC, *guide to good practice for digital and data-driven health technologies*; MHRA, *Guidance: Medical device stand-alone software*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Functional classification*; HAS, *Numérique*; MSS, *Stratégie nationale e-santé*.
Empowerment	"Digital health technologies can empower consumers to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life- threatening diseases, and management of chronic conditions outside of traditional care settings" (FDA, *Digital Health Innovation*).	Canada (n=2): ISEDC, *Economic Tables*; HC, *Notice*.
		United States (n=1): FDA, *Digital Health Innovation*.
		United Kingdom (n=1): DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=2): HAS, *Numérique*; MSS, *Stratégie nationale e-santé*.
		Multilateral (n=1): *Good Machine Learning Practice*.
Training	"FDA recognizes that many different types of genetics professionals may be involved in the curation and processes for evaluation as part of a team (e.g., genetic counselors, Ph.D.-level scientists, physicians). Adequate training and expertise of individuals evaluating variants plays an important role in the quality of variant review and evaluation" (FDA, *Use of Public Human Genetic Variant Databases*).	Canada (n=3): HC, *SaMD Guidance*; HC, *What we Heard*; ISEDC, *Economic Tables*.
		United States (n=2): FDA, *Use of Public Human Genetic Variant Databases*; FDA, *Guidance for Industry and Food and Drug Administration Staff*.
		United Kingdom (n=3): DHSC, *guide to good practice for digital and data-driven health technologies*; MHRA, *Guidance: Medical device stand-alone software*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Functional classification*; HAS, *Numérique*; MSS, *National Health Strategy*.
Safety & efficacy	"While stakeholders supported the need for oversight of these technologies, underscoring the importance of ensuring product safety and efficacy, they emphasized the need for it to be proportional with potential risks, benefits, uncertainties, and with consideration for the realities of providing frontline care. Stakeholders called for a flexible, risk-based approach that permits early or conditional market authorization while simultaneously ensuring robust ongoing product oversight, research, and surveillance" (HC, *What we Heard*).	Canada (n=4): HC, *SaMD Guidance*; HC, *What we Heard*; ISEDC, *Economic Tables*; HC, *Notice*.
		United States (n=4): FDA, *Multiple Function Device Products*; FDA, *Digital Health Innovation*; FDA, *Use of Public Human Genetic Variant Databases*; FDA, *Guidance for Industry and Food and Drug Administration Staff*.
		United Kingdom (n=4): DHSC, *guide to good practice for digital and data-driven health technologies*; MHRA, *Consultation on the future regulation of medical devices*; MHRA, *Guidance: Medical device stand-alone software*; DHSC, *Future of healthcare*; Health Foundation, *What will new technology mean for the NHS*.
		France (n=3): HAS, *Numérique*; MSS, *National Health Strategy*; MSS, *Stratégie nationale e-santé*.
		Multilateral (n=2): *Good Machine Learning Practice*; IMDRF, *SaMD*.

The eight issues briefly outlined here provide a good overview of the kinds of considerations about which regulators are concerned. Nine sources discuss concerns surrounding the capacity of digital tools to increase efficiency or the importance of efficiency of regulation of the same. Five documents describe concerns about the equity-relevant effects of digital health. Ten documents discuss transparency, 8 discuss confidentiality, and 6 include discussions about communications with patients and the public. Seven of the surveyed sources focus broadly on the capacity of digital tools to enhance patient and public empowerment; eleven involve discussions about user training. By far the most widely considered issue in the sources we reviewed, perhaps unsurprisingly, was safety and efficacy. Fully 17 of the 20 sources under review specifically addressed this theme. As the primary orienting purpose of medical devices regulation, we expected that most surveyed documents would in some measure consider how regulation and guidance can work to assure the safety and efficacy of digital health tools, including web portals. These points naturally do not reflect the entire scope of topics raised in the surveyed sources. Other observations, rules, and principles are considered in varying degrees throughout these documents. But the eight elements we describe here, and as we outline in further detail in the discussion below, reflect important consensus considerations for the developers and users of therapeutic portals.

While regulators appear sensitive to the ethical considerations that confront therapeutic portals, we also found that online portals for the sharing of health data are unlikely to be formally regulated under the existing regime. Regulatory agencies in each of the surveyed jurisdictions have signalled similar intentions to regulate software as medical devices when a manufacturer's intended function for a software system aligns with existing statutory definitions of the concept of a medical device. In Canada, for example, HC specifies that "when the intended or represented use of software is for one or more of the medical purposes set out in the definition of a device as stated in the [*Food & Drugs Act*], that software qualifies as a medical device." (6) The FDA takes a nearly identical approach, stating in its SaMD guidance that regulation is premised on whether a software system "meets one or more of the purposes described in the definition of a medical device." (7) MHRA guidance on standalone software likewise notes that systems with medical purposes are likely captured by the legal definition of a medical device (8). Following the European Union's Directive 93/42 (13), France similarly determines whether software is a medical device according to its manufacturer's intended purpose (9). Importantly, software intended to perform one or more medical purpose will generally not be treated under medical devices regimes if it merely operates as part of an independent hardware device, such as a medical imaging system (10). What constitutes a medical purpose is generally established in formal regulation and varies in small measure from jurisdiction to jurisdiction. Though we did not review these regulatory instruments directly, the subsidiary documents considered in this review give some idea of how regulators might assess medical purposes for software. SaMD must, in other words, function independently if it is to be regulated. In the language of several reviewed documents, it must be standalone (6). We outline how SaMD is defined in each of the reviewed jurisdictions in Table 3 below.

Table 3: Definitions of SaMD

Country	Definition of SaMD	Document title
Canada	The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.	HC, *Guidance Document: Software as a Medical Device (SaMD): Definition and Classification*
United States	The term "Software as a Medical Device" (SaMD) is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.	IMDRF, *Software as a Medical Device (SaMD): Key Definitions*; referenced by FDA on public webpage
United Kingdom	Software as a medical device (SaMD, being standalone software and software included in wider hardware) (including AI as a medical device (AIaMD)) has grown in market share and complexity. Increasingly it has applications in health and social care that could not have been envisioned when existing regulations around medical devices were developed.	MHRA, *Consultation on the future regulation of medical devices in the United Kingdom*
France	Indeed, not all the software and applications used in the field of health have [medical device] or IVDMD status. The qualification of a digital solution requires a case-by-case assessment based on the intended purpose and its specific features to characterise the medical intended use of the product.	HAS, *Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care*

This relatively cohesive approach signifies that online portals are likely to be regulated as medical devices only if they are intended by their manufacturer to perform *medical purposes* and are not otherwise functionally part of conventional device hardware.

In Canada, for example, HC notes that two factors influence assessments of medical purpose. A system is likely to be determined to have a medical purpose if it is used (a) to acquire, process, or analyze medical images or (b) to support or provide "recommendations to health care professionals, patients or non-healthcare professional caregivers about prevention, diagnosis, treatment, or mitigation of a disease or condition." (6) MHRA's guidance likewise sets out a list of factors that would militate for designation of a medical purpose. Software has a medical purpose in the United Kingdom if it functions, for example, to prevent, diagnose, monitor or treat a disease (8). Similar approaches are taken in France and the United States. The IMDRF notably includes in its definition of medical purpose – in addition to the points raised in Canada and the United Kingdom – functions related to supporting or sustaining life and the investigation, replacement, modification, or support of physiological processes (11). As above, we found that there is relatively widely distributed agreement that medical purposes relevant for the regulation of medical devices in the surveyed countries. Below, we explain in greater detail how these conceptions of medical purpose are likely to apply in the context of therapeutic portals for sharing health research findings with scientific communities and the public. From the outset, it is highly unlikely that therapeutic portals intended merely to function as a platform for facilitating access to non-specific experimental results would be interpreted by regulators to have a medical purpose. Table 4 outlines how regulators conceive of medical purpose in the surveyed countries.

Table 4: Definitions of medical purpose

Country	Definition of medical purpose	Document title
Canada	Health Canada generally interprets medical purposes as follows: • Intended to acquire, process, or analyze a medical image, or a signal from an in vitro diagnostic device or a pattern/signal from a signal acquisition system2 or imaging device, OR • Intended for the purpose of supporting or providing recommendations to health care professionals, patients or non-healthcare professional caregivers about prevention, diagnosis, treatment, or mitigation of a disease or condition.	HC, *Guidance Document: Software as a Medical Device (SaMD): Definition and Classification*
United States	The following [terms] as defined in GHTF/SG1/N71:2012 (*italics removed in this reproduction*) identify medical purpose applicable to SaMD: 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar *or* related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of: • Diagnosis, prevention, monitoring, treatment or alleviation of disease, • Diagnosis, monitoring, treatment, alleviation of or compensation for an injury, • Investigation, replacement, modification, or support of the anatomy or of a physiological process, • Supporting or sustaining life, • Control of conception, disinfection of medical devices, • Providing information by means of in vitro examination of specimens derived from the human body.	IMDRF, *Software as a Medical Device (SaMD): Key Definitions*; definition cited by FDA in *Software as a Medical Device (SaMD), Guidance for Industry and Food and Drug Administration Staff*
United Kingdom	A medical purpose is determined by what the manufacturer states in the device's labelling, instructions for use and any promotional materials. Has one or more of the following functions: • Prevention of disease, • Diagnosis of disease, an injury, or handicap, • Monitoring of disease, an injury, or handicap, • Treatment or alleviation of disease, an injury, or handicap, • Compensation for an injury or handicap, • Investigation, replacement, or modification of the anatomy or of a physiological process; control of conception.	MHRA, *Guidance: Medical device stand-alone software including apps (including IVDMDs)*
France	In order to be awarded MD or IVDMD status, the digital solution must have the following cumulative criteria: • Be intended for use for medical purposes in accordance with the MD or IVDMD definition. For example, it should enable diagnosis, diagnostic assistance, treatment, or treatment assistance, • Provide a specific result for the benefit of a single patient, • Carry out an action on input data, such as an analysis with a view to providing new medical information. For example, a data analysis application in respect of a patient's specific physiological signals and equipped with alert functions for medical intended use will be deemed to have MD status. This action must be different from storage, communication, or merely a search such as a database or a digital library incorporating data solely for the purposes of archival, without processing the data.	HAS, *Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care*

In considering the potential regulation of therapeutic portals, it is illuminating to note that many of the documents we surveyed communicate significant internal limits on the scope of the definition of medical purpose and, as a consequence, on the likely application of the regulations themselves. We found that France, for example, excludes from the ambit of medical purpose functions related to the communication of medical information (14). We likewise noted that HC's SaMD guidance describes sweeping exclusion criteria, according to which software may be specifically exempt from regulatory oversight, even if it performs a medical purpose (6). Software "that does not have a direct impact on the diagnosis, treatment, or management of an individual's disease, disorder, abnormal physical state or symptoms" will generally not be subject to regulation (6). HC's guidance lists four exclusion criteria, all of which must be satisfied for software that otherwise has a medical purpose to be excluded from formal oversight: 1) the software is not intended to acquire, process, or analyze a medical image or a signal from an IVDD, 2) the software is "intended to display, analyze, or print medical information about a patient or other medical information (such as demographic information, drug labelling, clinical guidelines, studies, or recommendations)," 3) the software is only intended to support decision-making about prevention, diagnosis, or treatment of a disease or condition, and 4) the software is not intended to replace the clinical judgment of a health professional (6). There is some lack of clarity in the way these exclusion criteria are formulated, particularly regarding the requirement that each of the four exclusion criteria must be met. In an annex to its guidance, HC addresses some of this confusion by providing examples of software excluded from regulatory oversight on this rubric. Notable for our purposes here, HC explicitly indicates that it plans not to regulate software enabling patients to track health information and software for collecting and storing health information as part of an electronic health record (15). These criteria might suggest that, even in the unlikely event that therapeutic portals perform medical purposes, they may be specifically excluded from regulatory oversight under emerging SaMD regimes.

Our principal finding here is that regulatory guidance applicable to SaMD in Canada, the United States, the United Kingdom, and France would likely exclude therapeutic portals from formal oversight as medical devices. This finding, as Tables 2 and 3 above suggest, is drawn from a small number of primary regulatory guidance on the regulation of SaMD. Supplementary sources provide additional context on the intentions of regulators with respect to SaMD oversight.

DISCUSSION

In reviewing the regulatory guidance documents outlined above, we noted that therapeutic portals are not likely to be regulated as medical devices under existing SaMD frameworks in Canada, the United States, the United Kingdom, and France. On one hand, therapeutic portals as we describe them above and in previous scholarship, will not generally have medical purposes. On the other hand, even for therapeutic portals with medical purposes, it may be that these are excluded from formal regulatory oversight insofar as they primarily operate to display or distribute health research information and are not intended to replace professional clinical judgment or to directly diagnose, treat, or manage illness. Just as medical software will have a wide range of purposes and functions, therapeutic portals will conceivably take numerous forms. Some of them will, in some jurisdictions,

likely have medical purposes as defined in regulation and guidance. But for the most part, the documents we survey here take the position that SaMD regulation does not apply to therapeutic portals. These sources nevertheless offer significant guidance about the kinds of issues and principles portal developers and users should address. Below, we examine briefly how each of these themes might be facultative for the development of therapeutic portals and other digital health technologies. We offer brief comments on how these considerations could be accounted for by portal developers and users.

Efficiency

Many of the documents we reviewed highlight the likely significant role Internet-enabled health tools will play in increasing the efficiency with which patients access health services and information about their care. The FDA's *Digital Health Innovation Plan*, for example, notes that software capable of assisting in diagnosis, treatment, and data management can "enable more efficient clinical practice." (16) In the UK, DHSC's *Guide to good practice for digital and data-driven health technologies* makes a similar point, suggesting that software developers should have a clear understanding of the role their technology is likely to play in accomplishing the broader social goal of achieving better healthcare, including in the achievement of greater system efficiency (17). Apart from the capacity of digital tools to make healthcare more efficient, several of the documents we reviewed also underscore the importance for regulators to build efficient regulatory responses to innovation, mechanisms that are transparent, predictable, and consistent (18). France's HAS makes a similar point, noting that governments have an interest in making investments in the development of health technologies that would create greater efficiencies in care delivery (19). In a related vein, Canada has signalled an intention to develop, by 2025, a digital health strategy that works to ensure efficient and interoperable digital health platforms (18).

Efficiency, then, is a complex and multilayered notion in the context of digital health, referring both to the capacity of digital tools to improve healthcare and the importance of regulation that does not impede efficient technological development. For our purposes, the former of these interpretations is likely the more significant, indicating that the developers of therapeutic portals should consider carefully how the technologies they implement may affect access to the healthcare system. While facilitating sweeping access to health information might generally be perceived to be in the public interest (20), for example, the details surrounding how such access is managed matter a great deal. Especially as public health systems become increasingly resource-strained, public access to personalized health information could have unpredicted effects. If such information is not presented accessibly and in sufficient context, it could have the effect of pushing portal users to seek unnecessary care to clarify or confirm information accessed online. Thus, while therapeutic portals have great potential to increase the efficiency of healthcare delivery, so too might poor design lead to a misuse of limited health system resources.

Equity

Equity is naturally a dominant consideration associated with how the sharing of information through a therapeutic portal might be managed. As above, this is a concern that can broadly be approached in two distinct ways. First, certain documents outline the potential for online tools to address existing health inequality. Health Canada's notice on its regulatory *Approach to Digital Health Technologies*, for example, suggests that digital health can help to address inequality of care access between rural and urban Canadians (21). In this mould, the availability of health information on a therapeutic portal might have the effect of promoting equality of care access, particularly in the case of rare or difficult to treat disease. Highly complex pathologies are often treated by highly trained specialist clinicians, many of whom may be located in urban centres, effectively unavailable to rural or Indigenous populations. An online therapeutic portal making diagnostic and treatment information widely available could work toward lessening the outcome effects of such disparity. Second, some of the documents we reviewed, rather than discussing the equity-advancing potential of digital health, focus on fair application of novel health tools. In the UK, DHSC's *Guide to good practice for digital and data-driven health technologies* stresses, for example, that technology developers should be "fair, transparent, and accountable about what data is being used." (17) In creating new SaMD, developers ought to be attentive to notion that everyone should be able to benefit more or less equally from the use of a publicly available digital system. It is, to be sure, one thing to state this as a principle, and quite another to put it into practice. Professional and regulatory guidance specific to publicly accessible therapeutic portals could begin to provide concrete direction in assuring equity in this context.

Transparency

Following the theme illustrated above, discussions surrounding transparency consist of two countervailing interpretations: one at the level of the implementation of digital health tools and another at the level of their regulation. First, some of the documents we surveyed refer to the importance of transparency in the communication of health information, especially when a digital system is empowered to make decisions that affect a clinical process. This is likely to become especially relevant as artificial intelligence plays a more focussed role in the management of health information. Following this perspective, the FDA recommends that database curators "make publicly available sufficient information regarding data sources and standard operating procedures." (22) Second, certain sources emphasize the value of transparent regulatory processes. This is a view taken by HC in its 2019 consultations, in which the agency notes a demand from stakeholders to provide transparency surrounding the classification of SaMD and other digital technologies (23). The UK's *Guide to good practice for digital and data-driven health technologies* ties transparency together with confidentiality and privacy, noting that "transparency will help to ensure that the rights of data subjects under the *Data Protection Act 2018* are maintained." (17) Insofar as therapeutic portals are designed for the benefit of clinicians, researchers, and patients alike, there may be particular pressures on their developers to ensure openness about how data is sourced and organized. Researchers, for example, will have a dominant interest in ensuring that information posted on a therapeutic portal is reliable and useful. Developers could work to promote

transparency by publishing raw data and relevant source code such that external observers could scrutinize a portal's functionality. To be sure, doing this will often be infeasible for intellectual property reasons. At minimum, portal developers should reference published research results where appropriate on the portal interface.

Confidentiality

We were not surprised to find significant discussion in the sources we reviewed on issues of confidentiality, privacy, and data protection. Much of the discussion straightforwardly revolved around the role of privacy regulation as a compliment to medical device regulations. Even in the absence of regulation under a SaMD regime, therapeutic portals and other digital technologies will generally be expected to comply with privacy legislation. The UK's DHSC, in its report on the future of healthcare, emphasizes this point by noting that "safe and secure data infrastructure that protects health and care services, patients and the public" is vital for the effective implantation of digital health (24). The FDA takes a similar view, underscoring that databases are unsurprisingly required to comply with "all applicable privacy laws and regulations." (22) In the case of therapeutic portals, and apart from the requirements of formal regulation, there may be strong ethical reasons to implement strong confidentiality practices. Considering the proposed public-facing nature of these kinds of portals, risks of data breach may be especially high. By a similar measure, maintaining public trust may be especially important. Strong privacy-protecting policies in compliance with applicable law and best practices may help on both measures.

Communication

We found limited, though important, discussion surrounding communication for emerging digital health technologies in the sources we reviewed. Discussion on this topic focussed largely on the ways digital tools can be used to increase and improve communication with a range of stakeholders. France's e-health strategy, for example, makes a point of mentioning that portals may be helpful in facilitating interactions between health systems and the public (25). The FDA signalled plans in its digital health strategy to develop additional regulatory guidance for researchers using online systems for patient communication (16). This kind of guidance, in the agency's view, would encourage "digital health innovation by redesigning our policies and processes and modernizing our tools so that they match the needs of digital health technology, and providing clarity on those policies and processes so that manufacturers and developers know what they need to do." (16) Though discussion surrounding the communication of health information was only a secondary theme in the sources we reviewed, it is in our view an important consideration in the context of the design and use of therapeutic portals. These kinds of portals, at least in our description of them, are after all fundamentally tools for the communication of research findings to a broad and diverse audience.

Empowerment

The documents we review here attended to the theme of empowerment in a relatively narrow frame. Much of the discussion focussed on empowerment as it relates to patients and users of digital health technologies. France's e-health strategy takes a fairly directive position on patient empowerment, stressing that citizens should be at the centre of any advancement in digital health. This means, in particular, that patient empowerment should be a central objective of any strategy that incorporates digital technologies into the healthcare system (25). The FDA, taking a similar tack, writes that "digital health technologies can *empower consumers* to make better-informed decisions about their own health and provide new options for facilitating prevention, early diagnosis of life-threatening diseases, and management of chronic conditions outside of traditional care settings." (16) Empowerment is presented as an opportunity for patients, though one that needs to be subject to certain restrictions, most notably that such opportunities need to be optional. Against this backdrop, it is important to note that therapeutic portals raise the possibility that both patients and physicians may be empowered to engage differently with the course of diagnosis and treatment. To the extent that patients have access to therapeutic portals, for example, they might be empowered to engage more fully in their care in virtue of having access to data about their condition, prognosis, and available treatment options. For physicians, therapeutic portals may be empowering insofar as they provide new methods for diagnosing and treating patients. Portal developers should consider the empowering effects on both patients and clinicians that the design and implementation of their online systems for health data sharing could have. As with other themes raised in this paper, information that is accessibly drafted and is contextualized with respect to relevant scientific evidence will tend to be more empowering than information that is presented less thoughtfully.

Training

With the development of novel health technologies, it may be justified to worry whether end-users will have an acceptable degree of technical background and training in applying the system. Untrained operators of sophisticated medical tools, after all, may become sources of significant error or misuse. The UK government's report on the future of healthcare makes precisely this point, noting that "health system staff should be trained in digital services skills. An open culture should be fostered, and relationships constructed with innovators, academics, industry staff, and patients." (24) While appropriate training might be straightforwardly valuable, HC's consultation summary problematizes the potential application of pre-implementation training regimes, suggesting that "innovators do not always have the resources…to train employees." (23) With the advent of therapeutic portals, training for proper use may be a distinctly important requirement for ensuring patient safety. Researchers or clinicians unfamiliar with platform data organization may overgeneralize or otherwise rely inappropriately on a therapeutic portal. These risks may be especially pronounced for patients accessing online resources, some of whom will misunderstand technical data relevant to their care. Therapeutic portal developers may consider introducing mechanisms to introduce users to a portal's functionality, including by posting mandatory training modules or introductory explanatory notes on the portal interface.

Safety & efficacy

As outlined above, nearly all the documents reviewed discuss the dominant role that safety and efficacy play in SaMD regulation. Considering that the primary purpose of medical devices regulation is to ensure that systems used in patient care are safe and effective, this nearly universal treatment is not surprising. Even insofar as therapeutic portals are not likely to be formally subject to regulation under existing SaMD regimes, this does not mean that safety and efficacy considerations are irrelevant in this context. While therapeutic portal developers may not have a legally enforceable obligation to demonstrate the safety and efficacy of the software they produce, they arguably have a significant ethical obligation to do so. Ensuring that therapeutic portals work and that they can be safely relied on by their intended end-users ought to be the dominant concern of any software developer operating in this space.

RECOMMENDATIONS

Against this backdrop, it is in our view essential that portal developers familiarize themselves with the evolving regulatory regime applicable to SaMD. Though this paper suggests that regulation as it is presently constituted likely does not apply to therapeutic portals as we have described them, it is conceivable that this may – and perhaps *should* – change. As medical practice increasingly implements elements of the "learning healthcare system" model by integrating research findings more directly in patient care, we imagine that therapeutic portals will become vital tools for physicians and patients alike. Physicians may use these Internet-enabled platforms to stay apprised of rapidly emerging biomedical knowledge while patients may use them to become better informed about their course of treatment, empowering them to become more active partners in their care. As this happens, these tools may end up being subject to greater regulatory scrutiny. If widely adopted in the clinic, therapeutic portals could entail significant risks of misdiagnosis, misuse, breaches of confidentiality, and others. Such risks may draw the attention of regulatory agencies in the interest of securing patient safety and public trust. We recommend, then, that regulators clarify how SaMD guidance should be interpreted to apply to web portals and other Internet-enabled programs. As we suggested above, the generally agreed definition of SaMD appears broad enough to include web portals that have medical purposes. It would provide significant certainty for developers, physicians, and the public to explicitly include web systems in future guidance iterations of SaMD guidance documents. This is not to say that therapeutic portals *ought* to be regulated as medical devices, but rather that we would encourage regulators to take a clear position one way or the other. At present, the situation is ambiguous and only likely to become more so as this space evolves.

CONCLUSION

This paper gives an overview of some of the ways regulatory guidance is likely to control the development and implementation of therapeutic portals. We reviewed 20 guidance documents prepared by regulatory authorities in Canada, the United States, the United Kingdom, and France. These documents tell us that therapeutic portals are not likely to be formally subject to regulatory oversight under existing medical device regimes. The reviewed documents also point to a number of normative and logistical considerations that ought to be top of mind in the creation of novel technologies for sharing health data with diverse audiences.

In our view, portal developers should be attentive to each of the eight ethical and regulatory concerns outlined above, even if they are not formally required by regulation to do so. We give brief and preliminary recommendations for portal developers engaged in this space. In broad strokes, portal developers should be thoughtful about the way their information is presented. While accessible and contextualized health information can promote patient empowerment and equity, also making care delivery more efficient, data that is presented in ways inattentive to these elements might actually harm portal objectives. There are also good scientific reasons to attend to the ethical and regulatory concerns raised by therapeutic web portals – more carefully designed medical software is likely to be more clinically useful. But there are good social and ethical reasons to do so as well. Public trust in health systems and institutions is, as several authors have argued, a critical element in the success of medical governance (26). One way to foster public trust in the development of health technologies is to ensure compliance not just with formal regulatory requirements, but with the principled spirit of the regulation that applies in this context. Insofar as the public might tend toward increased distrust when medical technologies are supported by or use the Internet, it will be especially important for the developers of therapeutic portals to be cognizant of the regulatory infrastructure intended to support patient protection.

REFERENCES

1. Swee-Lin Tan S, Goonawardene N. Internet health information seeking and the patient-physician relationship: a systematic review. Journal of Medical Internet Research. 2017;19(1):e9.
2. Van den Bulck SA, Hermens R, Slegers K, Vandenberghe B, Goderis G, Vankrunkelsven P. Designing a patient portal for patient-centered care: cross-sectional survey. Journal of Medical Internet Research. 2018;20(10):e269.
3. Lang M, Lemieux S, Hébert J, Sauvageau G, Zawati MH. Legal and Ethical considerations for the design and use of web portals for researchers, clinicians, and patients: scoping literature review. Journal of Medical Internet Research. 2021;23(11):e26450.
4. Black L, Avard D, Zawati MH, Knoppers BM, Hébert J, Sauvageau G, Leucegene Project. Funding considerations for the disclosure of genetic incidental findings in biobank research. Clinical Genetics. 2013;84(5):397-406.
5. Kalkman S, Mostert M, Gerlinger C, van Delden JJM, van Thiel GJMW. Responsible data sharing in international health research: a systematic review of principles and norms. BMC Medical Ethics. 2019;20:21.
6. Health Canada. Safe Medical Devices in Canada. Ottawa: Medical Devices Bureau; 2007.
7. Food & Drug Administration. Overview of Device Regulation. Washington: Center for Devices and Radiological Health; 2020.
8. Medicines and Healthcare products Regulatory Agency. Regulating medical devices in the UK. London: HM Government; 31 Dec 2020.
9. L'Agence nationale de sécurité du médicament et des produits de santé. L'ANSEM en bref. 2019.
10. Minssen T, Mimler M, Mak V. When does stand-alone software qualify as a medical device in the European Union?-The CJEU's decision in Snitem and what it implies for the next generation of medical devices. Medical Law Review. 2020;28(3):615-24.
11. International Medical Device Regulators Forum. About IMDRF.
12. Food & Drug Administration. Software as a Medical Device (SAMD): Clinical Evaluation: Guidance for Industry and Food and Drug Administration Staff. Washington: U.S. Department of Health and Human Services; 2017.
13. Council of the European Communities. Directive 93/42 concerning medical devices. No L 169/1; 1993.
14. Haute Autorité de Santé. Functional classification, according to their intended use, of digital solutions used in the context of medical and paramedical care. Saint-Denis: HAS; 4 Feb 2021.
15. Health Canada. Guidance Document: Software as a Medical Device (SaMD): Classification Examples. Ottawa: Medical Devices Bureau; 3 Oct 2019 (rev. 15 Nov 2022)
16. Food & Drug Administration. Digital Health Innovation Action Plan. Washington: U.S. Department of Health and Human Services; 2018.
17. Department of Health & Social Care. A Guide to Good Practice for Digital and Data-Driven Health Technologies. London: HM Government; 19 Jan 2021.
18. Innovation, Science and Economic Development Canada. Report from Canada's Economic Strategy Tables: The Innovation and Competitiveness Imperative: Health & Science. Ottawa: ISEDC; 5 Nov 2018.
19. Haute Autorité de Santé. Numérique: Quelle (R)evolution. Saint-Denis: HAS; 2 Jul 2019.
20. Cavallaro F, Lugg-Widger F, Cannings-John R, Harron K. Reducing barriers to data access for research in the public interest—lessons from covid-19. BMJ Opinion. 6 Jul 2020.
21. Health Canada. Notice: Health Canada's Approach to Digital Health Technologies. 18-104077-808. 10 Apr 2018.
22. Food & Drug Administration. Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics. Washington: U.S. Department of Health and Human Services; Apr 2018.
23. Health Canada. What we heard: A summary of scanning and consultations on what's next for health product regulation. Ottawa: Government of Canada; 10 Apr 2019.
24. Department of Health & Social Care. The Future of Healthcare: Our Vision for Digital, Data and Technology in Health and Care. London: HM Government; 17 Oct 2018.
25. Ministère des Solidarités et de la Santé. Stratégie nationale e-santé 2020. Paris: MSS; 2016 (rev. 18 Mar 2022).
26. Gille F, Smith S, Mays N. Why public trust in health care systems matters and deserves greater research attention. Journal of Health Services Research & Policy. 2015;20(1):62-4.