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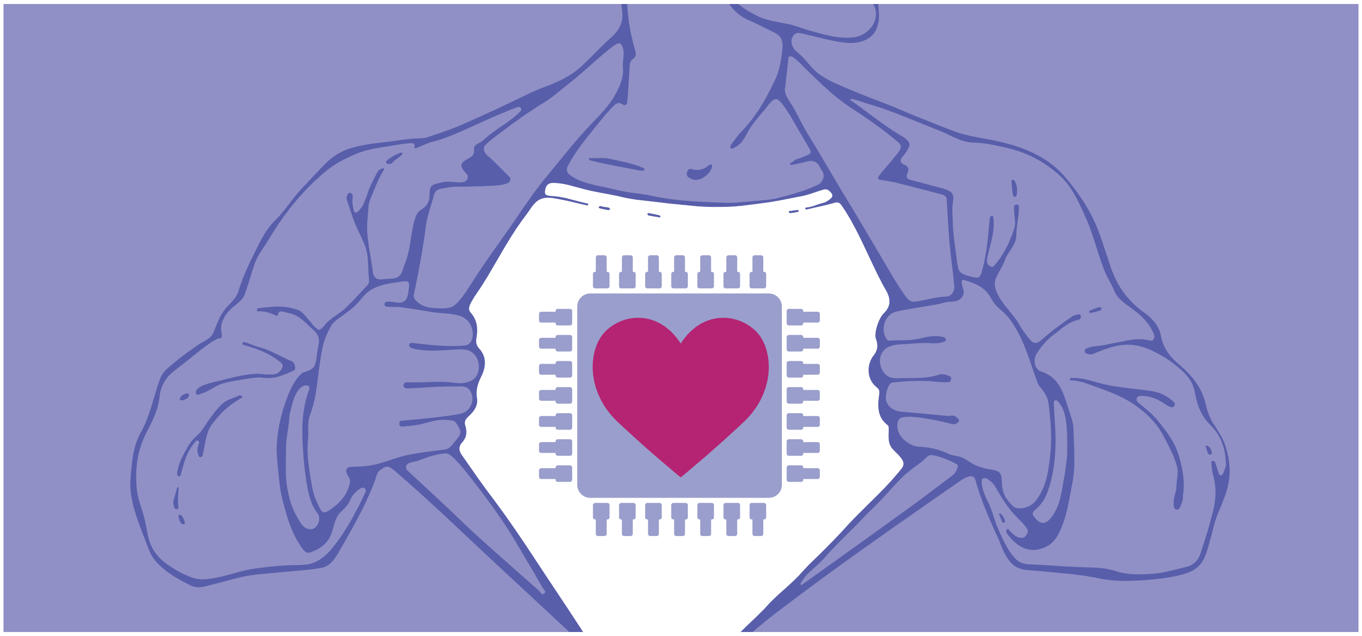
Empowering Patients and Caregivers in the Era of Digital Health:

A Briefing Document



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AMS healthcare
Transforming Education and Practice

Empowering Patients and Caregivers in the Era of Digital Health:

A Briefing Document

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This briefing document is one of a series of reports sponsored by AMS Healthcare. The goal of these reports is to inform health professionals, educators, patients, families, caregivers and leaders about the opportunities and challenges of emerging health technologies.

AMS Healthcare is a Canadian charitable organization with an impressive history as a catalyst for change in healthcare. AMS strives to improve the healthcare of all Canadians by innovating education and practice, championing the history of medicine and healthcare, supporting leadership development, and advancing research in the health humanities.

The AMS Compassionate Care in a Technological World Initiative focuses on: (1) promoting the education and practice of compassionate care; (2) fostering new delivery models of compassionate care; and (3) facilitating the leadership needed to realize the promise of technology, while safeguarding humanistic care in our rapidly evolving healthcare system.

Contents

Executive summary

This document aims to empower patients and caregivers by illuminating the implications of health technologies. It considers the risks and benefits of given interventions, as well as the larger cultural changes that will enable the widespread implementation of beneficial digital health technologies.

- One of the most significant potential benefits of digital health is empowering and enabling choice among patients and caregivers.
- Achieving substantive patient and caregiver engagement will require transparency, proactive communication, and enhanced digital health literacy.
- The following digital health tools have been implemented within Canada or elsewhere or are advanced enough to consider adopting into a larger digital health strategy. Each carries unique benefits and risks:
  - Electronic health records
  - Telemedicine
  - Mobile health apps and wearables
  - Chatbots
  - Augmented/virtual reality
  - Robotics
  - Artificial intelligence and predictive analytics
  - Genomic sequencing and precision medicine
- As an extension of healthcare, digital health innovations are accountable to established ethical commitments to prioritizing patient safety and maximizing benefit.
- Core ethical principles that should be considered in the design and evaluation of digital health include choice and autonomy, privacy, health equality and accessibility, evidence of benefit, and patient engagement.
- Emerging cultural shifts supporting digital health — including continuous learning, changing notions of privacy and ownership of health data, and partnerships with industry — will require reshaping our priorities and values.

Introduction

> *Extraordinary accomplishments, from dissecting and defining DNA to creating such pervasive electronic technologies that immediately and intimately connect most individuals around the world, have unwittingly set up a profound digital disruption in medicine. Until now we did not have the digital infrastructure to even contemplate such a sea change in medicine. And until now the digital revolution has barely intersected the medical world. But the emergence of powerful tools to digitise human beings with full support of such infrastructure creates an unparalleled opportunity to inevitably and forever change the face of how healthcare is delivered.*
>
> Dr. Eric Topol, Cardiologist and Medical Futurist [1]

The use of digital tools has immense potential for transforming the Canadian healthcare landscape, giving people more control over their own health than ever before. These digital solutions may alleviate much of the burden on our stressed healthcare systems, streamline workflow processes for healthcare providers, improve the patient experience, and lessen healthcare costs. Yet, these opportunities also bring challenges. For example, digital solutions can create distance between healthcare providers and patients. If we lose sight of these varied effects, we risk failing to meet the original purpose of a digital health landscape: to improve healthcare delivery. Looking beyond health outcomes alone, we can adopt a more proactive strategy where patient input is factored into the selection, design, and use of digital health technologies.

Patients and caregivers should have opportunities to become involved, formally and informally, in the design and implementation of digital health tools. But meaningful participation requires adequate knowledge and education among patients and caregivers, enhancing the quality of their collaborations with healthcare professionals. This briefing document lays groundwork that will enable patients and caregivers to participate in shaping the values, meaning, and incorporation of digital health technologies within the Canadian healthcare landscape.

This document is organized into four sections as follows:

1. **Digital health tools: Benefits and risks.** This section introduces prominent categories of digital health tools and explores the distinctive benefits and risks of each.
2. **Ethical principles for a digital health strategy.** This section introduces core principles that should underpin the design, selection, and use of digital health tools.
3. **How will digital health transform healthcare?** This section describes the emerging cultural shifts associated with digital health.
4. **Opportunities to support patients and caregivers.** This section describes opportunities and priorities for promoting patient and caregiver engagement.

1. Digital health tools: Benefits and risks

Digital health encompasses a vast array of computer-enabled tools that are used for the purpose of improving health. The field is evolving rapidly, and no list of tools should be considered ex-haustive, but the following review captures the most prominent and relevant categories of digital health tools to date. Some essential definitions of concepts underlying many of these tools include:

Artificial intelligence (AI): Broadly defined as the ability of computers to process and act upon environmental cues, health AI is 'narrow' (meaning an AI tool is able to perform one task with high efficiency).

Machine learning (ML): ML is the methodology that can achieve AI by explaining associations that appear in real-world patterns of data. ML is largely "descriptive" in this sense: an ML model is developed by learning relationships within data that can be applied to new, unseen cases. This method allows for the "prediction" of a future health state by drawing from how previous cases developed.

User: The scope of users considered in this document includes patients, caregivers, providers, and health advocates (e.g., patient navigators). Any person who must interact with a given digital health tool may be considered a user.

Electronic health records

The electronic health record (EHR) has revolutionized healthcare but remains a bit controversial. Medical errors have decreased, patients are receiving better care, and documentation is more consistent and thorough.[2] Despite generally agreeing with those improvements,[3] physicians are highly dissatisfied with EHRs.[4] Many have noted that the extensive documentation required by EHRs takes time away from patients.

Benefits

Consistency: Prior to the EHR, documentation was subject to institutional culture and the behaviour of individual clinicians. The EHR has promoted better consistency in documentation, which has allowed for more systematic collection of information. Clinicians now have mandatory fields that must be completed to ensure that important metrics are collected for each patient. This systematicity has been helpful in preventing many medical errors.

Availability: Having health information on a digital platform enables linkage with other platforms across services, as well as providing the means for users to access their health information. A connected network for health information facilitates information-sharing to diminish administrative burden, decrease duplication of documentation, and enable better communication across services. These platforms should enable information-sharing between primary care clinics, hospitals, mental health services, and community-based social services.

Risks

Accessibility: For health information to truly be beneficial, it must not only be available but also accessible. Patients and caregivers must be made aware of how they can go about finding and reviewing their information. Options must be available for persons with disabilities that limit their ability to access information, for example, being unable to navigate to a website. Moreover, companies lobbying to limit data-sharing should not be allowed to implement barriers that inhibit people's access to their own health information.

Usability: All the information may be present, but platforms vary in their usability. As the population adjusts to a digital health age, a focus on usability of methods to access one's health record should prevent those with lower digital literacy from being left behind. To ensure true accessibility, the method of access should be tested on users across the spectrum of digital literacy.

Privacy: Linking datasets is associated with increased risk of a privacy breach. Methods of encryption, de-identification, and controlled access will need to be specified and communicated to the public to protect privacy.

Telemedicine

Telemedicine is the provision of healthcare services over a distance. It allows patients to connect with clinicians (generally physicians and nurses) via text, audio, or visual consultation to avoid an in-person visit or to determine the need for one. Regular follow-ups can be conducted via telemedicine, as well as mental health visits and other talk-based therapies.

Benefits

Efficiency and minimizing burden: Telemedicine has enormous potential for alleviating a proportion of the burden on hospitals and urgent care clinics. It also minimizes practical challenges to patients and caregivers such as transportation and related costs, difficulty taking time off work, and finding childcare. In-person visits may still be necessary, but telemedicine can lessen overall the number of times patients visit the hospital or urgent care clinic for issues that could easily be handled over the phone. Telemedicine services have also been associated with lower non-attendance rates, which affect cost of care, delivery of care, and resource planning.

Expanding access: Due to the practical challenges listed above, many people cannot or choose not to seek healthcare if they feel the problem is not that bad. Telemedicine provides an incentive for those individuals to reach out to healthcare services where they would otherwise have none, including populations living in remote areas. Telemedicine also allows for patients and caregivers to connect with healthcare providers about more minor health concerns that do not require an in-person visit. These may be minor, but they can cause anxiety and worry. Limiting the number of people treated in hospitals for minor health issues is a substantial advantage.

Risks

Resourcing: Telemedicine services must be appropriately staffed and well-resourced to cope with the demand. If patients have to wait too long to connect with providers, or if the connection is unreliable or inconsistent, there will be less incentive to use the service. Considerations about how to appropriately manage these services are also important; having dedicated staff or ensuring that providers have protected time to respond to queries is essential to maximizing the benefit of telemedicine.

Mobile health applications and wearables

Mobile health applications (“apps”) are proliferating rapidly and from many sources. These apps allow people to collect and maintain records of their own health information and look at trends over time. Data can be shared with healthcare providers and analyzed in conjunction with data collected from other sources (e.g., lab results, genomics). They can allow people to check their symptoms, book and manage appointments, view EHRs, order prescriptions, and engage in research. Those enabled with AI/ML technologies can include features such as real-time feedback and suggestions based on environmental information. For example, analyzing information about your heart rate and movements, the app can prompt you to go for a walk, as well as identify when you are in a target heart rate range to promote your health goals.

Wearables are devices enabled with sensors that pick up on signals from your body, record them, and provide analytics. An app often enables this process, allowing you to track these signals over time. Some wearables and/or apps are being prescribed as “digital therapeutics.” These can include watches, biosensors applied to the skin, or ingestible, pill-like sensors.

Benefits

Patient empowerment: These tools can be empowering, enabling better control over one's own health and increasing attentiveness to health-promoting behaviours. The information collected through apps enables patients to come to their physician visit equipped with more information to inform discussions about their health. For example, tests to analyze your heart rate over a period of time require a referral to a cardiologist, appointment to get set up with a monitor, data collection over 3 days, interpretation of the results by an expert, and returning to the clinic to review the results. These more rigorous monitoring approaches may still be necessary, but the use of apps may decrease the frequency of burdensome tests. Some apps enable individuals who need some assistance with activities of daily living to remember to do the things that allow them to continue living independently.

Safety: Some sensors can automatically alert a preferred contact when the user is in trouble, or signal emergency medical services to come to the location recorded by the device.

Continuous data collection: Sensors provide a continuous data stream to enable a more naturalistic view of a patient's symptom and sign trajectory that is difficult to replicate outside of a hospital setting. The ability to visualize trends in data over time is very valuable and going over this with the patient can help to contextualize the data.

Risks

Data quality: Problems of data quality from sensors continue to be a challenge for app developers and for interpretation. While the technology is rapidly improving, sensors on the skin are not a perfect equivalent of a medical-grade sensor. Moreover, questions have been raised about how well all populations are represented in the data used to develop apps. If the app is not trained on enough cases of individuals from different groups, those that are under-represented will have less useful predictions about their health.

Interpretation in context: Many apps present your health information back to you in real time. But for certain kinds of health concerns, patients may prefer receiving results from a human rather than viewing them through an app. Deciding which results are communicated straight to the user and which signal the need for a visit to a healthcare provider, who would then discuss the findings with the patient, is a design aspect that would benefit from user involvement in the development stage.

Validity: Currently, some apps are developed within academic healthcare institutions, some in conjunction with industry, and others by industry alone. Health Canada is moving toward an approval framework for apps that help manage health conditions. This framework should help to ensure that 1) the apps have been validated and are safe and 2) their claims are appropriate given the technology and performance.

Appropriateness: The Canadian Medical Association (CMA) recently released a guidance document that stressed two main points about wearables[5]: 1) mobile health apps should complement and not replace the physician–patient alliance, and 2) the appropriateness of the specific app to the person's health needs must be considered. This guidance highlights the importance of discussions between patients, caregivers, and healthcare providers surrounding apps and sensors to understand the best way to integrate them into a care management plan.

Access: Some wearables and apps are cost-prohibitive for many patients. As more apps become validated and have demonstrated value, insurance companies may move to supplement some of these costs. Some apps may be free to download but prompt the user to pay for additional features. Some apps will notify the user that there is a result of interest before signaling that to receive the result a payment is required. The payment is proportionate to how quickly the user wants to view the result. This practice capitalizes off of inducing worry about one's health.

Privacy: Information collected by apps is not always immediately clear, nor are the ways in which companies use the data they collect. This concern pertains to data that are obviously collected within the app (e.g., a symptom diary where the entered information is collected by the app company) as well as to information that is peripherally related to the app's purpose.

For instance, some apps will ask for location data, contacts, and camera/microphone access for no apparent reason. It is not clear how companies use this information, and the end user agreements are cumbersome and opaque. The information collected that aligns with the purpose of the app also has privacy implications as companies may sell this data to other companies without informing users.

Chatbots

Chatbots are enabled by a branch of AI called natural language processing (NLP). NLP draws from computational linguistics and computer sciences to support the analysis, synthesis, and derivation of meaning from human language. Most voice assistants (e.g., Amazon's Alexa, Apple's Siri, Microsoft's Cortana, and Google Assistant) on smartphones currently use a form of NLP. These tools process language through microphones (verbal) or via text (written). Areas where these tools may impact healthcare include triaging, mental health, and clinical documentation. In triaging, chatbots intend to streamline the intake process and identify needed supports more quickly to facilitate faster care according to patient-identified needs. In mental health, chatbots are already able to identify elements of disordered thinking that may contribute to states like anxiety or depression. These tools can enable the delivery of care to people who cannot access in-person services or to outpatients in between clinic visits. Clinical note documentation is a particularly exciting area that is in development. Rather than manually typing in clinical information during a clinic visit, healthcare providers could use chatbots to automatically record and synthesize information obtained during the clinical encounter.

Benefits

Accessibility: Chatbots in mental health have the benefit of increasing the reach of healthcare services and facilitating access where necessary. These tools are trained to recognize important inputs to prioritize resources according to need. For example, chatbots in mental health are equipped with the ability to recognize speech patterns associated with suicidality and can mobilize the necessary resources quickly. Others can identify barriers to care such as financial constraints and automatically pull up applications for financial aid that patients can then complete.

Streamlining care: Chatbots can facilitate referral services or other care coordination services to ensure that all relevant tests, forms, results, and other medical documentation are collected prior to a patient being seen in a specialist clinic. This will minimize errors, prevent patients having to be sent out for more tests before coming back, and decrease the administrative burden on administrative and clinical staff.

Comfort: Many people may feel more comfortable initially interacting with a chatbot, particularly for stigmatizing conditions. Chatbots can thereby provide a bridge for some who otherwise might not seek care.

Risks

Errors: The methods that have attempted clinical note documentation are not quite good enough to be safely used in clinics. It is essential that these tools are validated prospectively in real-time clinical settings. It is also important to maintain a human-in-the-loop design to verify the outputs. For triage tools, some chatbots have been scrutinized for failing to undergo proper validation prior to implementation and for misleading marketing claims.[6] Ensuring that clinically meaningful errors are limited and caught when they do occur is essential to their success. Other errors from chatbots are more of a nuisance, but they point to the need to have a redundancy system built in. Many have noted that chatbots can sound scripted and fail to respond to nuances. This can result in user frustration. These limitations point to need to have a back-up in place should the patient still need help.

Confidentiality: While patients may initially take comfort in confiding in a chatbot rather than a human, a lack of transparency about how information is gathered during the encounter can be a barrier to trust. In a clinical encounter, patients are informed of the limits of confidentiality. User agreements for digital health tools may describe such limits, but without ensuring that users have actually read and understood them, they fail to achieve informed consent.

Automation: While chatbots may indeed enhance accessibility, they should not be used to supplement for proper mental health services. At present, there is no prospective evidence that mental health chatbots can deliver the same quality of care that a psychotherapist, psychologist, or psychiatrist can. Remote areas are a particular concern as mental health resources are already scarce and chatbots may be more cost-efficient than employing mental health experts. They should not be used as an excuse not to provide proper mental health resources to these communities.

Augmented reality/virtual reality

Augmented or virtual reality (VR) has been in medicine since the 1990s and involves computer-generated sensory data (e.g., visual, auditory) to create an immersive experience for the user. Advances in computing technology have recently made these more effective and affordable, as well as more enjoyable for users.

Benefits

Reducing pain and distress: VR technologies have been demonstrated to be effective for reducing pain and distress in some patients. They have also been successfully used in some mental health contexts for posttraumatic stress, anxiety, and phobias.

Relieving boredom and providing positive experiences: VR has recently been introduced into palliative care, geriatrics, and long-term care contexts where patients may have limited ability to ambulate and are confined to the hospital or hospice. Boredom can lead to depression, and patients miss out on many experiences that could bring joy and pleasure to their lives. VR provides the opportunity to feel as though one is visiting a lake, viewing a favourite vacation spot, playing a game, or attending a loved one's wedding.

Preparing patients for procedures: Some VR experiences in paediatrics can help prepare patients for surgical procedures, scans, or other interventions to help them feel less nervous and let them know what to expect.

Risks

Physical risk: Neck strain and dizziness can be side effects for some patients.

Psychological risk: Over-dependence on VR could be problematic in the long term, but so far there is limited evidence to support this concern in the medical context.

Robotics

Robotics are used in a wide variety of ways in healthcare, including surgery, accessing and viewing internal anatomy, and in rehabilitation. They can also be used in conjunction with telemedicine to enable a physician to interact remotely with a patient where the robotic device can measure vital signs and send live images to the physician. "Social robots" are a type of robotic companion deployed in some areas of the world where they are intentionally supplanting human social connections (e.g., for older adults living alone). Robots have also been used to help children on the Autism spectrum to improve communication skills, provide education, and develop interpersonal and behavioural skills.

Benefits

Anatomical visualization: Robotic devices can use fine motor movements that are better than human performance and can access anatomical areas that would otherwise be unreachable.

Enhancing telemedicine: Robotics can complement telemedicine services as indicated above to improve the quality of care patients receive remotely. With the aid of a robot, the treating physician can engage physically, by proxy, with the patient, which expands the scope of issues that can be addressed in a telemedicine encounter.

Supplementing human involvement: With social robots, there is an opportunity to bring human-like encounters to people who otherwise have no one, or who have challenges interacting with humans (e.g., people with Autism). These robots are used in some areas as companions for persons who are in long-term care facilities and have no family.

Risks

Safety: Some surgical robotic devices have implications for patient safety and may present new risks. Thorough evaluation of the short- and long-term safety of robotic devices that involve penetrating procedures is essential.

Human connection: An overall aversion to robots in healthcare reflects the common desire to connect with other human beings, particularly when in a vulnerable state. While many services may be supplemented with robotic-assist devices, for others, patients will prefer to have an in-person connection with their provider. Determining under what circumstances robotics should not be used is a key area for patient and caregiver input. For social robots, there are persistent and unresolved ethical concerns about whether we should be using robots to replace efforts to promote human connections. Similar concerns have been raised about the use of robots with children because we have little understanding of how children perceive robots and what the implications are for their ability to form meaningful human relationships in the future.

Artificial intelligence and predictive analytics

The use of algorithmic risk scores has been around for a long time in medicine, but, with advances in AI methodologies, predictive analytics now can compute more complex data in real time for individual patients with better accuracy. Their use presents an opportunity to move from reactive to preventative interventions. For example, identifying patterns in vital signs data that predict a likely cardiac arrest can enable, at least, a mobilization of resources to intervene as early as possible and, at best, prevention of the event altogether.

Benefits

Prevention: The ideal for predictive analytics is the prevention of harmful events. Often medicine is forced to be reactionary and must respond to an event that has already been initiated. The prediction of likely events with the use of AI will hopefully decrease the rate and severity of adverse events.

Preventing errors: Because many predictive analytics involve continuous or consistent updating of an individual's level of risk, they minimize the chance that one patient can fall through the cracks. AI-enabled tools can be an additional set of eyes on the patient so that busy providers can be alerted to attend the right patient at the right time.

Risks

Black box systems: Many AI-enabled predictive analytic tools are described as "black box" systems, meaning that the reasons behind a given prediction cannot entirely be known. To compensate, developers may use "explainability" metrics (like identifying the clinical feature that was important to the given prediction) but this is still an immature field. There is some evidence that such metrics can be falsely reassuring. Clinical judgment is still strongly required for interpretation of these predictions because AI tools can and will make mistakes for a subset of cases. Patients and caregivers may also have more information that is not considered by the tool that may also be relevant to the risk of a given condition.

Excessive interventions: Sometimes a shift toward prevention can result in over-intervention. For example, the clinical benefit of cancer screening is often debated[7] because despite its ability to identify cancer early, screening is generally agnostic to whether an abnormal growth will develop into a malignancy or whether it will remain benign. But because something has been identified, there is an obligation to act; this can involve further biopsies and testing on a benign growth, which is burdensome and of limited benefit. Identifying cases where the harms outweigh the benefits is very important to prevent over-intervention.

Genome sequencing and precision/personalized medicine

The ability to "read" a genome has been one of the major medical advances in recent history. Many medical futurists predict that the use of information from genomic sequencing will become a routine part of clinical care, with the sequencing itself potentially conducted right from birth. As genomic sequencing becomes more cost-effective, this prediction may easily become reality. Aside from whole genome sequencing (WGS), genotyping can estimate an individual's level of risk for specific known diseases. The same technique can also be used to sequence samples of tumours, microbiomes, or bacteria to inform the development of targeted treatment options.

Precision (aka "personalized") medicine is an emerging movement which generally refers to making the application of medicine more "precise" by incorporating a variety of information about an individual patient to determine the best treatment. Information sources will almost always include genomic data. The other so-called "omics" (the study of biological molecules) can incorporate information about our proteins, metabolic markers, the molecules that read genes to make proteins, and many others. Knowing the specifics of these markers can allow physicians to administer more targeted treatments.

Benefits

Information: Genomic sequencing can reveal highly useful and actionable information to help individuals manage their lifestyle, inform their life choices, and choose treatments. Some applications of precision medicine have been helpful in identifying subsets of patients within a single disorder who require a different treatment based on their genome.

Targeted interventions: In line with the benefit of having more information, treatments targeting an individual's particular genome can produce better clinical results for some types of patients. Using the genome of biological samples (e.g., tumours, bacteria) can also improve research efforts to develop more treatment options and enable a better understanding of disease processes more generally. Cancer is one area where precision medicine will likely be the most effective, given the range of genetic variation in tumour profiles.

Risks

Cost: While the cost of sequencing is declining, precision medicine generally is associated with a hefty price tag. Responsible use of resources requires us to consider where precision medicine is and is not of benefit to patients.

Clinical significance: Much of the early excitement about genomic sequencing was dampened with the realization that the relationship between genes and behaviour is not straightforward in the majority of cases.[8] Genetic variations associated with many diseases are not always causal, or their clinical expression can vary a lot across individuals with the same variation. There are "variants of unknown significance" which means that a patient may present to clinic with a particular problem, and a particular genetic variation is identified, but one cannot ascertain whether this variant is causing the clinical problem. There are known risks for genomic sequences (discussed below) and so many feel that the decision to sequence one's genome should only be done when there is a good medical reason.

Implications for family members: Because our genome is inherited, particular genetic disorders implicate family members as well. This means that an individual who finds out information about their own health may also know things about a family member's health—and other family members may or may not want to know this information about themselves. This can cause a great deal of family conflict.

Incidental findings: ”Incidental findings” are information that comes up in the course of testing that is unrelated to the reason the test was ordered in the first place. For example, if a patient had their genome sequenced for a suspected autoimmune condition but the testing also revealed a propensity for breast cancer, the latter would be an incidental finding. Many times people prefer to test only for a suspected genetic condition rather than having their entire exome sequenced because of the risk of incidental findings. Knowledge about one’s health information is a personal choice. Some want to know everything; others only want to know some things. Patients and caregivers should always be given information about which results are always disclosed and which are optional to have returned as part of the consent process for WGS.

Implications for children: Genomic sequencing from birth has raised questions about who is entitled to this information. In some cases, genomic information can help parents make better decisions on how to care for a child with particular health needs. But in others, parents may receive information about the risk of adult-onset conditions that may or may not actually develop. It is widely accepted that children have the right to an “open future” which includes the ability to make a choice as an adult about what information they want to receive about their health. When parents have information about a child’s future health status, they may (intentionally or unintentionally) restrict certain choices in ways that the child may not have wanted later in life.

2. Ethical principles for a digital health strategy

As a strategy for improving Canadian health more generally, digital health should prioritize patient benefit. Digital heath may improve patient outcomes, enhance people’s control over their own health, improve experiences of care, or offer other secondary benefits (e.g., easier navigation of the system, less driving to appointments), and an improved patient experience. Beyond the commitment to patient benefit, the overall strategy of digital health may be augmented by drawing from the following ethical principles: choice and autonomy, privacy, health equality and accessibility, evidence of benefit, and patient engagement.

Choice and autonomy

Since the 1990s, a stronger focus on patient autonomy has transformed medicine toward a prioritization of shared decision-making. This shift means that physicians must explain their reasoning and discuss patients’ values to collaboratively establish goals of care. Digital health tools can enhance a patient’s ability to collaborate with clinicians by putting more control of their health information into the patient’s own hands. Digital health has immense potential to promote autonomy by allowing individuals to have greater control over their health. Autonomy is dependent on individuals being able to make a choice that is free of coercion and undue influence. For example, if mobile apps or sensor use is a criterion of receiving health insurance, then the use of these tools is not promoting autonomy. What can feel helpful and supportive for some will feel confining and intrusive for others. Medical ethics and the law prioritize autonomy so highly that capable individuals (defined as the ability to understand and appreciate the risks and benefits of the available options) are allowed to make decisions about their health that are against their best interests. In order for digital health tools to maintain the prioritization of autonomy, they must not be implemented in ways that restrict individuals’ ability to choose. We can look at choice as the opportunity to choose between different digital health tools, but patients should also have the option to not choose one as well.

Privacy

Privacy has been a mainstay of Canadian society and is in line with the autonomy principle. Health data has always been subject to privacy legislation, but new information about the limits of techniques to “de-identify” data (meaning data that is stripped of identifying information like medical record number, social insurance number, and birthdate) have raised new challenges for privacy. Moreover, de-identified data can be linked with other de-identified data to reveal personal identities. People have varying concerns about the significance of re-identification because many prohibitions are in place to prevent problems like discrimination. In the interest of facilitating better information-sharing and improving the experience of patients and caregivers navigating the healthcare system, most Canadians feel it is acceptable to share private health information with certain approved parties.[9]

Many people feel that giving up some level of privacy to further research into health conditions, or for the benefit of others, is an appropriate trade-off. In order to promote an effective choice, individuals must be made aware of what precisely the trade-off is. What information is being used? Who will have access to it? Where and how will it be made available to researchers? Patients and caregivers have the right to accessible, transparent information about how their data is being used.

Health equity and accessibility

Persistent health inequalities remain a problem in Canadian society, with a range of social determinants affecting the development of many health problems. A worry is that access to digital health solutions may become a new variant independently influencing health outcomes. Where digital health solutions are demonstrated to be effective in improving patient outcomes, these should be available to all patients with a given health issue. By analogy, the evidence supporting breastfeeding as being beneficial for mothers and infants has prompted many insurance companies to compensate for devices like breast pumps. These incentives help more mothers breastfeed by making the cost of pumps less prohibitive. The same considerations could reasonably be applied to digital health technologies as well (where evidence is available).

Evidence of benefit

Where digital health tools (e.g., predictive analytics) involve risks to patients, the corresponding benefit must be greater. Concerns have been flagged about the performance of other digital health tools that were deployed without proper testing and validation. Eric Topol, author of the highly influential The Topol Review,[10] describes robust validation as an essential step in implementing digital health tools. As a regulator of medical devices, Health Canada review ensures that patient safety is evaluated prior to implementation of technologies to prevent deployment of unsafe tools. This process encourages the thoughtful adoption of high-quality digital health solutions, though it cannot prevent some of these tools from being marketed directly to individuals without proper validation. Patients and caregivers should feel confident to ask about validation and testing of digital health tools to make an informed decision about whether to use them.

Patient engagement

Collaborations between developers, healthcare providers, and patients and families are essential to the creation of meaningful digital health tools. Using the principles of service delivery,[11] Shaw and colleagues suggest value proposition design (VPD) as a means of maximizing the benefit of digital health technologies. A VPD framework centres the experience of the intended beneficiaries of the technology as essential to determining the value of a given tool. This process is iterative and adaptable as needs change, which stresses the need for ongoing patient and caregiver engagement. Moreover, their input should be considered in decision-making surrounding what kinds of tools should be prioritized, how they should be developed, and how they prefer to be involved along the way.

Identifying meaning may differ depending on the context. Some tools are meaningful so long as they enable people to feel more in control of their health. Others may only be meaningful if they have a demonstrated change in outcomes (e.g., fewer in-person clinic visits). Clinicians may have one view of a meaningful tool but patients may have another. Caregivers may have another view that is directly relevant to many health applications, particularly for those who care for persons who require assistance in activities of daily living. Including the patient and caregiver voice not only promotes better health through the use of digital tools but also ensures the tools will actually be used as intended and will be viewed positively.

3. How will digital health prompt cultural shifts in healthcare?

The Topol Review identified the digital health revolution as a period that will require cultivation of a "Culture of Learning." Healthcare providers will have to absorb more information to act as effective coaches and navigators for patients and caregivers. As technology evolves and new tools come to healthcare, providers will need to keep up with advances. Many institutions are leveraging data for research and quality improvement. These initiatives will need to be communicated with stakeholders, and patients and caregivers should have the opportunity to shape how these initiatives look.

Given that these activities are enabled by health data, a cultural shift in notions of ownership of health information may be underway. Typically, we have felt that health information is essentially a by-product of our own bodies, making it our "property." While health information belongs to the individual to whom the information pertains, the chart itself may be owned by the physician or institution. But this concept neglects the interests that others may have in our data as well. Some feel that consent or permission for research involving health information should not be mandatory, given that there is almost no risk to the individual. Research into public perspectives of health data use[12,13,14,15] consistently notes that many people view data as more of a public good and willingly provide it for the betterment of societal health. However, there is also a consistent minority of people who strongly feel that consent should always be required, and many people would not provide it. These concerns can stem from deep mistrust of medicine and institutions more broadly. With the revision of privacy legislation and the increase in learning healthcare activities, part of the cultural shift may be how we view the data we produce.

A final change may be in our attitudes toward collaboration with industry partners. Nearly all of the digital health technologies listed above involve some collaboration with industry, as healthcare institutions are not resourced sufficiently to develop tools in-house. Yet, people become less trusting when industry is involved as profit-making is viewed as being at odds with the goals of healthcare researchers.[14] To encourage a cultural change and earn the trust of the public, both industry and their healthcare collaborators should enhance transparency and clear communication with the public. Patients and caregivers should consider what kinds of actions would encourage their trust and which would diminish it.

4. Opportunities to engage and support patients and caregivers

The cultural shift required for an engaged public reaping the benefits of digital health requires a proportionate and proactive attempt to build capacity among patients and caregivers to engage with health technologies. The "digital divide" is a term that describes how some groups of individuals can benefit from technology while others face substantial barriers. Digital literacy is a term that describes an individual's ability to meaningfully interact with technology. A significant challenge for digital health is that many individuals who could benefit from technology have low levels of digital literacy. For example, a big area of interest is the development of apps to enable older adults to live independently for longer. Some populations who have had less access to technology may also have challenges engaging with digital health apps. A strategy for maximizing digital health literacy must be informed by the individuals one is looking to target; these stakeholders know best what tactics will be effective and how best to increase knowledge.

To promote meaningful engagement among patients and caregivers, there is a significant knowledge gap that needs to be addressed. Particularly with digital health tools, members of the public cannot participate meaningfully without being given sufficient knowledge to inform their input and encourage meaningful collaboration. Access to training and education to help people learn how to use digital health tools is essential to realizing their benefit. Options are important: some people prefer to read a manual, others watch a video, some require coaching.

There is no standardized guidance for these tools and no current requirement to having training resources available. Suggested areas for further training and education include:

- Proactive communication with the public to provide education about how health data is currently collected and used [16,17]
- Clear communication from institutions about how they are using health information and which activities (e.g., research initiatives) are being facilitated by this work
- Better outreach for opportunities for stakeholder engagement (e.g., participating in research ethics boards, patient advisory boards, stakeholder input opportunities)
- More options for engaging patients that allows for more diversity
- Development of resources to enhance digital health literacy, including (but not limited to):
    - Descriptive information about the scope of digital health solutions
    - Helpful questions to ask about a digital health tool
    - Helpful questions to ask a physician about using digital health tools
    - User tutorials available through multiple formats to suit a variety of unique learning needs
    - Guidance in navigating privacy policies regarding data sharing practices for industry-developed digital health tools

Conclusion

This briefing note has considered a digital health strategy and what this means for patients and caregivers. We have explored the benefits and risks of a wide range of digital health tools that are currently being used to transform healthcare, including electronic health records, telemedicine, apps and wearables, chatbots, virtual reality, robotics, AI and predictive analytics, genome sequencing, and precision medicine.

Some key ethical principles that ought to underlie a digital health strategy are described, all with the goal of promoting patient benefit: choice and autonomy, privacy, health equity and accessibility, evidence of benefit, and patient engagement. Finally, we have considered significant cultural shifts that will characterize the changing healthcare landscape as a result of digital health tools. This discussion highlights some potential opportunities to maximize the benefit of digital health technologies.

Advances in technology have historically been a “disruptive” force, and healthcare is not exempt. People are apprehensive about that which is unfamiliar, even when they stand to benefit greatly from it. As those who shape the digital health landscape seek to build trust, patients and caregivers have a crucial place in deciding what is worthy of trust. As the funders and beneficiaries of a public healthcare system, they also have a say in where our precious resources should be allocated so that funding priorities are in line with those of the public. The information outlined in this briefing document is intended to lay the groundwork for these discussions to realize the goal of the co-creation of a digital health strategy that centres the needs of patients.

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