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# Patient safety and health information technology conceptual framework

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**Abstract:** Health information technology (HIT) refers to the deployment of electronic systems health care professionals and patients use to store, share, and analyze health information to improve patient safety and outcomes. Some of the best practices to heighten HIT use include procuring and analyzing data, prioritizing interoperability, building dynamic content, accounting for evolving patient expectations, recognizing the human element, and respect for the patient as the health consumer. Providers should target patients with the appropriate HIT information that is tailored to their needs and circumstances. Thus, careful evaluation is required to ensure it meets the needs of the patients. In this paper, we describe the current state of electronic health records use in Canada along with a patient safety and technology conceptual framework. We use this framework and metal hypersensitivity, a medical device-related adverse event, to highlight how health information technology can be leveraged to create a

learning health system and enhance patient safety.

**Keywords:** Metal hypersensitivity; Health information technology; Patient safety; QR codes; Learning health system

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#### 1. Introduction

The Institute of Medicine (IOM) recommends the use of health information technology (HIT) to decrease medication errors and improve patient safety (Kohn, Corrigan, & Donaldson, 2000). This presents infinite opportunities for healthcare providers (HCPs) in collaboration with HIT experts to continue advancing electronic health records (EHRs) to improve patient safety effectively and efficiently. When patient safety is prioritized, future workplace can be redesigned to apply outside of the box solutions to enhance safety at the point of care (Asan et al., 2021). A well-designed, web based EHR system is the ideal model to effectively record, monitor and recollect patient information to proactively capture adverse events or vulnerabilities (e.g., allergies) while eliminating preventable harm to the patient (Kai & Lipschultz, 2015).

A key challenge to the use of HIT to assure patient safety is the development of valid and feasible strategies to assess safety concerns (Singh & Sittig, 2016). For the system to be successful, the quality of information and the means of communication must be easy-to-use, allow timely patient-care status, and enable patient and family direct access to information and encourage active involvement in their care (e.g., diagnosis, plan of care, procedures, medications, diet) to ensure success. In this way, the care is individualized to promote safety. The importance of reliable exchange of information among the users within a community or region is dependent on having the appropriate

technological support. Simple interventions can make significant contributions to patient safety (Aggarwal et al., 2010). There are various ways in which HIT can prevent errors and adverse events. It can track and provide instantaneous feedback about patient vulnerabilities based on the medication profiles. It can also be designed so that a patient enters their personal information or reason for the visit directly into the EHR when they encounter the health system (e.g., hospital admission, emergency department) which can enhance confidentiality and promote safety by centering the patient as the driver of the encounter.

Overall, to assure patient-centred and individualized care for improve patient outcomes, the best HIT strategies should include tools that improve communication, make information accessible, and inform clinicians automatically in real time by providing reliable data (Bates & Gawande, 2003). For example, the HIT Safety conceptual framework (Singh & Sittig, 2016) offers the foundation for patient safety and quality improvement, to monitor prospective risks, healthcare processes and outcomes; and identify potential safety concerns before they occur. This conceptual framework leverages HIT to collect data that will be stored in the EHR directly from patients and families, engages patients in the quality and safety of their care, promotes change in patient behaviour, and empowers them to be active participant in the health data that are generated on them. The purpose of this article is to describe another conceptual framework for promoting patient safety using health information technologies, and to use metal hypersensitivity as exemplar to discuss how the EHR can be leveraged to address patient safety issues.

#### 2. Current state of EHR in Canada

The feasibility of any technological implementation is dependent on the current state of the healthcare context. Connected health is a model which explains the use of technology to allow for connection and monitoring of the patient, remotely or in-person, to allow for an efficient method of healthcare management (Mathivanan et al., 2018). Though Canadian health system has made significant progress, there is still no single national electronic health record for primary, secondary, or tertiary care (Larsen & Hutchison, 2019). Electronic health records in Canada vary from province to province, and even within cities, because physicians across the country have different requirements for EHRs or choose to invest into an EHR system that works best for them (Larsen & Hutchison, 2019). Zhao (2019) notes there is simply no way to build an EHR that would satisfy all the different users in Canada - especially when some providers have already existing EHRs. However, the good news is now that information is evolving into cloud-based environments and single EHRs may no longer be needed as long as existing EHR systems can integrate and interconnect with one another (Larsen & Hutchison, 2019). Moreover, the health system was late in embracing technology as a conduit to facilitate healthcare delivery, foster patient engagement, and ensure improved patient outcome. In doing so, it lags other sectors in introducing technology, but this phenomenon benefitted the healthcare field because other sectors have trained HCPs and consumers to use technology in a more efficient manner (Donovan, 2019). In sum, the appropriate use of the right technology in Canada has the potential to improve patient outcome by improving efficiency, quality, safety, and lower the cost of care.

#### 3. What is behind the push for technology-driven solutions

The inefficiencies of the current methods of supporting patients with chronic diseases over the trajectory of the disease progression is a major push for technology-driven solutions. The traditional methods of delivering disease self-management by health professionals to patients have been in one-on-one or group settings. For this conventional approach to be effective, however, it must be patient-centred, continued over long periods, with short follow-ups, and regular reinforcement. These aspects of patient care are expensive to implement and difficult to maintain across the care settings (Hale et al., 2015). Therefore, innovative and less intensive interventions are needed. In this case, mobile technologies offer a powerful platform for affordable and practical solutions. Additionally, mobile technologies promote increased patient participation, which is an integral component of the health system and has shown promise in self-management of chronic diseases. For example, U.S. based physicians have discussed mobile health technologies with patients and 26% have been asked about mHealth by a patient (Bene et al., 2019; Rowland et al., 2020).

Another factor that is behind the push for technology-driven solution is the prevalence of smart phones, which offer an accessible platform for health applications, allowing for personalized care to be delivered at the patient's convenience. According to the Pew Research Center (2019), 96% of Americans own a cell phone and the ownership of smartphones has grown from 35% in 2011 to 81% in 2019. The number of mobile apps downloads worldwide increased from 140 billion in 2016 to 204 billion in 2019 (Clemens, 2020). Other factors contributing to the increasing adoption of technology in healthcare include social values of autonomy and self-determination; recognition of the importance of patient participation; withdrawal of previously delivered services at the point of care; and changes in how the patient is viewed from flat and silent to collaborative problem solvers (Ringdal et al., 2017; Vahdat et al., 2014). Overall, increasing disease management complexities of chronic multi-morbidities and the emergence of new platforms for easy accessibility to technologies have made it both necessary and feasible for health consumers to become more actively involved in their own healthcare. Patients are now driving changes in the provision of healthcare services, and the control of and access to their health records. By providing patients with the tools, such as patient portals to help them manage and participate in their own care, we can help them stay healthier while easing the burden on providers.

#### 4. Patient safety and technology (PaSTech): A conceptual framework

Building upon prior theoretical models (Holden & Karsh, 2009; Singh & Sittig, 2016), while considering the World Health Organization's (WHO) (2021) initiative on Global Patient Action Plan 2021-2030, we propose a specific, testable, and multilevel conceptual framework to guide the designing of HIT for patient safety: The Patient Safety & Technology (PaSTech) conceptual framework. To address patient safety, the PaSTech include these main elements: safety culture, patient involvement/engagement, data privacy, and patient portals (Fig. 1).

#### 4.1. Safety culture

Safety culture can be developed based on teamwork, organizational characteristics (e.g., less complexity, resources), incentives and regulations, and availability of a system that may be tailored to the patient needs. Health technology should consider evolving patient

expectations. To motivate and appeal to patients, there is the need to change content and mode of communication. Use of varying medium, such as text, email, phone, or regular mail to connect with patients at a reasonable frequency is more likely to have a positive impact on patient actions. To optimize patient safety and engagement, the human element behind HIT must be highlighted. Patients need to know there are real human beings, and not robots, behind all the technology. In general, people relate to people better than they do to machines. When patients begin to feel there is someone there looking out for them, they relate better and are more likely to adhere to their care plans and follow self-care instructions. Patients appreciate direct phone calls more than automated text messages.



Fig. 1. PaSTech framework

#### 4.2. Patient involvement

Patient involvement or engagement in all phases of health information monitoring and recollection, understanding and participation in decision-making including diagnosis process that influence safety. For example, in the waiting room patients can answer specific health-related questions (e.g., demographics, allergies) directly into a computer monitor, use quick response (QR) codes or barcode scanner to facilitate the health encounter (Faggiano & Carugo, 2020). QR codes are not new technology; it has already been utilized in different aspects of healthcare to store data for easy access for both providers and patients. Patient involvement via engagement tools may improve reliability of the collected data (Wang & Huang, 2013).

Prioritizing interoperability (the ability of HIT to exchange and use information) of any patient-centred technology is only as useful as their ability to provide a holistic view of the patient. Thus, a complete picture of the patient requires complete medical history, including all encounters over the phone, in-person or via the patient portal. Interoperability provides a complete picture of the entire patient journey (Siwicki, 2020).

Similarly, traditional patient technologies stored in separate disparate systems of records, apps, and platforms are only as useful as they could be integrated. Thus, the only beneficial way to optimize patient engagement technologies is the sharing and aggregation of the data across apps and platforms between the patient and provider and across populations in the community.

Implementing HIT for patients' use means much more than deploying a piece of technology to physicians and providers; rather it is delivering technology to health consumers whose interest must come first. In short, health technology with low usability may be acceptable to the physician but may not meet the needs of the patient (Siwicki, 2020).

#### *4.3. Data privacy*

Data privacy is enhanced when patient enters the information directly into the EHR to avoid charts and manual processes, which is a barrier to efficient care. Having similar EHRs province-wide with all clinicians and HCPs having role-based access can enhance interoperability and address issues of data privacy. Gough et al. (2017) evaluated QR code stickers placed on patients' casts for ease-of-use post-operation. The information stickers contained a phone number to contact the healthcare provider and a QR code leading to a webpage to provide patients information about recovery and any complications that may arise. Responses from patients were overall positive, and many patients revealed reassurance of the code's placement (Gough et al., 2017). Unlike the information available from the URL (Uzun & Bilgin, 2016), the QR code can be accessed not only by healthcare providers and patients, but anyone with access to the QR code. The best approach to obtain enough information for the patient, while retaining security of information, is to balance the minimum amount of information that can be accessible while keeping within the current restrictions of the Canadian EHR systems. The approach can be to try to either limit the information shown to the patient, which would increase ease-of-use, or to enforce security on the side of the EHR for patient access, which would require patient education. Either option is viable, however more work and evaluation would have to be done to determine the weights of either of the methods provided.

#### 4.4. Patient portal

Patient portals, as part of a comprehensive EHR, allow individuals to access their health records and outcomes anytime from anywhere, provide important health-related information, improve patient safety by enhancing on-demand appointment scheduling. Patient portals have already been successfully implemented in several countries, and in some of them, patient access to their records is seen as a legal right (Neuner et al., 2015; Van Mens et al., 2020). To ensure successful and efficient use, the portals must be engaging, user-friendly, and support patient-centred outcomes. Furthermore, the portal must be an extension of an existing EHR, integrated into clinical encounters, for care providers to use it to provide health related information, effective patient communication, and support self-management (National Learning Consortium, 2013). The use of patient portals is associated with an increase in engagement with healthcare professionals, which helps improve quality of care and patient outcomes (Hoogenbosch et al., 2018). Despite the associated benefits, the mere availability of portals to patients does not guarantee they will be used. Patient portal use is influenced by technological literacy, ease of use, perceived usefulness, and the intention of use. Although the main objective of patient portals is to promote patient engagement, the people who need it the most are less likely to adopt it (Turner et al., 2019). For example, older adults have higher utilization rates of

healthcare resources, but have lower rates of portal adoption due to barriers such as lack of access to and experience with technology, and low health and numeracy skills (Irizarry et al., 2017).

Currently, there is no integrated HIT system that seamlessly link clinical experiences of medical devices or drugs directly to regulatory bodies. Patient portal can offer a possible avenue to be explored to capture real time data for post-market tracking of medical devices or drugs. For example, patient portal platforms can be leveraged in the case of COVID-19 to capture post vaccination experiences outside of traditional clinical trial reporting mechanisms.

#### 5. Metal hypersensitivity as an example

Metal hypersensitivity is a delayed type IV immunological response that can occur when metal ions are released from the device during corrosion – a process that all metallic devices undergo when implanted in the body (Hallab et al., 2001). The ions bind to protein molecules in the blood to form complexes that can trigger an immune response (Hallab et al., 2001). It is largely unknown why some people develop these immunological reactions and others do not. However, we do know that those with a history of sensitization to metal tend to be at higher risk while others become sensitized after receiving the device (Ekqvist et al., 2007).

Metal hypersensitivity is described as a rare complication of metallic devices. However, in an ongoing scoping review, we found over 200 citations that document the occurrence of these events since 1960s (Dordunoo et al., 2021a). The studies - generally retrospective case reports - detailed allergic responses to various metals including gold, titanium, cobalt, and tantalum (Bonutti et al., 2013; Svedman et al., 2005; Suwarsa et al., 2017). These reactions can occur amongst patients undergoing various types of procedures with devices made of metal, including hip replacements, spinal implants, and even intracoronary stents (Aliağaoğlu et al., 2012).

Symptoms of metal hypersensitivity are often vague and can be misattributed to other illnesses. Presenting symptoms include unexplained skin rash overlying implantation area (can also present more generalized), chronic pain localized to implant area, aseptic loosening, and implant joint stiffness (Christensen, Samant, & Shin, 2017). These symptoms have insidious onset and can appear months to years following implantation (Anand et al., 2009; Gao et al., 2011). Lack of consensus on diagnostic tests for metal hypersensitivity reactions often prolongs the duration of suffering for the patient as differential diagnoses - such as infections are ruled out when antibiotic therapy prove ineffective.

Compounding the difficulty of establishing the correct diagnosis of metal hypersensitivity is that many clinicians are unaware of the metal compositions of the implanted devices nor the association between prior sensitization to metals and poor outcomes following implantation (Dordunoo et al., 2021b). This lack of information affects the decision-making processes of both the healthcare provider and the patient. Without accessible information about the metal composition of the device, clinicians are unable to make a concrete diagnosis, leaving the patient unsupported to seek out solutions on their own.

To use HIT to facilitate the monitoring for metal hypersensitivity within the health system, an overall organizational effort needs to be placed on promoting a culture of safety. Studies show that developing a safety culture or safety climate in healthcare is

directly related to healthcare providers' attitude towards safety issues, such as error reporting, reduced adverse events, and reduced mortality (Weaver et al., 2013; Mardon et al., 2010; Pronovost et al., 2003). Despite this focus, finding the right approaches to promote effective safety culture has not been always successful (Weaver et al., 2013). Efforts are being made in healthcare organizations to promote the value of positive safety culture with the use of strategies such as daily team huddles, leadership walk rounds and unit-based interventions on safety climate measures (Weaver et al., 2013). The issue of metal hypersensitivity can be raised in these various settings to increase organizational awareness and promote the use of HIT within the microsystem to address patient safety.

In the case of metal hypersensitivity, lack of awareness among clinicians and mechanism for tracking patients overtime contribute to the under-reporting and misdiagnosis of it. Moreover, electronic health records were identified as a barrier to implementing metal hypersensitivity screening in the healt system because EHRs hinders the HCPs ability to document this type of allergy due to the lack of prompts i.e., no explicit question pertaining to metal hypersensitivity and no dedicated space to write this information (Dordunoo et al., 2021b). These barriers present an opportunity to think of ways in which HIT can be reconfigured to allow clinicians to properly assess, document and monitor patients with metallic implantable devices overtime for signs of hypersensitivity reactions. To do this well, requires the right mix of HIT to support the creation of a learning health system that links the patient level data to device level data (e.g., manufacturer, metal composition) with embedded screening tools that gather periodic data about the patient's experiences throughout the lifespan of the device. A learning health system is a conceptual strategy "where science, informatics, incentives and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience" (Smith et al., 2013, p. 136). Done well, patient reported outcomes data from this learning system could be aggregated anonymously and integrated into current medical device adverse events reporting system (e.g., Manufacturer and User Facility Device Experience database) to allow for as much information to be learned from every patient as a by-product of health service delivery (Smith et al., 2013). This will also improve patient safety by creating a systematic approach to data capture. Moreover, this level of data acquisition with the use of learning health systems, would allow for the creation of patient journey maps to further enhance patient safety by identifying gaps in the care continuum for patients with implantable devices and specific technologies to optimize the care processes (Borycki et al., 2020; Joseph et al., 2020; Kushniruk et al., 2020).

#### 5.1. Patient portal

The patient portal aspect of the the PaSTech framework is critical to assuring patient safety with regards to metal hypersensitivity. Patient portals can be used to allow the patient to enter information about their experience periodically. Questionnaires (e.g., pre-operative screening tool, post-operative patient-reported experience measures and patient-reported outcome measures) could be incorporated into EHRs to elicit responses from patients. The patient portal should also allow the patient to enter concerns ad hoc. For example, patients with hypersensitivity reaction to metal report "bleeding rashes" as one of the symptoms of metal hypersensitivity. The patient portal would allow them to enter these symptoms ad hoc as it occurs. In this way the HIT encourages patient involvement for the continuous monitoring of the device performance.

The use of patient portals further supports the collection of the post-market data about implantable devices. Currently, most medical devices are cleared for marketing through the 510 (k) pre-market mechanism which does not require a clinical trial (Johnson, 2016). Patient portals could provide a direct access to patients to allow for further collection of data. Moreover, collecting data directly from the patient, centres them as the "expert" with the real-world data about the device performance. Leveraging the patient's knowledge and experience could also further support patient-oriented research initiatives by allowing patients to drive the research agendas as much of device related research focus solely on its functionality and very little on the impacts of the device or the device composition on the human body or activities of daily living.

#### 5.2. Data privacy and patient involvement

The PaSTech framework invites the deliberate attention to data privacy. For the learning health system approach to address gaps in care about metal hypersensitivity and generate new avenues for research to improve patient safety, the appropriate HIT needs to allow data to be captured at the patient level but anonymized and aggregate before it is integrated with external systems (e.g., Manufacturer and User Facility Device Experience database). Patient involvement is a critical aspect in creating the learning health system to allow for detection and management of hypersensitivity reactions to implantable devices. Active involvement of the patient would allow for specific standards around data privacy to be created. Currently, there is no national EHR in Canada thus integrating a new HIT system to address the issue of metal hypersensitivity would be challenging. However, a measure like QR codes could be a temporary solution because it can function solely but can also be integrated once a national EHR is implemented. One way to utilize the QR codes for identifying metal hypersensitivity would be to use it to store data about the patient, type of surgery and device composition to be accessible by the patient and various healthcare providers who the patient might encounter. This way, when a patient presents with symptoms and has metal in situ, the metal composition is easily accessible and entering of the symptoms could trigger intelligent pathway to alert the HCP about the possibility of metal hypersensitivity and points to other potential hypersensitivities. The metals composition information would also be available to allow prompt testing to decipher the offending metal(s). Thus, for metal hypersensitivity, it is not enough to have patients enter symptoms into HIT systems without appropriate follow-up from HCPs. Using various medium, patients would be alerted to new information about the implanted device along with symptoms they should be aware off. This all require active patient involvement.

#### 6. Conclusion

Technology is now at the core of the health sector. Current trends in the emergence of technology have made it both necessary and feasible for consumers to become more actively involved in their own healthcare. Consumers are now driving changes in the provision of healthcare services, and the control of and access to their health records. The proposed PaSTech framework provides an opportunity to think broadly about how HIT can be utilized to promote patient safety by focusing on the optimal use of patient portals, maintaining data privacy while encouraging patient involvement. In the case of hypersensitivity reactions to implanted metallic devices - an under recognized patient safety issue, HIT can be configured to address it using a learning health system approach. By providing patients with the tools to help them manage their own health, keeping

records of evolving symptoms and integrating this with available evidence on metal composition could allow them to connect with HCPs, feel supported through the process of diagnosis while easing the burden on providers and health system in general. The deployment of the appropriate technology leads to increased efficiency, improved quality and safety, and at a reduced cost. If done correctly, using technology results in facilitation of communication between clinicians, improving medication and medical device safety, reducing potential medical errors, increasing access to medical information, and encouraging patient-centred care.

#### Author Statement

The authors declare that there is no conflict of interest.

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