National efforts to improve health information system safety in Canada, the United States of America and England

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ABSTRACT

Objective: In this paper we review progress as well as challenges encountered in Canada, the United States and England with regard to ensuring safety of health information technology.
Method: A review of major programs and initiatives for ensuring safety of health information technology in the three countries was conducted. Published literature and Web resources from national programs were reviewed for relevant information.
Results: It was found that in all three countries the issue of technology-induced error has been recognized as being of critical importance. The three countries have developed approaches for dealing with the issue that have some commonalities; however, they are at varying different stages of maturity, with England having the longest standing and most well developed safety programs, while Canada and the United States are at earlier stages. The types of approaches employed have included work on developing standards related to usability and interface design, certifications, directives from regulatory bodies, educational initiatives in health information technology (HIT) safety as well as research into safer HIT design and implementation methods.
Conclusions: HIT promises to lead to improved patient safety. However, it has become recognized that if not designed and deployed appropriately, such systems can lead to new types of errors. Based on this recognition, a variety of initiatives are being undertaken in Canada, the United States and England to promote the safe design, procurement and deployment of HIT. It is concluded that improved approaches to system design, testing, regulation, error reporting, safety education and cross-country collaboration will be needed to further promote safer HIT.

1. Introduction

Health information technology is expected to increase the efficiency, effectiveness and safety of healthcare worldwide.

Indeed a number of ambitious national projects have and continue to be undertaken in North America, the United Kingdom and other countries having the objective of promoting the widespread use and adoption of healthcare information technology (HIT) [1–3]. However, in addition to a large body

of evidence indicating that HIT can improve patient safety, in recent years there has also been a growing body of evidence that if HIT is not designed, implemented, deployed and maintained effectively, the technology itself may have unintended consequences, and introduce new types of errors – namely "technology-induced errors" [4]. Technology-induced errors are errors that result from the use of health information technology when it is implemented within healthcare settings and contexts. Such errors may arise from different phases in design, development, implementation and use of HIT and are often only detected once systems are deployed within complex real-world contexts and environments. The manifestations of such errors are often revealed in the complex interactions between health professionals, the new information technology and the complex human factors associated with their use in varied healthcare contexts and settings [4–6].

With the proliferation of a wide range of HIT (including electronic health record systems (EHRs) and associated technologies) there has been a concern that the level of quality and safety associated with system use is highly variable, with calls being made for improved design and development processes, risk management, the need for reporting systems and new regulations related to ensuring system safety to maximize the benefits of HIT. This work is being done internationally [7,8]. Indeed, recently the Institute of Medicine in the U.S. has released a report outlining the issues surrounding improving the safety of healthcare IT. In Canada, new efforts are underway to ensure that HIT applications meet safety standards. In England efforts have been underway for some time in the area of reducing technology-induced errors. In this article we will describe efforts currently being undertaken at the national level in Canada, the United States and England to improve the safety of HIT, in particular in relation to identifying, preventing and reporting about errors related to human factors issues and system safety.

1.1. Human factors issues and HIT safety

Human factors issues are increasingly seen as being at the core of many problems with HIT that are being reported internationally. This has included reports of systems inadvertently "inducing" or "facilitating" error by health professionals. For example Koppel and colleagues identified 22 ways in which a commercial system could "facilitate" error [6]. These included examples such as information errors generated from fragmentation of data and lack of integration as well as a range of human–machine interface flaws. Koppel et al. illustrate examples of the wrong patient file being selected from multiple files open on a computer screen, selection of wrong medications from lengthy screens, and unclear log on and log off screens leading to patient data going into the wrong patient record. In related work conducted in the same period, Kushniruk and colleagues conducted research showing a statistical relationship between serious usability issues and technology-induced error [4]. For example, it was found that specific user interface features, such as a lack of visibility of alerts, default dosages displayed that are not appropriate for a patient, and user issues in navigating through a complex user interface were highly associated with the occurrence of technology-induced error (i.e. leading to a range of medication errors).

Other studies of systems such as medication administration systems integrated with bar coding have shown that under certain emergency situations, user interaction designs that were deemed as being safe actually can become safety hazards (i.e. when a rigid workflow sequence dictated by a medication administration system has to be overridden during time critical emergencies). Along these lines, Beuscart-Zephir and colleagues have described how usability issues in computerized physician order entry (CPOE) can be associated with medication error [73] and socio-technical issues in the design of CPOE have been linked to error by Aarts [74] and Ash and colleagues [5]. Sittig and Singh describe several criteria for such error, including the following: (1) the HIT system is considered unavailable for use, (2) the HIT system can be considered to be malfunctioning, and (3) situations where users do not use the hardware and software as intended [75]. Calls for improved electronic health record (EHR) safety have led to proposals to take into account the full life cycle of EHRs from design to implementation and continuous improvement after implementation [76]. Others have argued for improved oversight regarding HIT vendors [77] and arguments for the creation of an oversight infrastructure for EHR related patient safety hazards [78].

Human factors approaches to understanding and modeling technology-induced error in healthcare have borrowed from the work of Reason and others [79]. For example, Sitting and Singh have described an eight-dimensional model of sociotechnical challenges involved in the design, implementation and use of HIT [80]. Zhang and colleagues have developed a theoretical and conceptual cognitive taxonomy of medical errors, based on cognitive science and human factors [81]. Along another line of research, a model developed by Borycki and colleagues illustrates how technology-induced error may originate from multiple sources that range from flaws in policy and regulation (at the blunt end of Reason's classic model of error) down to issues that occur during system development, deployment and use by clinicians (at the sharp end of Reason's model) [30].

At the level of system development there have been calls for improved methods for systems analysis, design and testing to mitigate the risk of technology-induced error [76]. However, it has also been argued that unless there are specific policy changes and the introduction of governmental regulation, the situation may not likely improve. In this paper we consider national initiatives in three countries that are focused on addressing issues related to technology-induced error and that can be seen at a policy level and regulatory approaches to improving the safety of healthcare IT that impact on human factors and safety of HIT at different points in system design and deployment. The paper will be organized using a framework for considering national efforts and for selecting safety approaches to be reviewed. This framework will consider safety initiatives in terms of their impact on the following: (a) their level of recognition of the problem, including requirements for action, (2) usability and design considerations related to safety, (3) implementation issues related to safety, and (4) post implementation issues and error reporting (see Fig. 1). The discussion is based on where in the system development life cycle (SDLC) the initiatives are concerned, targeted, or may have impact.

Fig. 1 – A framework for considering the impact of efforts at improving HIT Safety.

2. Developments for health information system safety in the United States

2.1. Recognition of the problem and the role of policy and regulation

In the U.S., many studies have been done suggesting that safety can be improved with implementation of HIT [9], in particular medication safety [10]. Because of the potential benefits of electronic health records with respect to safety, quality and efficiency a robust national program has been implemented to provide incentives for providers to adopt HIT [11]. In addition, a variety of studies have been done that have shown that with implementation of health information technology and electronic health records, unintended consequences regularly occur, and these can create safety issues [5,12,13], even when the intent is to improve safety.

In part as a response to these concerns, the Office of the National Coordinator for HIT commissioned the recent report of the Institute of Medicine to address the issues of how substantial the safety problems are, and what can be done to prevent them. The committee concluded that there are a number of anecdotes demonstrating that safety issues can be created (with six papers being identified as reporting quantitative results), and that the vendor community has not been as responsive as it should be to address them. The committee made a number of recommendations, but among them was that the Secretary of Health and Human Services should ask the Food and Drug Administration to develop a framework for regulation of electronic health records and clinical decision support, and to consider implementing them in a years time if substantial progress does not occur [7]. In July of 2012 the Food and Drug Administration Safety and Innovation Act was signed into law which contains sections directly relevant to HIT, including the unique device identifier regulation (i.e. serial numbering scheme for devices). In addition, in the report is stated that no later than 18 months from the date of enactment of the Act that the Secretary of Health and Human Services (in collaboration with the National Coordinator for HIT and the Federal Communications Commission) will complete a new strategy and safety recommendations for a risk-reduction based regulatory framework for HIT, including mobile medical applications [82]. The impact of this on clinical decision support systems and electronic health records remains to be seen.

2.2. Usability and design considerations

The problem of usability was addressed at some length by the committee commissioned by the National Coordinator of HIT to address the risk of HIT with respect to patient safety [7].

Much of the software which is currently in place in the U.S. scores relatively poorly from the usability perspective [14,15]. The federal government has set up a certification program for electronic health records, and to be eligible for financial incentives providers and hospitals must show that they are using a certified record [11]. However, certification (through bodies such as the Certification for Health Information Technology (CCHIT)) has focused on ensuring that records include a number of specific features, and are set up as pass/fail. To be certified, an electronic health record needs to include all the required features, but there is no assessment of usability, which is more subjective and is usually scored on a continuous scale [16]. Vendors in the U.S. have resisted making their products available for public comparisons of usability. Many have also resisted making information which is commonly used in comparisons such as screen shots publicly available. Another practice that emerged was that many vendors try to discourage the sharing of error reports involving their software, even among other users of the same software [17]. The Institute of Medicine committee recognized and underscored the need for publicly available data on usability, and also said that vendors should be required to make available screen shots, both for reasons relating to usability assessment, and also when a particular screen was felt by a provider to have led to an error, as well as emphasizing the need for providers to be able to share information in situations in which they believe software led to an error [7]. It should be noted that work by the US National Institute of Standards and Technology is also underway in the area of providing technical evaluation, testing and validation of the usability of electronic health records [83]. In addition, the Agency for Healthcare Research and Quality has also published guidelines for the reduction of technology-induced error in electronic health records [84].

2.3. Implementation issues

Another issue which has emerged with respect to safety is that many hospitals appear to have done a poor job with implementing even some of the most important medication safety alerts—it is important that usability be good, but content is also important. In a study led by Metzger, the alerts hospitals had implemented were evaluated using a CPOE "flight simulator". The study included 62 hospitals from across the U.S. which voluntarily participated. Key findings were that the CPOE systems detected only 53% of orders that would have been fatal, and only 10–82% of orders that would have caused serious ADEs [18]. These data suggest that it is probably important to do such testing on an on-going basis, and one of the IOM committee's (i.e. the committee that was asked to address the risks of HIT with respect to patient safety) addressed this point [7].

2.4. Post implementation and reporting of error

It remains to be seen how extensively the recommendations from the committee which was asked to address the risks of HIT will be taken up. The report was released relatively recently, and the government and other stakeholders are only now in the process of responding to it. It will be very helpful if the recommendations around reporting of errors and more public release of data around usability are taken up. The recommendation around potential regulation of the Food and Drug Administration around software could be more disruptive, depending upon the position taken by the FDA. The development cycle for software development is fairly short, and introducing regulation could introduce undesirable delays into a process in which the vendors are already feeling tremendous strain because of their need to meet the many and growing requirements of meaningful use [7].

In considering error reporting, a number of studies have been undertaken of data contained in the FDA's Manufacturer and User Facility Device Experience (MAUD) database. In one study, it was found that 32 categories of HIT problems could be identified from reports from 1100 reports about HIT from January 2008 to July 2010 [85]. In another study, three large national adverse event medical device databases were examined for reports for HIT problems, including missing or incorrect data, data displayed for the wrong patient, and problems resulting from system downtime [86]. It should be noted that although the databases studied contained information about HIT problems, the databases were not specifically designed for reporting of such problems, which may lead to underreporting and need for development of new error reporting approaches and mechanisms focused around HIT problems.

3. Developments for health system safety in Canada

3.1. Recognition of the problem and the role of policy and regulation

Much like the United States, Canada is in the early stages of dealing with the emerging issue of technology-induced error in healthcare. As in the United States, the problem of information systems that may themselves be safety issues is becoming increasingly recognized as both a potential and existing problem. The Canadian perspective is beginning to be influenced by the work of the Institute of Medicine in the United States, in particular their newly published report (as described in the section above) that has provided a description of the problem and recommendations at multiple levels [7]. Along these lines Health Canada and COACH (Canada's Health Informatics Association) have created new initiatives to further define electronic record regulation and help disseminate information and strategies for coping with technology-induced error. To date, this work has included identification of a range of stakeholders, including HIT vendors, governments, health professionals and patients themselves (very much in line with the analysis of the IOM in the United States) with the intent of

developing guidelines to support and guide safer HIT implementation [19].

3.2. Usability and design considerations

In response to many of the issues and concerns described above and the general acknowledgment that technology-induced errors exist and need to be mitigated, in 2009 Health Canada began to classify certain types of patient management software as medical devices, with the expectation that this would lead to tighter control and regulation of such software. Indeed, software such as picture archiving and communication systems and other related software are being included under this classification. However, the applicability of this type of regulation has been essentially limited to software that provides the only means and opportunity to capture or acquire data from a medical device [28].

Other developments in Canada related to usability and design issues have emerged from university research in the area of initial work linking usability to the potential for technology-induced error. This has included work which has statistically shown correlation between poor usability of HIT user interfaces and specific types of technology-induced error [4]. This work has shown how specific user interface features of medication administration systems may lead to high probability of medication errors. By testing computerized physician order entry systems (CPOE) and medication administration systems in clinical simulations prior to releasing systems for widespread use, it has been shown that errors can be identified and rectified before going live [4,30]. A growing body of Canadian work in this area is also concerned with developing improved methods for early detection and mitigation of such error through improved and enhanced testing of systems and development of new methods (including the use of "clinical simulations" involving testing HIT under realistic local conditions using an "In-situ" approach) prior to deployment of HIT for use with live patients. Such work can help health care organizations to determine if systems imported from other countries have a strong fit with local policies, procedures, culture, organizational and health care system practices [26,31]. In addition to this, research that better characterizes the "degree of fit" between vendor based HIT, healthcare organizations and country health care systems up front during the system procurement and selection process is beginning to have an impact in Canada and internationally [26,31].

3.3. Implementation issues

Although there are a number of differences in the situation in Canada and the United States (which will be discussed), as many commercial vendor systems purchased for use in Canada are from the United States (in particular large hospital-based systems) considerations and concerns arising in the United States are shared in Canada. In addition, the potential for lack of "fit" between systems developed outside of Canada (e.g. by vendors from the United States or other countries) and healthcare practices, policies and organizations within Canada has lead to further concerns and to new classes of technology-induced error that result from mismatched policies, procedures, cultural and organizational processes

embedded within information systems imported from other countries and implemented in Canada [20–22]. This is an area that has received attention in other countries, including Australia and England, where the "importing" of vendor systems developed in other countries – often without appropriate testing and customization to local and regional conditions – has been tied to systems that may not respond in a way appropriate in the purchasing country, which in a number of published reports was not determined until after the systems were implemented [e.g. 24,25]. Furthermore, as in the United States there has begun to be criticism of purchasing practices for complex healthcare information systems, such as electronic health record systems [7]. For example Koppel has described the issue of the "Hold Harmless" clause which is contained in contracts for many procurements in the United States, which can hold the vendor of many types of complex healthcare software "harmless", whereby vendors may not be held liable for errors that could have occurred due to flaws in the system design and programming [25]. As well, concerns have been raised about the inability of providers and purchasing organizations to exchange information about potential system-related issues. Some vendors have suggested that such exchange of information could lead to their losing their "competitive advantage" when competing for contracts while healthcare organizations experience difficulty in fully understanding how the system can be effectively and safely implemented [7]. These issues have also been flagged as a concern during the procurement of some systems in Canada as well [26]. According to Koppel [25] and Ash [27] these issues or concerns necessitate improved legal counsel for healthcare organizations in setting up procurement contracts and may need intervention by regulatory bodies.

3.4. Post implementation and reporting of error

An area that is currently receiving attention but is in its nascent stages is the need for reporting systems that will allow health professionals and others using HIT to be able to effectively and anonymously report errors resulting from use of HIT. In the United States, the FDA's MAUDE database (although not initially designed for reporting technology-induced error) has been used to report user errors that may be related to healthcare information systems, and furthermore, this reporting has been made public [29]. A number of organizations within Canada are now working on developing analogous approaches to reporting of technology-induced error as a first step in understanding and characterizing the nature and scope of the problems that may arise from technology-induced error [30].

As described above, in Canada there are a number of organizations and groups that are taking the issue of technology-induced error in HIT very seriously and are working on improving different facets of the problem (e.g. reporting methods, procurement, testing and implementation methods) [4,19,28,30,31]. A joint report involving Canada Health Infoway pointed out that HIT may sometimes reduce rather than enhance patient safety [8]. Additionally, Canada Health Infoway has promoted use of HIT standards in Canada and system certification. However, it can be noted that in general groups and stakeholders in Canada have been working

somewhat independently, and in some cases have been waiting to see the implications of reports like the IOM's in the US (that are considered to be of importance to Canadians as well). In summary the potential problem of technology-induced error in HIT has been recognized, but the response to it is currently in a state of flux.

4.   Developments for health system safety in England

4.1.   Recognition of the problem and the role of policy and regulation

England has taken an especially active and 'multifaceted' approach to improving patient safety across the National Health Service (NHS) through the application of Health Information Systems. It should be stressed that since the political devolution of 1997 (i.e. England, Wales, Scotland and Northern Ireland all run separate and, to some extent, divergent health services [32]) some of the initiatives apply to all four 'home countries' but this portion of the paper confines itself to England.

Patient safety, through the application of well-designed software and resilient IT systems has been championed from the start of the UK National programme for IT in 2003. The employment of a National Clinical Director for Safety has been critical in establishing (in 2009), a formal and compulsory clinical safety management system and developing safety standards for health IT for the NHS in England [87,88]. The first standard is a framework of documentation set out for suppliers to use during development of health systems, comprising: (1) Hazard assessment – review of patient safety issues which the supplier's system may encounter, (2) Hazard mitigation – systematically designing controls for the identified hazards, (3) Evidence – ensuring the controls have been effective in managing the risk to the patient. The second standard offers a health organization "a framework within which patient safety hazards associated with the deployment and implementation of new eHealth systems can be managed". These combined requirements establish an end to-end Clinical Safety Management System. Implementation of this standard also puts procedures in place to allow an organization to comply with IEC80001 – Clinical risk management of IT networks containing medical devices [89].

The creation of two bodies has also been pivotal. The actions of the Care Quality Commission [41] (CQC) and the National Patient Safety Authority [42] (NPSA) have made major changes to the NHS's attitude toward safety. This, in turn has led to a more mature environment for the governance, development and deployment of Health Information Systems. Clinical safety was also embedded into the English NHS Connecting for Health 'National Programme' [43,44].

As a measure of how far change has come, a current 'grass roots' campaign has called "for every NHS provider organization to consider appointing a chief clinical information officer to provide clinical leadership on information management and information technology projects (IM&IT) and the use of information to support improvements in clinical care" [45].

Standards have also been vital in delivering Semantic Inter-operability between General Practitioner's Systems allowing direct transfer of records [46], reducing the need for re-entry of data and associated errors as well as increasing utility. Work continues on increasing this project's scope as well as the 'Interoperability toolkit' to 'support interoperability within local organizations and across local health communities' [47]. At the same time as the organizational changes outlined above were occurring there have also been concerted efforts to embed Informatics into Clinical Education [48] (eICE) as well as formalize information governance [48,50], professionalism [42,51] and specific safety training [49].

The EU Medical Device Directive (MDD) reached broadly similar conclusions to that held in the US, in that if software is part of a medical device, the whole system is subject to the classification, and also where software is used for remote monitoring it would fall into a higher class (e.g. Class IIa) if it is used for decision making. Likewise if the system is interoperable it is sufficient to show that it works with one and to claim equivalence for others. However, it is the intended use that is the critical factor in determining classification. For example, in the EU there are guidelines that define whether different aspects of digital X-ray systems ('PACS') are classified, with the elements used for the storage and viewing of images for non-diagnostic purposes ruled as being outside the definition of a medical device. Even where software, or a device containing software, is seen as a medical device there can still be anomalies in the way that device is classified. For instance the same EU ruling on PACS systems introduces a concept that performing algorithms makes software a Class II (medium risk) device. The same logic might be applied to a body mass index (BMI) calculator that uses height and weight to produce a result.

The recently introduced amendment to the EU MDD recognizes this confusion: "It is necessary to clarify that software in its own right when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device as a medical device. Software for general purposes when used in a healthcare setting is not a medical device" [69]. Following the recently enforced revision of the MDD, the Medicines and Healthcare Products Regulatory Agency (MHRA) has interpreted the reference to software to read: "that software intended by its manufacturers to be used specifically for diagnostic and or therapeutic purposes are now regarded as medical devices in their own right." The MHRA has provided some examples of the types of devices which fall into this category [71]:

- the NHS software algorithm to screen for swine flu infection
- Software providing a cognitive training/stimulation programme for patients with specific conditions or impairments in order to cause improvements
- A system which detects specific changes in patients using an algorithm acting on data from a number of inputs (e.g. movements, voice analysis, etc.) in order to propose clinical interventions, medication, hospital referrals, etc.
- Software facilitating remote large-scale online patient screening, for example to identify ophthalmic conditions diagnosed by qualified hospital ophthalmologists

- Software that carries out complex analysis/trending of measured physiological parameters which clinicians rely upon when making a diagnosis.

Many embedded mHealth systems would be likely to fall under the category covering "A system which detects specific changes in patients using an algorithm acting on data from a number of inputs".

4.2. Usability and design considerations

The first event to mention was the inception of the Information Standards Board for Health and Social Care. Since 2001, this organization has matured into one which continuously assures standards in health and provides thought leadership [33] across a broad range of domains [34]: (a) clinical, (b) management, (c) technical, (d) social care, (e) information governance, and (f) public health and statistics. The first nine items of the NHS Connecting for Health Common User Interface (CUI) Programme's [35] early output have recently been ratified as 'initial standards' and are now 'for implementation' nationally by 2015 [36]. This work has focused on developing user interface standards for creating a common user interface "look and feel" for NHS systems, in order to lead to more consistent and safer user interfaces. This work is also related to development of specific safety guidelines that can be applied to designing user interfaces for systems such as electronic health records for safe on-screen display of medication information (to avoid confusion arising from non-standard drug names, abbreviations, drugs with close spellings, and display of numbers and dosages that could lead to misinterpretation) [90].

This work is also of significance in recent professional record keeping developments. This work continues and legislation before Parliament (Health Bill 2011 [37]) at time of writing will "establish a duty for health and social care organizations to follow information standards". Standards will be set by the NHS Commissioning Board [38] for the NHS; and the Department of Health for public health and adult social care. The governance for the approval of standards has yet to be defined" [39]. Further work also continues on e-prescribing to evaluate current system functionality and safety [40] and work toward the standardization of 'prescribe, review, dispense and administer' events through professionally derived record keeping standards.

4.3. Implementation issues

Multiple national infrastructure projects have delivered increments in increased safety. NHS mail [50] is an email system and directory service available to all (i.e. more than 1.2 million NHS organizations and employees). It is accredited to 'Government Restricted' status and held to be secure enough for the transfer of identifiable patient data. Another example is a comprehensive programme to manage and deliver a single identifier for healthcare (The NHS number [49]) from birth to death. This is also backed up by a national programme [53–60] to both embed and administer Automatic Identification and Data Capture (AIDC – Barcode/RFID, etc.) standards [53,56]. A nationally mandated security architecture with egif

level 3 [55] access control (two factors: something you have, and something you know) is also in place [58] and underpinned by a national 'Care record Guarantee' [59] through the National Information Governance Board. A comprehensive National Infrastructure Maturity model [61] is also in place and being refined by real-life implementation experience across the NHS.

Early in the life of the UK National Programme, it was realized that the introduction of new hardware into the healthcare environment could add new infection risks. Two collaborations led to the development and deployment of innovative hardware. The first was the 'infection resistant keyboard' which not only performed as designed but also increased the rate of clinician hand cleansing [62]. The second was a collaboration with Intel [63] and over six hardware manufacturers to instantiate a new form factor for mobile healthcare devices [64]. Over 15 software vendors are also involved and the devices are in use all over the world. Mention should also be made of the Industry-wide collaboration of the Continua Alliance [64] where over 240 vendors and providers are working to deliver standards-based, interoperable personal care. The NHS was one of the founding members of this alliance and continues to contribute strongly at all levels.

The need for clinicians to engage with the structure and content of their new information systems has been recognized for many years [52,65,66]. It is only very recently that a national initiative has been framed which will start to deliver the required concerted and coordinated approach necessary [67]. This new initiative makes two main ambitious but authoritative recommendations:

- the establishment of a [National] Professional Record Standards Development Body (PRDSB) that would lead the development and professional assurance of clinical record standards across all specialties and clinical disciplines. The standards will provide the foundation upon which to base the collection, storage, communication, aggregation and reuse of structured clinical information across organizational boundaries throughout health and social care.
- that an interim body is appointed under the auspices of the Academy of Medical Royal Colleges [68] with the task of establishing the final structure, governance and funding of the PRSDB.

Considerable professional and consumer support has already been documented. Building upon the technical standards which already exist [70], this new approach should harness and direct future developments in all clinical and consumer-facing systems.

4.4. Post implementation and reporting of error

It should be noted that the NHS in England has recently adopted the IEC80001 standard [72] as the main standard for managing health software in IT networks (this standard superseding ISO/TS 29321:2008(E)). This places a greater emphasis on active, in-service risk surveillance and management (processes) than on prescriptive definitions of functionality. Also, risk management standards are being applied to ensuring patient safety, not only for device safety [91], but also for the

management of clinical risk that may be related to the deployment and use of healthcare software [92].

In terms of error reporting the NHS's Clinical Safety Management System (CSMS) was established in 2005 as a safety incident management process, with incidents related to HIT being reported and logged (with close to 1000 such incidents having been reported). The incident reports are assessed and managed by a clinical safety group. Examples of errors reported include identification of entry and retrieval (using HIT systems) of the wrong patient, the wrong notes, wrong results and wrong procedures. Problems due to data migration are reported and data corruption issues (e.g. over-writing of patient information in an electronic health record). This is also related to initiatives aimed at providing training for accreditation and safer implementations [93].

This review of innovations in England has been, of necessity, brief. Most of the initiatives, we believe, having controlled for organizational differences, have global applicability and underline how similar the problems are. That we are currently solving issues and problems at the individual level through to the country level points to the need for urgent evaluation. The safety and quality of our care depends upon it.

5.   Challenges for Canada, the United States and England

5.1.   Overall approaches and stages of development

The U.S, England and Canada have much to learn from the others experiences with respect to the impacts of technology-induced errors on patient safety. All three have, to date, developed similar and different strategies to address the issue, which is partly due to the underlying differences between the three healthcare systems. There is an increasing realization, however, that the underlying problems are similar when the obvious organizational and healthcare system differences are controlled for.

Both the U.S. and Canada have been successful at an early stage in recognizing the potential harm technology-induced errors may cause; however, U.S. efforts seem to be more coordinated than Canadian efforts as exemplified in the recently published IOM report that included a wide range of perspectives from various institutions and researchers in the field. Within Canada, the work on technology-induced errors continues to move toward better coordination among the major Canadian institutions such as Canada Health Infoway, COACH, and Health Canada. Even though the recent IOM report will influence Canadian efforts in addressing the issue of technology-induced errors, a more collaborative effort within Canada is still needed. This is primarily because the Canadian healthcare system perspective is essentially different from that of the United States on various policy, financial, political, organizational, technological, and cultural levels. The recent announcements of the PRSDB in England insert a strong professional and consumer drive into the development of health information systems. In order to achieve the best results from this approach, however, it will be necessary for a strong culture of usability and user centric design to develop among software

vendors in order to rapidly develop and refine cross cultural healthcare and organizational prototypes.

5.2.   Relationship to vendors

Another major challenge moving forward for all countries will be working with the vendor community in the creation of safer systems that are built on user-centered design principles. As suggested by the IOM report, user-centered design principles should be considered at the outset during acquisition and continue during the implementation and subsequent maintenance stages. The vendor community has been slow in their response to address these issues and more action is needed from the vendor community in designing better systems to reduce technology-induced errors. Because many of the health information systems in Canada are essentially systems designed for the U.S. healthcare system, much work will be needed on behalf of the vendor and health care community in Canada to create a better "fit" between Canadian healthcare practices, policies, government regulations and health information systems. Many of the secondary care information systems in England are from similar vendor backgrounds but primary care information systems are exclusively built for the English marketplace. This creates its own tensions as a standards-based approach is promoted. It opens up wider markets to vendors but also threatens the current saturated home market (since the inception of the 2003 'Quality based' new GP contract over 99% of GPs use a clinical information system) Users and researchers should have access to test versions of EMRs and study technology-induced errors from various vendor systems [7]. Their experiences should be shared and recommendations to vendors on how to improve their systems should be shared with vendors to help inform vendor or system improvements. Although, it may be difficult to have vendor co-operation, hospitals purchasing EMRs can make it a requirement to test the usability of vendor systems in a simulated or real environment prior to purchasing a system. Such purchase requirements have been made by some French hospitals as part of their purchasing process where usability studies are conducted on EMRs prior to system acquisition [36]. An evaluation of the safety of all secondary care prescribing systems available in the UK was delivered in 2009 but its results are only available to UK Healthcare providers.

5.3.   Error reporting

Reporting technology-induced errors will be another challenge for both Canada and the U.S. because there are no current national reporting mechanisms or policies that explicitly track technology-induced errors [7]. This presents a major challenge and moves the accountability of collecting, analyzing, and reporting adverse technology related outcomes on to individual, healthcare practitioners, and healthcare organizations. In England, a National NPSA reporting and learning service performing this task has been in place since 2003 and is now the largest source of patient safety incident data in the world. It is currently in an interim state with a view to re-procurement within two years and will come under the control of the new NHS Commissioning Board in due course. Even though US efforts have involved capturing technology-induced errors from an incident reporting system perspective, a more comprehensive and national effort to develop a framework and guidelines on how to capture, analyze, and report such data is needed. Perhaps, one of the major challenges for reporting incidents of technology-induced error will be the ability to define what constitutes a technology-induced error and how to accurately describe their occurrence (such that the root causes of the error can be identified). As of now, there are no comprehensive guidelines or criteria to accurately represent and describe a technology-induced error because of the difficulty in determining how the adverse event was caused by the health information system (leading to potential underreporting of technology-induced error from the analysis of data collected from currently used incident reporting systems).

Reporting errors will be another challenge as hospital, regional health authority and government policies need to define who (e.g. patients, computer programmers, systems implementers, physicians, nurses, administrators) should be reporting technology-induced errors. Once we identify who should report an error, there will be a need to provide the appropriate training or awareness to know when a technology-induced error occurred and what details need to be reported. Without education and training of those who use and develop systems, it will be a challenge for the patient, clinician, hospital, vendor, etc. to identify when a technology-induced error has occurred. Furthermore, there is a need to ensure timely data analysis and feedback (form reported errors) to ensure the sustainability and usefulness of the reporting.

5.4.   Education and training

Education and training will need to be undertaken, across disciplines. Systems designers, developers and implementers will need to be trained to recognize and report errors. As well, health care professionals will also need to learn about technology-induced errors. Training will need to be health care specific, health care system/organization specific and health information specific for it to be effective. In addition to this, training will need to take place at all levels in diploma, undergraduate and graduate degree programs in health professional programs as well as traditional health information technology and health information science programs for it to be effective. Training will also need to be extended to include those health professionals and health information systems professionals who are currently practicing. This should include training on human factors and usability methods to ensure that user design principles are implemented and used effectively. Beyond reporting errors, training will need to focus on methodologies that can be used to identifying errors prior to systems implementation and after a system has been implemented (in addition to using processes to identify the root causes of errors after harm has occurred).

5.5.   Classification of error

Classification is another issue that is a concern for the both the U.S. and Canada in relation to technology-induced errors. In 2009, Canada began to classify various types of patient software as medical devices which have been limited to

applications (such as picture archiving and certain telehealth systems) that provide the only means and opportunity to capture or acquire data from a medical device. In the U.S., the IOM report reveals that discussion centered on making health information technology a Class III FDA medical device. One of the main criticisms to this approach would be that it would add another layer of complexity that would be placed upon vendors and might stifle innovation within the health IT sector. Very similar EU legislation exists and is causing similar vendor concerns.

5.6. *Cross-country exchange of information*

Lastly, given that many health information system vendors are international in nature (i.e. their systems may be in use in Canada, the United States, England and other countries) there is a need for international reporting of the occurrence of such technology induced errors. Technology-induced errors have been reported by researchers in varying countries. Many of these errors are similar in nature. Other such errors differ and arise from health care system and health information system interactions. There is a need to understand how technology-induced errors are propagated throughout a healthcare system and how they arise in differing countries where health professional practice, organizational policies and procedures and health care systems interact to lead to a technology-induced error. Such learning amongst countries and organizations would lead to greater knowledge about errors, enhance prevention, and more importantly would lead to best practices in systems development, implementation and evaluation specific to improving the safety of health information systems at a global level. For this to occur, there will be a need to engage in transparency in reporting and to develop mechanisms at the international level for groups to work together and learn from each other's experiences and approaches to managing this global issue.

6. Conclusions

It has become increasingly recognized internationally that deployment of health information systems can improve healthcare's effectiveness and safety. However, there is a growing awareness that information technologies such as the electronic health record and related systems can also introduce new types of errors if not designed and deployed carefully. In the three countries discussed in this paper, namely the United States, Canada and England this awareness has reached the level of national bodies and organizations. A range of approaches are now being deployed in each of the three countries to mitigate the inadvertent technology-induced error and risks associated with new information technology. It can be concluded that despite the differences in approaches taken and stages of their maturity, recommendations for improving the safety of HIT are forthcoming and will likely lead to improvements in the current situation. However, it is stressed that in order to make significant progress in addressing error and risk associated with HIT, the sharing and communication of ideas, methods, findings and recommendations across nations is highly recommended.

Summary points
Previously known situation:

- Health information technology (HIT) has been previously shown to increase patient safety throughout the health informatics literature (with seminal papers from the 1990s) and this has influenced the move across major nations to implement HIT on a national basis.
- In 2004 a number of articles have emerged describing the potential for HIT to introduce new type of errors known as technology-induced error.
- With the recent release of reports by the Institute of Medicine in the United States and related work in Canada and England, national efforts aimed at reducing technology-induced error are underway.

What the article reviews:

- In Canada, the United States and England the problem of HIT safety has been recognized, and a number of national efforts have been undertaken in the area of ensuring HIT safety in each country.
- In the United States this has included recent recommendations by the Institute of Medicine to improve the current situation, including recommendations for development of a framework for regulation of electronic health records and some discussion of the problem of usability of such systems, with current approaches to system certification not addressing usability.
- In Canada, a number of efforts have been undertaken, including work by COACH, Canada's Health Informatics Organization, new regulations by Health Canada and foundational research work from the academic sector. However, efforts so far have not been well integrated and work at a national level for improving HIT safety is at an early stage.
- In England a variety of nationally sponsored programs have been in effect for several years and continue to be refined, including an information standards board for healthcare, the care quality commission and the national patient safety authority. This has also included establishment of a national professional record standards development body and work in England has also been affected by the EU medical device directive.
- Although the nature of the problem has been recognized nationally in all three countries, a number of challenges exist including: working with the respective vendor communities, need for greater collaboration and integration of efforts, reporting of technology-induced error and need for greater education and training.
- Although the countries reviewed are at different stages of addressing the problem of technology-induced error in HIT, there is considerable knowledge that can be shared across the countries and internationally to help improve the safety of HIT.

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