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Viewpoint

Data Safe Havens and Trust: Toward a Common Understanding of Trusted Research Platforms for Governing Secure and Ethical Health Research

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Abstract

In parallel with the advances in big data-driven clinical research, the data safe haven concept has evolved over the last decade. It has led to the development of a framework to support the secure handling of health care information used for clinical research that balances compliance with legal and regulatory controls and ethical requirements while engaging with the public as a partner in its governance. We describe the evolution of 4 separately developed clinical research platforms into services throughout the United Kingdom-wide Farr Institute and their common deployment features in practice. The Farr Institute is a case study from which we propose a common definition of data safe havens as trusted platforms for clinical academic research. We use this common definition to discuss the challenges and dilemmas faced by the clinical academic research community, to help promote a consistent understanding of them and how they might best be handled in practice. We conclude by questioning whether the common definition represents a safe and trustworthy model for conducting clinical research that can stand the test of time and ongoing technical advances while paying heed to evolving public and professional concerns.

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KEYWORDS

trusted research platforms; data safe havens; trusted researchers; legislative and regulatory compliance; public engagement; public involvement; clinical research support; health record linkage supported research; genomics research support

Introduction

The challenges of secure electronic health care records reuse and its trustworthiness are well recognized [1]. The international clinical research community is nevertheless continually recognizing the significance of big data for driving research and deriving further benefit for patient care and outcomes [2,3]. While these challenges remain internationally applicable, we focus in this paper on the recent experiences across the United Kingdom to illustrate an ongoing dilemma and challenges around the sharing and wider linkage of health and social care records encouraged by the big data trend, and how established protection strategies must continue to evolve to meet them.

In considering the ongoing dilemma, we discuss the paradigm of the data safe haven (DSH) that has garnered increasing interest across the UK research community. This paradigm is a commonly recognized, state-of-the-art approach for handling information derived from health care records in clinical research, which has also achieved international recognition. While the paradigm has developed to include a set of 12 criteria, including the need to take account of societal concerns and anxieties when handling data within any environment that claims to be a safe haven [4], there remains work to be done to develop a more inclusive definition of trustworthiness in this context, specifically with regard to the public and its views on security [5]. But what does the paradigm look like in practice and how does it measure up against developing dilemmas and challenges in the age of big data? We aim in this paper to answer this question by discussing the practical experience of establishing and running DSHs. With reference to a series of case studies across the 4 nodes of the Farr Institute of Health Informatics Research, which spans the United Kingdom, we build upon the understanding that has developed around the DSH paradigm and the need to apply a more developed and inclusive understanding of trust as it applies to different stakeholders.

We use the case studies to identify comparable features of the 4 nodes as they have developed and evolved independently. Using this and a detailed consideration of the legal, regulatory, and information security requirements, we examine the ramifications of their implementation in practice for clinical research with regard to the established criteria. This provides a basis to recommend an approach for fostering and nurturing trust across stakeholders as the linkage trends and dilemmas continue to evolve. We argue that the development of such trust relies on the engagement with and involvement of the public in the requisite governance and oversight of any system if it is to be trusted. We emphasize that, in practical terms, the DSH paradigm crucially must recognize that the management of risk and support of trustworthy, careful working practice is not a feature provided solely by encryption and access control solutions, the physical security of data centers, or the control of dataset release, but also by effective training, education, and accreditation of the people using those systems so that they understand how best they can work safely and securely, in compliance with legal, regulatory, and ethical requirements. While the focus of the work has been on the UK experience, the discussion is intended to inform the identified challenges of electronic health records reuse internationally.

The Big Data Dilemma

Big data in practice involves linking information from electronic health care records with records contained in disease registries and data generated by genome sequencing initiatives such as the 100,000 Genomes Project [6] or the Electronic Medical Records and Genomics Network [7]. The potential to link with data collected from social care services has also been identified as a key theme for research strategy [8], and there is governmental support for both in terms of funding [9] and legislative focus, for example, to aid health and social care policy development [10].

This trend has been controversial, and anxieties about upholding the medical profession's duty of confidence to their patients, protecting the patient's right to a private life, and compliance with data protection legislation have continued to emerge. Studies that have explored attitudes toward using health and other social care records for research point to general support for research uses [11], which may, however, be conditional on obtaining consent [12]. This must be taken in the context of an identified "data trust deficit," where the UK Royal Statistical Society has found that people trust organizations' (such as the UK National Health Service, NHS) uses of data less than the organizations themselves [13]. There have also been public anxieties over the handling of initiatives such as the care.data program in England [14] and more recently proposed initiatives in Scotland [15]. Some concerns have been expressed about the use of health record information for profit by industry [16], and there is evidence to suggest that legal and regulatory compliance may not be enough to win wider public and professional support for all of the intended uses of information captured during health care [17].

This apparent dilemma is compounded when viewed both from the research—especially from the epidemiological—perspective, where there is evidence that gaining explicit consent using opt-in from participants reduces population sample sizes significantly and can introduce selection bias [18-23], and from a realist perspective, where gathering consent is not always possible or rules out a firm basis on which to process data [22,24,25]. This must be coupled with discoveries that research participants are expecting greater transparency about [26] and a "louder voice" in how research is conducted [27]. The dilemma is clearly one that straddles both ethical and legal requirements and requires balancing the rights of the individual—particularly around autonomy—and the rights of the wider citizenry to benefit from scientific progress [5].

In addition to this, and regardless of the measures taken to protect participants as guided by the law and research ethics, there remains some residual risk of harmful outcomes, particularly if participants are accidentally or with some effort deliberately re-identified within a research dataset. Methods to render records anonymous cannot guarantee anonymity [28-30], meaning that risks of participant re-identification, and therefore of harm, remain. These risks are becoming recognized as being more likely with genome research [27]. De-identification might, however, not always be the best approach to take: in 2006 the UK Academy of Medical Sciences identified in its report on

using personal data in health research that meaningful research needed varying degrees of identifiable data because "...most important research using personal data requires access to identifiable data at some point for some purpose..." [31]. This issue has surfaced in practice, where de-identification is being used as a means to limit disclosure and protect the confidentiality of health care records at the expense of data utility for research [32] and is an impediment to research itself [33]. This is further illustrated when the risk of detrimental effects to data quality and efficiency is heightened if disclosure risk is handled in isolation. This is problematic in cases where analytic strength needs to be "borrowed" from one data source by another to realize its public benefit, where data being borrowed can be processed without needless re-identification provided its governance is not handled independently of the borrower dataset [34].

A balance therefore needs to be found between the extent of de-identification and the utility of data for research, which reemphasizes the importance of handling these risks according to legislated requirements and meaningfully supported, trusted, careful, and secure working practice that works at scale. But what does that entail in practice and, crucially, what extent is needed to protect participants and the research community, and also to meaningfully address public concerns while honoring the rights of the individual?

What Is the Data Safe Haven Paradigm and Where Did It Come From?

The concept of the DSH pertaining to the United Kingdom has been developing since the early 1990s and continues to elude a rigid or specific definition [4]. The garnering of the DSH paradigm in the UK research community in particular is well illustrated by the 2008 Data Sharing Review [35], which emphasized the importance of handling health care data safely and securely for research purposes. It recommended the development of safe havens, which were identified as secure working environments that required levels of accreditation for researchers, as well as certification for data handling facilities that were in line with high standards of information security.

The more recent Information Governance Review in 2013, in which information-handling practices in England were extensively reviewed by an independent, Department of Health-appointed panel, has endorsed this recommendation [36]. It identified the importance of the safe haven paradigm and made further recommendations about levels of compliance with existing codes of practice. These included the Information Governance Toolkits across the UK jurisdictions, as well as independent certification of compliance with standards such as the International Organization for Standardization (ISO)/International Electrotechnical Commission 27001 standard on information security management [48]. The ISO standard establishes the requirements for information security management and helps to mold legal prescription into practical tools for use in working practice. ISO 27001 offers an opportunity for independent certification by ISO-accredited information security experts, which in turn provides higher levels of assurance around the security of certified systems.

In 2014, the Academy of Medical Sciences hosted a meeting about DSHs in research to better understand what had been developed and how they were working. The meeting identified a need for developing a common definition of the DSH in practice. Additionally, emphasis was placed on the importance of developing these DSHs with due regard to providing performance metrics and success criteria, research, training, and educational needs, as well as understanding public expectations by means of meaningful, ongoing engagement and potential involvement [37]. By reviewing the state-of-the-art in safe working practice for clinical research, the aim of the meeting was to bring a common understanding to the wealth of legislative, regulatory, and practical requirements that underpin information governance in clinical research practice.

Since the 2014 meeting, commentary and discussion around the understanding of the DSH paradigm have continued, and evidence has emerged that this is becoming an internationally recognized concept. Burton et al [4] have provided a set of 12 criteria to define the meaning of DSH. The criteria are focused on trustworthiness and reliability of the data that are provided, on upholding legal and ethical requirements, and on managing and releasing data within the bounds of social acceptability. The criteria also relate to maintaining the security of the data, specifically around the preservation of confidentiality, integrity, and availability of the data, and appropriate and secure access to identifying data and their protection [4]. Knoppers and Chadwick conclude that "[c]lear systems of governance, public trust in data security, personal empowerment and the responsibility it brings re 'knowing' (or not) as well as transparency of research outcomes are to be welcomed..." [5]. They have further developed an understanding of the ethics involved in this area and expanded the scope of "trustworthiness" to include the public and its views on the security of safe havens. In this paper, we consider these 12 criteria and the more inclusive scope defining trustworthiness with a deeper discussion of legal, ethical, and risk management requirements.

Bases in Law for Information Governance in Research in the United Kingdom

We refer to the main acts of law and common law that are in place to govern health research and protect information as it is used for these purposes in the United Kingdom. We use the UK legislature to describe the bases in law because we will discuss implementations of the DSH paradigm in research platforms across three jurisdictions in the United Kingdom: Wales, Scotland, and England. To summarize, the bases in law stem from a focus on protection of individuals and the definition of professional duties with the common law duty of confidentiality and its variations across UK jurisdictions. There are also statutory provisions around consent for research and protections for vulnerable groups in the Children Act 1989 [38] and the Mental Capacity Act of 2005 [39], and for using biological samples for research in the Human Tissue Act of 2004 [40]. The legislature further recognizes the right to a private life in the Human Rights Act of 1998 [41]. The more data-focused Data Protection Act of 1998 [42] defines statutory requirements for handling data to protect the individuals about whom data have been recorded, compliance with which is overseen by an

Information Commissioner who has powers to fine organizations for serious breaches. The Information Commissioner also oversees compliance with European regulations regarding electronic communications [43].

Further statutory provision exists in the form of the Health and Social Care Act of 2012 [44], which provides a basis in law for processing information to support health and social care services, as well as the Health and Social Care Information Centre in England, an organization responsible for handling health and social care information and for gathering large research datasets, which was originally identified as an accreditor of safe havens. The Care Act of 2014 [45] defines the need for ethical approval of health research via processes laid out by the Health Research Authority in England and Wales, and requires that the Health and Social Care Information Centre handle data with due regard to privacy. Additional support in England and Wales lies in Section 251 of the National Health Service Act of 2006 [46], which empowers the Secretary of State for Health to set aside the common law duty of confidentiality, where applicants must show regulatory compliance and show a substantial public interest for setting aside the common law, a power that in Scotland lies with Caldicott Guardians, senior figures who safeguard the confidentiality of patient data in the NHS and enable appropriate information sharing. While this armory of legal protections enforces the requirement of careful working practice and processing that should not undermine reasonable uses of health care data, it does not offer an immediate answer to information reuse dilemmas, nor does it alter the risks of re-identification in de-identified datasets. These legal protections need both understanding and interpretation before uses of information can be governed in practice.

Requirements and Motivations: Risk Management in Practice

The legal requirements must nevertheless be enacted in practice. Data Protection Act principle 7 requires data to be handled securely; however, enacting this requirement in practice is not a simple or trivial task. Perhaps the most authoritative resource for developing information security management is the ISO 27000 series of standards [47]. Within this series the most pertinent standards are 27001 (which defines the requirements for information security) [48] and 27002 (which defines a code of practice for implementation of the elements of ISO 27001) [49]. An accredited ISO auditor can certify compliance with 27001 independently, while 27002 relies on an understanding of and success criteria set by the organization that is implementing the requirements established in 27001. This makes it difficult to certify independently, but it is certainly internally auditable. A prime example of ISO 27002 exists in the form of the Information Governance Toolkits and their variations across UK jurisdictions [50]. These have been developed to incorporate requirements from legislation and good practice guidelines for organizations that handle health care information and provide a basis for establishing levels of compliance.

A key element of 27001 and its certification is to define the scope of the security requirements. It then mandates the development of an information security management system (ISMS), which must be well supported by management and responsible parties. The ISMS provides a basis for organizations to run risk assessments and analyses on data use, and to refine the findings into mitigation strategies that are developed in policies for data use. These policies must be understood by the people that they are supposed to govern and must define a basis for configuration of software tools responsible for access control and privilege management. There is a focus on engagement for and with people working with information, which in turn mandates that they should be well informed and guided in working practice. Bearing in mind the particulars of security practicalities, the safe haven concept is focused on mitigating risks, whether risks to participants and their re-identification, risks to organizations who process the data, risks to organizations who have control and responsibility for the data, or risks to continuing research and public appetite for the support of research.

To summarize, ISO 27001 allows for an independently certifiable process to show that organizations are compliant with the internationally recognized core requirements of good information security practice, while ISO 27002 provides a basis to contextualize those core requirements through the Information Governance Toolkits in the context of health care research. Recognizing these criteria, the apparent evolution of the safe haven concept has included work in the research community to seek independent certification for compliance with ISO 27001 to provide additional practical security and support for research communities as well as public reassurance. While these help provide assurance that some of the 12 criteria provided by Burton et al [4] are met, the extent to which this reassurance supports trustworthiness remains unclear.

Requirements and Motivations in Context: Evolution of the DSH Paradigm Through Information Governance Research

The 2013 second Caldicott review of information governance recognized that the research community had worked hard to overcome perceived impediments of information governance when handling health care information for purposes beyond health care, that “significant lessons regarding data sharing from public health and research” and “...the approach to information governance adopted in public health and research may be helpful...” to other sectors [36]. The next section focuses on the experience of what this means in practice using 4 independently developed examples of DSHs across the United Kingdom to illustrate the practicalities and the need to involve and engage with the wider public to satisfy their interest in research work and understand their concerns over the use of health and social care records.

We discuss the examples of the 4 nodes of the Farr Institute of Health Informatics Research as small case studies to illustrate the developing paradigm. The Farr Institute comprises 4 nodes across the United Kingdom: one in Wales, one in Scotland, one in the southeast of England, and one in the north of England.

The Institute was founded in 2013 and has incorporated a series of research platforms that have been developed independently of each other in partnership with research funders and local NHS trusts and health boards. Each of these nodes has also

developed and evolved its own information governance frameworks, systems, and processes. The Welsh and Scottish examples have achieved international recognition for their initiatives [51], and the English examples have achieved independent ISO certification in line with the recommendations in the second Caldicott review. But do these examples represent a common view of the original safe haven concept? We discuss the 4 nodes in the next sections, which are structured according to the common features identified across each node that have emerged during the case studies.

Safe Havens in Research: Farr Institute Node Case Study Examples

Farr Health eResearch Centre (North England)

Core Governance Framework

The Farr Institute Health eResearch Centre in north England is a collaboration between 4 universities in the region, the NHS, and industry. It is governed by a steering group that meets periodically to develop and maintain strategy, as well as to monitor performance of the Centre and its facilities. This steering committee comprises senior representatives of the universities involved with the Centre (including Liverpool, Lancaster, and York), independent NHS representatives, users, and industrial collaborators, as well as patients and members of the public.

Independent Ethical Review, Certification, and User Accreditation

The Centre will host a DSH at the University of Manchester, where the equipment on which it is run is held within a physically secure environment. This includes the infrastructure for data storage, archiving, and networking that serves academic research collaborators and includes connections to components held within the NHS network. The safe haven is compliant with the requirements of an ISO 27001 ISMS, where some components have achieved independent certification and the others are expected to have done so by early 2017. The NHS networked component is compliant to level 2 of the Information Governance Toolkit and is run within the governance framework of the NHS. The safe haven and its use are governed by security policies and standard operating procedures in line with the ISO ISMS. Once projects have received required approved, the safe haven provides both NHS users and researchers with secure local and remote access to virtual machines that offer a suite of analytics tools tailored to the analysis needs of their projects.

Cataloguing and Data Management

This suite of tools, termed the dLab (for data laboratory), will provide researchers with a dataset catalogue, providing metadata descriptions of data available within the safe haven environment. The dLab will further provide desktop access to data, applications, compute power, and storage, along with appropriate authentication, authorization, and auditing infrastructure. The safe haven offers additional features to link datasets where appropriate permission has been granted and an archiving feature for virtual machines on which analyses have been run once the researchers have confirmed they are completed. Additionally, an eLab data management facility [52] will be provided to researchers. Where appropriate to the level of sensitivity of data being accessed, both the dLab and eLab components of the safe haven will provide remote desktop access using 2-factor authentication. In the longer term, the dLab software stack will be provided to the equivalents in the other Farr Institute partners for exchange of scripts, data, and research objects [53], with the potential for implementing a single sign-on mechanism between Farr Institute partners. The implementation of remote access is designed to reduce the need for additional copying and physical transfer of data. Additional facilities within the safe haven include a data deposit facility to receive sensitive datasets on behalf of Farr Institute Health eResearch Centre consortium members. Pseudonymized data can be received from NHS partners through periodic data feeds via the N3 network, again mitigating any need for excess copying or physical transportation of data.

Future Ambitions and Developing Protection: Opportunities for Public Involvement

In addition to existing approvals requirements, the Centre is working toward establishing an independent governance board, comprising both expert and lay members, to review research project proposals and approve them before the researchers can have access to the tools and datasets that they need to answer their research questions. The Centre intends to make any approvals dependent on the governance board's assessment of the scientific validity of the project's proposed research questions in combination with the results of independent ethics reviews. The governance board will also approve the researchers themselves, and this relies on ensuring the researchers have undertaken information governance training as required by the standard operating procedures.

Farr Centre for Improvement in Population Health through E-records Research (Wales)/Secure Anonymised Information Linkage Databank

Governance Framework

The Centre for Improvement in Population Health through E-records Research (CIPHER) (Wales) node of the Farr Institute uses the Secure Anonymised Information Linkage (SAIL) Databank at Swansea University. Conceptualized in 2006, SAIL has since been evolving continually. At the heart of the SAIL model was and is the need to find and maintain a balance between preserving individual-level privacy and harnessing the potential to use health-related data to their full potential for the benefit of public health [54]. Seven essential objectives were set: secure data transportation, reliable data matching between datasets, robust anonymization and encryption, disclosure control, data access controls, scrutiny of data utilization proposals, and external verification of compliance with information governance. SAIL has developed in partnership with NHS Wales and continual consultation with the Welsh Government, regulatory bodies, and professional and public groups.

Independent Ethical Review, Certification, and User Accreditation: Opportunities for Public Involvement

SAIL insists on data sharing agreements being in place between SAIL and all data providers. Through the SAIL gateway, data are provided to each project on a predetermined basis. All research proposals are submitted to an independent information governance review panel, which includes representation from the British Medical Association, Public Health Wales, NHS Wales Informatics Service (NWIS), National Research Ethics Committee, and the public (members of the Consumer Panel for Data Linkage Research). Approval is given only if the research is appropriate and in the public interest, and the research can proceed only on receipt of full approval from this panel. Project analysts are then assigned permissions within the SAIL gateway to match the independent information governance review panel application, with access controlled through an automated security system. Project-specific data views are created to provide tailored data subsets.

All persons accessing the SAIL gateway have to be approved researchers (have undergone accredited training) and are required to sign a comprehensive data access agreement about their use of the data in SAIL. The research is carried out within the SAIL secure gateway environment. Results can be taken out only via a request process, which involves scrutiny by SAIL senior analysts for information governance issues, such as small cell counts, and other breaches of the SAIL output release policy.

Access to the SAIL databank is remote, via a firewalled virtual private network known as the SAIL gateway. It uses enhanced user authentication, auditing of all SQL commands, and configuration controls to ensure that data cannot be removed or transferred unless authorized.

Cataloguing and Data Management

Robust anonymization is provided by a trusted third party, NWIS. All data are transferred using Web-based secure file upload facilities, with incoming datasets being split into a demographic component (personally identifiable information) and a clinical or event component. The demographic component is sent to NWIS, which then assigns an anonymous linking field to each individual, thus ensuring anonymity and encryption. The clinical component is sent to SAIL. At SAIL, the anonymous linking field is linked to the clinical or event data and reencrypted.

Future Ambitions and Developing Protection

SAIL is engaged in a constant program of improvement and has moved to a purpose-built data science building, which will also house the Administrative Data Research Network. The physical security for the new data science building will be configured such that it will accommodate successfully the physical security requirements for all projects and research programs based within the building, including the storage of Administrative Data Research Centre for Wales de-identified government data (classified to official/official sensitive) requiring the highest level of security (security zone 5) within the building. The external ISO 27001:2013 ISMS certification process for the SAIL program was completed in November 2015.

Farr Scotland/Scottish Health Informatics Programme

Governance Framework

The Scottish node of the Farr Institute builds on the progress and success of the Scottish Health Informatics Programme (SHIP), which ran from 2009–2013. Through SHIP, a principled proportionate governance model was developed in order to streamline research applications and approvals for data linkage, while simultaneously ensuring that research was scientifically sound and ethically robust. Risk mitigation played a central role within the SHIP model, and access to health data for research was contingent on performing a privacy risk assessment and meeting the benchmarks of safe people, safe environments, and safe data, as described by Sethi and Laurie [55]. Farr Scotland [56] is building on these contributions (and requirements) from SHIP in tandem with the Scotland-wide Data Linkage Framework, the Scottish Informatics Linkage Collaboration, National Records of Scotland's Registrar General, and the Administrative Data Research Centre.

Independent Ethical Review, Certification, and User Accreditation: Cataloguing and Data Management

Access to the national safe haven and national data (located at the NHS National Services Scotland) is provided via the electronic Data Research and Innovation Service. This service assigns (approved) researchers (who have undergone accredited training) to a dedicated research coordinator who offers support for the process of submission of the initial data access application (including study design and coding) right through to data analysis. All data uses must abide by the key benchmarks set out under SHIP. The research coordinator also acts as an intermediary between data controllers and researchers, who must all abide by the Guiding Principles for Data Linkage established by the Scottish Government. Streamlined approval for access to more than one NHS board dataset for research purposes was granted by the Privacy Advisory Committee for Scotland which, as of May 1, 2015, is to be subsumed under the new Public Benefit and Privacy Panel for Health and Social Care.

The Scottish Government is leading the establishment of procedures to provide independent accreditation of safe havens (safe settings), mechanisms for monitoring compliance (safe projects), guidance on coding, terminology, and disclosure (safe outputs), and the development of training for researchers (safe people). A significant challenge for the Farr Institute is that Scotland lacks legislation "defining the status of accredited safe havens, but the review of the Patients' Rights Act, due in 2016, may provide an opportunity to make clear in law the status of the safe havens" [57].

Future Ambitions and Developing Protection: Opportunities for Public Involvement

The Farr Institute will be embedded within a network of safe havens, which includes the NHS National Services Scotland national safe haven and 4 lead NHS Research Scotland nodes. Quite what this network will look like and how it will operate

is still very much under development. The national safe haven currently consists of 2 stand-alone computer terminals that accredited researchers can access remotely via a secure network or server.

The recent Scottish Government report *A Health and Biomedical Informatics Research Strategy for Scotland* [58] considers the potential and challenges involved with establishing such a network of safe havens. It has identified the following key challenges in order to facilitate interoperability between safe havens: technical challenges, the practical details of how a network of safe havens should operate, and determining whether a single point of entry should be necessitated (or whether there can be multiple points of entry). On this latter issue, a balance must be achieved between having a single point of entry, and support and provision of local expertise for researchers. Indeed, additional safe havens may be established, and the question arises as to whether these safe havens can join the network and, if so, which standards and accreditation procedures they will be subject to. In this vein, a Safe Haven Charter for Scotland (based on the core principles of ISO 27001) is being developed, which will include a set of high-level principles around technical, practical, and overarching governance considerations [59]. The biggest challenge will be striking a further balance between determining and meeting common and consistent data standards while facilitating flexibility between local nodes. Farr Scotland has a dedicated work stream committed to civic engagement and will strive to explore and feed in to governance approaches and public attitudes around such uses of data.

Farr London

Core Governance Framework

The London node of the Farr Institute is a collaboration between University College London, the London School of Hygiene & Tropical Medicine, and Queen Mary University of London. The DSH has been established within the School of Life and Medical Sciences at University College London as an identifiable data handling service, comprising a technical solution for the secure storage of identifying or pseudonymized data, and a service within which the technical solution is mapped that provides individual health research projects guidance on how to develop their own working practices and achieve Information Governance Toolkit compliance.

Independent Ethical Review, Certification, and User Accreditation

The research projects running within the Farr London node are subject to their own contractual obligations with data providers, as well as independent ethical approvals and oversight, where any changes to approved information handling, linkage, or wider sharing must be authorized by the ethics committee that provided the original approvals via University College London, the London School of Hygiene & Tropical Medicine, or Queen Mary University of London boards, or the NHS research ethics committees, where needed.

The technical solution comprises a "walled garden" approach, which uses secured virtual sessions run from within a secure infrastructure. This element has achieved ISO 27001:2013 certification and is audited annually by accredited ISO auditors. All steps use a 2-factor authentication, and the session forbids any download of data (including copying and pasting and some screen capture). All projects are logically segregated from each other within the safe haven, and access is controlled and permitted only to those users who have been registered and attended information governance awareness training courses, as well as completed online information governance tests annually for their reaccreditation.

The identifiable data handling service provides guidance on how to achieve appropriate levels of Information Governance Toolkit compliance, preparation for seeking Section 251 exemption from the common law duty of confidentiality where applicable, and wider information security framework development, including the drafting and execution of data sharing agreements and codes of practice. The identifiable data handling service also routinely tours the partner institutions with awareness sessions and runs training courses and the online annual information governance reaccreditation tests for registered users. In addition to this, the identifiable data handling service is governed by a user group, which routinely meets and offers usage feedback to the School of Life and Medical Sciences, and an executive project board, which oversees budgeting and approves the execution of upgrades and changes to the service and systems. The outreach to the user community is tailored to help them understand the security and good practice requirements and the change in working behavior within this managed environment.

Cataloguing and Data Management

The technical solution also includes a patient indexing service, which is based on bespoke de-identification and record linkage software developed by Belgian security company Custodix [60]. This service allows for datasets to be anonymized or pseudonymized where appropriate, so that these datasets can be securely shared under any required authorization with other Farr Institute nodes or authorized research collaborators. The linkage software can merge records across different projects held within the safe haven where this is permissible. Functionality includes a feature where clinical data sources are, on registration, able to upload identifiable datasets securely using a dedicated upload service. Research project recipients are then able to access the uploaded data and transfer it to a suite of licensed database and analytical tools over a secure virtual session.

Future Ambitions and Developing Protection: Opportunities for Public Involvement

The identifiable data handling service is considering the establishment of an ethics oversight committee to include a panel of researchers, clinical and legal expertise, and involvement from patient groups or members of the public to help consider any ad hoc collaborations across research projects or wider interventions.

Discussion

A Common Paradigm?

Across the 4 Farr Institute nodes, common features of the information governance frameworks have been developed. In

all cases, there is a recognized compliance with the Information Governance Toolkit or the Scottish equivalent. The English nodes have been certified to ISO 27001, and the CIPHER node received certification in November 2015. Each node comprises or is in the process of establishing a series of committees and panels for oversight, development, and governance, with some cases including public and lay representation. Each node also requires that researchers undertake training and education before they can use the facilities.

The following appear to be consistent features for a safe haven across the Farr partners that build upon the 12 criteria offered by Burton et al [4] and the need identified by Knoppers and Chadwick [5] for expanding the definition of trust to include the wider public and their trust in security:

1. Independent certification for establishing good working practice, which includes a focus on people and behaviors when handling information and the development of steering committees and working groups

2. Training, education, and accreditation of people who work within the environment, including assessment and professional certification

3. Working practice within the prescription of jurisdictional legislative relief, which includes reviews by ethics committees for research activities

4. Cataloguing and data management, which includes an updated resource for defining not only what data are available, but also the requirements for using them in research within these environments

5. Participant contact for research or appropriate exemptions under the law

6. Developments in protection and future ambitions

7. Opportunities for public engagement and involvement, including events and workshops to disseminate research findings, as well as having lay representation on panels, steering committees, and working groups. This helps ensure that the public have a voice in the policy, use, and development of the infrastructure.

Is This Enough?

Our proposed common definition illustrates the key aspects for developing the DSH paradigm into trusted platforms for clinical research. It emphasizes that we must implement and maintain concrete examples of what is safe in terms of protecting participants and researchers, and what is trusted by those same participants, funders, the academic research community, and the wider public. This common definition builds on the criteria established by Burton et al [4] and takes into account the need for a more inclusive understanding of what is meant by trust, reinforcing the proposals of Knoppers and Chadwick [5]. This work further develops these themes and findings by providing not only exemplars of how these aspects are established in practice, but also a proposed framework for the ongoing evolution away from the static notion of the safe haven as a physical environment alone. It is moving the understanding toward a trusted research platform that handles societal, individual, and professional concerns, and offers reassurance and the opportunity to govern its operation beyond the research and regulatory communities. It supports the notion that an environment view must also include the people who work in, govern, and contribute to that environment, and their support. Trust must be won and nurtured, and it will vary according to the stakeholders who are involved in doing research, or indeed about whom the data have been collected; this relies on involvement and informed dialogue.

Such a requirement will not be met by focusing on the integrity, reliability, or security of the technical solutions within the platforms themselves in isolation from the training needs of the researchers and their education of what good working practice entails. Nor can this in turn be handled in isolation from independent ethical oversight of how data can be used, or without encouraging and supporting lay representation on steering groups for the platforms or research consortia that use them. The provenance of the data themselves must provide assurance to the research community that the data are fit for the purposes of their research, but cannot be the focus of efforts without ensuring that they are adequately catalogued. Critically, none of these aspects can be isolated from ongoing public engagement and education, which involves a 2-way communication between the academic research community and the public about how information is used and what the benefits are.

To fully articulate what we mean by safe and trusted, we must reemphasize that at the core of the DSH paradigm is the notion of risk management. We have discussed how risks of participant identification remain regardless of the methods used to render records anonymous, and we have highlighted that the research community needs more identifiable attributes for realistic utility and should not handle risk management across datasets in isolation, at the cost of reasonable use and sharing. The DSH paradigm is ultimately about managing those risks, so no basis for an open dialogue with the public or their meaningful involvement can take place without being transparent about the existence of those risks. But the DSH approach does not guarantee, and nor should it, that risks will not remain; rather, they operate within an independently certified environment that will more likely be able to adapt to the changing nature of known and emerging risks, with due respect to interest from the public and their concerns, and ongoing mindfulness of the ethics around the research, its data use, and its outputs. Such environments are made up as much of people and their actions as of hardware, software, and policies.

It is for individual members of the public to decide how they feel about the ways in which information recorded about them is being looked after, and while they do not always get a say in whether information is shared for purposes other than their direct care, the DSH paradigm must emphasize the importance of highlighting the benefits of the information sharing in spite of the risks of re-identification, at the very least to give people an opportunity to develop an informed opinion, rather than erroneously guaranteeing them a risk-free solution. To win the trust of any stakeholder, this means that we must encourage shared ownership of the problem with the public and patient

communities while being transparent and open about how health information is used and why it is important that it is being used.

Conclusions

We have described the motivations behind developing the DSH paradigm to support the big data, epidemiological research drive. In doing so, we have discussed the basis for the paradigm and introduced a series of requirements from a legal, ethical, and information security perspective, building on established work in this area. We have emphasized that these alone do not represent clear public anxieties about and interest in how research is conducted and information is protected. Through this discussion, we have proposed a common definition of the DSH paradigm by considering and describing the technical infrastructure, ethical oversight, researcher training and education process, the internal governance, and external, independent audit and public engagement and involvement drives of 4 independently established clinical research platforms and the common features among them.

We have critically reviewed the proposed definition by emphasizing the importance of involving the public and engaging with them openly and transparently, especially with regard to risks or re-identification and how the risks are managed. The focus of the DSH paradigm cannot be solely on technical or procedural approaches to risk mitigation. Engagement with people is paramount, and not exclusively with the public but also the researchers who use the platforms underpinned by the DSH paradigm. This includes responding to their educational needs and supporting their ability to do the research with guidance on ethical requirements and due diligence for understanding funder requirements. It is particularly vital to understand the needs and expectations of all these stakeholders if the clinical research community is to inspire trust in their research platforms. While this paper has focused on experiences across the United Kingdom, the findings will be of interest internationally to help manage the challenges that exist for electronic health records reuse in clinical research.

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Conflicts of Interest

None declared.

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Abbreviations

CIPHER: Centre for Improvement in Population Health through E-records Research
DSH: data safe haven
ISMS: information security management system
ISO: International Organization for Standardization
NHS: National Health Service
NWIS: NHS Wales Informatics Service
SAIL: Secure Anonymised Information Linkage
SHIP: Scottish Health Informatics Programme

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Original Paper

Creation of an Accurate Algorithm to Detect Snellen Best Documented Visual Acuity from Ophthalmology Electronic Health Record Notes

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Abstract

Background: Visual acuity is the primary measure used in ophthalmology to determine how well a patient can see. Visual acuity for a single eye may be recorded in multiple ways for a single patient visit (eg, Snellen vs. Jäger units vs. font print size), and be recorded for either distance or near vision. Capturing the best documented visual acuity (BDVA) of each eye in an individual patient visit is an important step for making electronic ophthalmology clinical notes useful in research.

Objective: Currently, there is limited methodology for capturing BDVA in an efficient and accurate manner from electronic health record (EHR) notes. We developed an algorithm to detect BDVA for right and left eyes from defined fields within electronic ophthalmology clinical notes.

Methods: We designed an algorithm to detect the BDVA from defined fields within 295,218 ophthalmology clinical notes with visual acuity data present. About 5668 unique responses were identified and an algorithm was developed to map all of the unique responses to a structured list of Snellen visual acuities.

Results: Visual acuity was captured from a total of 295,218 ophthalmology clinical notes during the study dates. The algorithm identified all visual acuities in the defined visual acuity section for each eye and returned a single BDVA for each eye. A clinician chart review of 100 random patient notes showed a 99% accuracy detecting BDVA from these records and 1% observed error.

Conclusions: Our algorithm successfully captures best documented Snellen distance visual acuity from ophthalmology clinical notes and transforms a variety of inputs into a structured Snellen equivalent list. Our work, to the best of our knowledge, represents the first attempt at capturing visual acuity accurately from large numbers of electronic ophthalmology notes. Use of this algorithm can benefit research groups interested in assessing visual acuity for patient centered outcome. All codes used for this study are currently available, and will be made available online at https://phekb.org.

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KEYWORDS

visual acuity; best documented visual acuity; best corrected visual acuity; electronic health record; electronic medical record; phenotyping; data mining; ophthalmology

Introduction

Visual acuity is one of the most important records of data in an ophthalmic examination. To an eye care provider, it is the equivalent of a vital sign, such as heart rate or blood pressure. In most electronic health records (EHRs), it is recorded as a free text in a defined field and not as pure structured data. Additionally, in a single clinical visit, visual acuity for a given eye may have several different values recorded within the EHR note. For example, a new patient seen by an ophthalmologist without correction (glasses) may see 20/100, with an old correction may see 20/30, but the "best corrected vision" with new glasses will see 20/20. In this scenario, three different visual acuities for a single eye would be recorded in one clinical note.

The vision assessed in an examination with the patient not wearing any glasses or contact lens correction, is recorded as "uncorrected visual acuity." If the patient is wearing glasses or contacts, it is recorded as "corrected visual acuity." In a person with normal eyesight who does not need glasses, their vision without glasses ("uncorrected" visual acuity) is expected to be 20/20. In myopic (near-sighted) or hyperopic (far-sighted) patients who wear appropriate glasses and otherwise have a normal visual system, their vision with glasses ("corrected" visual acuity) would also be expected to be 20/20. If a person has an eye problem such as a cataract or diabetic eye disease, their "best corrected" vision glasses may be worse than 20/20.

Patients often present to an ophthalmologist's office because of blurred vision, which may be due to the use of a lens prescription that is outdated for their eyes. It may also be due to an underlying disease of the eye that is limiting vision. In either situation, a test called refraction may be performed. Refraction (measuring for glasses) will measure the appropriate lens strength to focus light on the retina and determine the eye's visual potential or best corrected visual acuity (BCVA). Clinically, it is the single BCVA for each eye that represents the maximal visual potential, and this value is of most interest to clinicians and researchers [1].

Patients with an eye disease such as cataract may see 20/100 with their old glasses. They may be subsequently refracted but may only be able to see 20/50 with the new lenses because the cataract partially blocks the vision. Technically, the BCVA can only be determined if a patient is refracted during the visit. In the preceding example, the BCVA is the same as the best documented visual acuity (BDVA), that is, 20/50. If the patient above was not refracted during that visit, the BDVA for that encounter would have been 20/100 and the BCVA would be unknown.

Sometimes a quick test such as the pinhole test can approximate the best refraction or BCVA, but is not as accurate as the "gold standard" of refraction. Also, in some office visits, no refraction or pinhole test is performed, so the only visual acuity is the "current" visual acuity, and the BDVA may or may not be equal or even close to the true BCVA. Therefore, while BCVA is the commonly used clinical term, when abstracting visual acuities from an EHR, BDVA is the appropriate terminology used.

In the example illustrated in Table 1 , a patient had three office visits to three different eye care providers over a span of 1 month. In the first visit it was noticed that the patient had blurred vision in both eyes and the patient was refracted. It was discovered that the patient's right eye had a limited vision due to diabetic retinopathy and the left eye needed updated glasses. During this visit, the BCVA was found to be the same as the BDVA. During the second visit, the retina specialist did not refract the patient, but used a pinhole to estimate the BCVA. In this visit, the BDVA was close to, but slightly different than, the true BCVA, which was not determined as the patient was not refracted. During the third visit to an eyelid specialist, the specialist only checked the vision with the then used glasses and did not refract or pinhole as it was not relevant to the reason for this visit. In this case, the BDVA was "worse" in each eye, but that was due to the lack of attempt to measure or estimate the BCVA.

Table 1. Sample clinical encounters and corresponding BDVAs.

Visit			
A. First visit with doctor for new glasses			
	Vision with correction	Right=20/100	Left=20/40
	Manifest refraction	Right=20/60	Left=20/20
	BDVA	*Right=20/60*	*Left=20/20*
B. Second visit with specialist to evaluate retina problem			
	Vision with correction	Right=20/100	Left=20/40
	Pinhole	Right=20/70	Left=20/25
	BDVA	*Right=20/70*	*Left=20/25*
C. Third visit with eyelid specialist for eyelid lesion			
	Vision with correction	Right=20/100	Left=20/40
	BDVA	*Right=20/100*	*Left=20/40*

[a]*BDVA:* best documented visual acuity.

A proper algorithm will assess all visual acuities in defined fields for an encounter and return the one with the best vision in each eye.

In the clinical setting in the United States, visual acuity is most commonly measured using a Snellen chart, where the patients view a standard set of letters at a distance equivalent to 20 ft. to determine their own visual acuity compared with what a "normal-sighted" individual would see at 20 ft. (ie, 20/20.) The numerator is the distance at which the test is performed and the denominator is the distance at which the smallest letter identified by the patient subtends an angle of 5 arc min [1]. A higher number in the denominator is indicative of worse vision, that is, 20/100 is worse than 20/20. Visual acuity is generally checked in each eye individually for diagnostic purposes. There are other standards used to determine visual acuity, such as metric Snellen equivalents or logarithm of the minimum angle of resolution (LogMAR). Jäger values (J1, J2, and so on) or font print size (8, 10, 12, and so forth) are used to test near visual acuity.

Recent work supports the use of data in EHRs for accurate and efficient identification of specific disease phenotypes [2-9]. The Electronic Medical Records and Genomics (eMERGE) consortium has demonstrated numerous successes identifying disease phenotypes. Past work specific to ophthalmology utilized a combination of approaches to identify cataract cases from EHR-based phenotyping of clinical notes [10]. However, despite the importance of visual acuity as a primary measurement of how well a patient can see, no standard method exists for the rapid and accurate extraction of BDVA from EHR notes.

This paper describes an algorithm we developed to capture distance visual acuity data from ophthalmology EHR clinical notes. We applied the algorithm to 295,218 patient records in Northwestern Medicine's Enterprise Data Warehouse (NMEDW). We then compared our detection method to a chart review of a random sample of 100 patient notes under the direction of a board-certified ophthalmologist to test accuracy.

Methods

Algorithm Development

Within the Northwestern Ophthalmology clinics, the EPIC EHR (EPIC Systems Corporation, Madison, WI) has been in use since 2007. The structured visual acuity ("Snellen–Linear") field in the EPIC EHR allows for discrete abstraction of the results that are entered by the provider. There are three different standard units that can be used while designating the results for the visual acuity examination (Snellen, Jäger, and font print size). With the current version of EHR, visual acuity is entered as a free text option that allows the provider to choose to manually type in the results or choose from a drop-down menu. As a result, a large variety of responses can be entered in various visual acuity sections. In total, we identified 5668 unique responses, all of which we mapped back to a standard Snellen visual acuity notation from the list in Textbox 1.

Textbox 1. List of visual acuities used in algorithm development

- 20/10
- 20/20
- 20/25
- 20/30
- 20/40
- 20/50
- 20/60
- 20/70
- 20/80
- 20/100
- 20/125
- 20/200
- 20/400
- CF (counting fingers)
- HM (hand motion)
- LP (light perception)
- NLP (no light perception)
- LP (light perception)

Visual acuity measurements can be recorded in at least eight structured fields within our EHR note for each eye. In our EHR, a separate visual acuity can be measured for each eye with or without correction, with a pinhole device, refraction before dilation drops, refraction after dilation drops, autorefraction, and near vision with or without correction.

To further complicate the data, while visual acuity is recorded in defined fields, it is entered as free text, making a direct abstraction less meaningful as a single measurement could be recorded in a variety of different ways. For instance, providers could often write other clinical information in the visual acuity field that may be helpful in future clinic visits. Examples of responses entered included: “20/20 slow,” “after waiting 1 min 20/20 in lighted room,” “20/60 w/head tilted down,” and “20/60 blinking with ointment.”

We extracted these data from our NMEDW using Structure Query Language (SQL). This language allows for the manipulation of the data in a convenient fashion and is the standard for most clinical databases. SQL allows for “keyword” searches where one can designate that a result must include a certain text string. All of the responses that included these were then manually mapped to one of the visual acuity categorizations in Textbox 1.

To address the fact that the 5668 unique responses found in the EHR do not represent every possible future input value, we developed a mechanism to categorize text not currently in the vocabulary list. It employed string searches for known visual acuities that were initially entered in the “visual acuity” structured field from the EHR notes. This was accomplished by taking all visual acuities listed in Textbox 1. The algorithm only used this method if it came across a result that could not be mapped back to a previously categorized response, as the human curated vocabulary was considered the “Gold Standard.”

Visual acuities were then ranked in terms of best to worst as designated by their numeric representation. For example, the categorized result of 20/10 was ranked number one, 20/20 was ranked number two, and so on. This ranking allowed for additional coding to determine which visual acuity was the best for a particular patient note (Figures 2 and 3). All codes used for this study are currently under publication and will be later available at https://phekb.org for open use. Figure 1 illustrates the algorithm’s acuity mapping and ranking logic. Figures 2 and 3 detail an example of a BDVA determination from a clinical note.

Figure 1. Algorithmic Determination of Best Documented Visual Acuity.

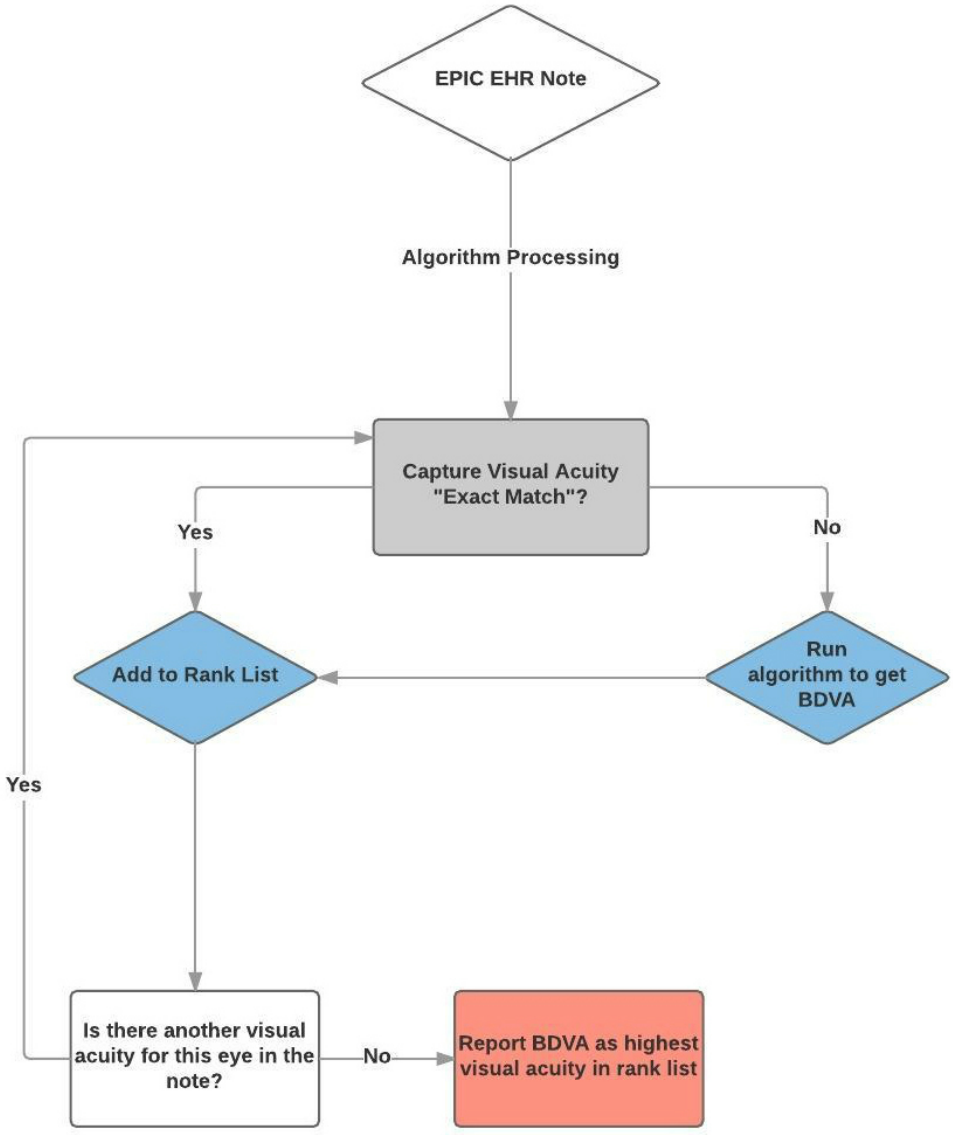


Figure 2. Screenshot of EPIC EHR provider input. Red Box outlines all fields containing visual acuity data (Right Eye: 20/50 and 20/30. Left Eye: 20/30, 20/20. Blue Box outlines what the algorithm detected as BDVA for each eye (Right Eye: 20/30, Left Eye: 20/20). ©2016 Epic Systems Corporation. Used with permission.

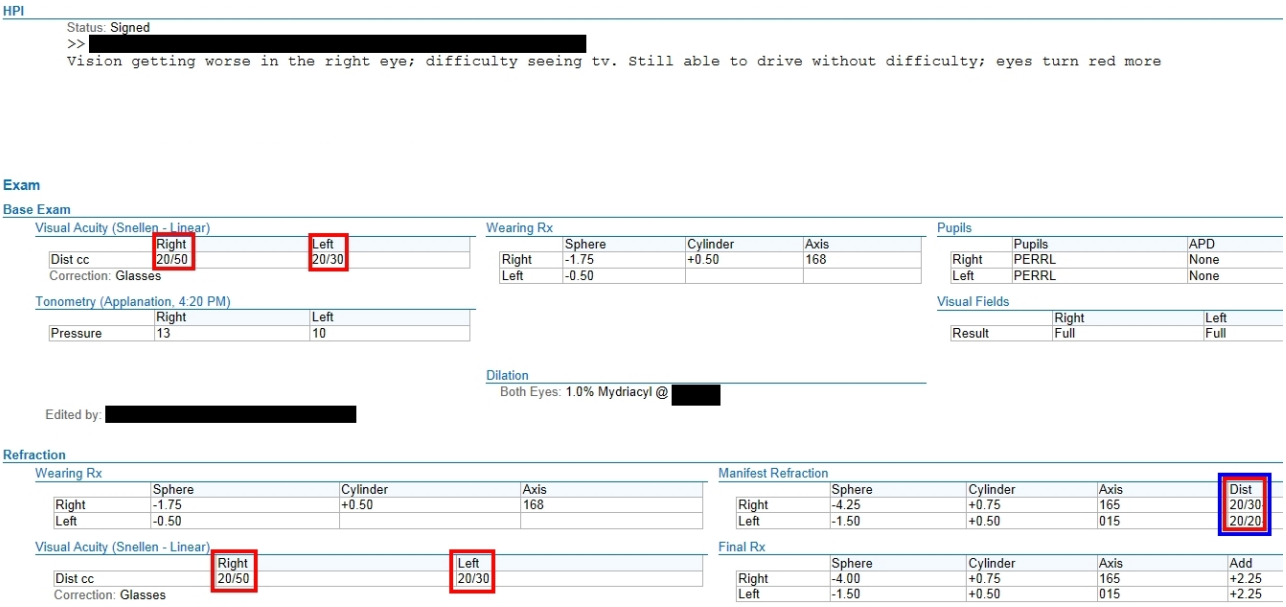
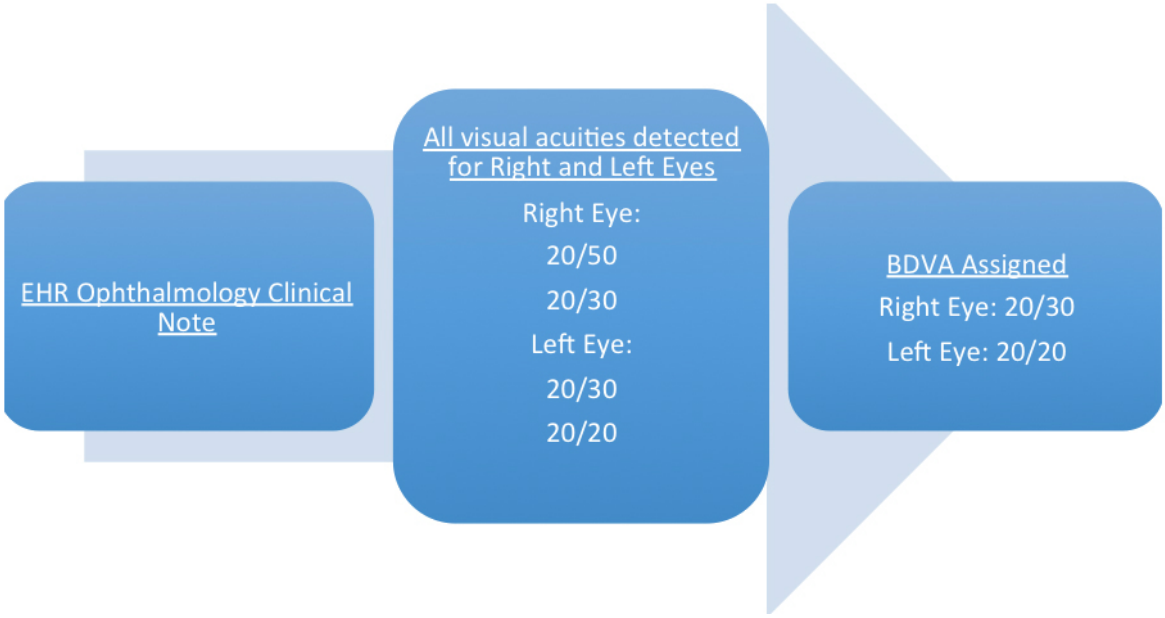


Figure 3. Flow diagram for algorithmic processing of the ophthalmology EHR note in Figure 2.



Data

We extracted the data from the NMEDW. The NMEDW is a joint initiative across the Northwestern University Feinberg School of Medicine and Northwestern Medicine. Its mission is to create a single, comprehensive, and integrated repository of all clinical and research data sources on the campus to facilitate research, clinical quality initiatives, healthcare operations, and medical education. The study began in early 2007 as this was the year when the ophthalmology clinic transitioned fully to an EHR.

The data for this study was obtained from the Northwestern Medicine Department of Ophthalmology adult outpatient ambulatory clinic visits at Northwestern Memorial Hospital, which uses the EPIC EHR. All patients aged between 18 and 89 years were included in the study. Additionally, all notes where a record included any measurement of a visual acuity (Snellen–Linear) were used to develop the algorithm. There were a total of 298,096 clinical notes from the Ophthalmology clinic between January 1, 2007, and December 31, 2014. Of these, 295,218 notes from 57,317 unique patients had at least one visual acuity measurement recorded in the chart and were therefore included in the analysis.

In order to evaluate the accuracy of the results of the algorithm, two reviewers, an ophthalmology attending physician and a medical student (PB, MM), independently reviewed 100 additional ophthalmology clinical notes and documented BDVA for each eye. For internal validation, a proper correlation was found between the two reviewers every time.

These BDVAs were then compared with those generated by the algorithm. Using clinician chart review as a gold standard, we evaluated the accuracy for our algorithm.

The protocol was approved by the Northwestern University Institutional Review Board Office in Chicago, Illinois.

Results

About 295,218 ophthalmology clinical notes were found to have visual acuity data present. This represented 57,317 unique patients who had at least one eye examination for which visual acuity was captured. The overall average age of patients in this study was 57.6 years (range of 18–89 years). Most visual acuities detected in patients were 20/100 or better (86.2%; Figure 4); "20/20" was the most common visual acuity recorded (38.7%), followed by "20/25" (18.9%).

For each clinical note, there was an average of 1.48 and 1.49 visual acuity recordings for every right and left eye respectively, with a range of 0–7 acuities for each eye. Of the 295,218 clinical notes, 54% (158,786) had more than one visual acuity recorded for either the right or left eye. There were 5668 unique responses recorded in any of the defined visual acuity fields.

When examining specific documented Snellen visual acuity values, approximately 80% of the time there was an exact match of the documented visual acuity when compared with the Snellen values in Textbox 1. The breakdown for each Snellen equivalent of exact match versus those acuities requiring interpretation by the algorithm is shown in Figure 5.

A random sampling of 100 patients (200 eyes) for which visual acuity was captured was used for a clinician chart review, and was conducted in a fashion similar to previously published work [10]. The BDVA noted by the clinicians was compared with the value captured by the algorithm. The algorithm was found to have an overall accuracy of 99% (99% right eye; 99% left eye), as shown in Table 2. Visual acuities documented in areas of the chart other than the structured visual acuity fields, such as the "History of Present Illness" portion of the clinical note, accounted for two (1.0%) instances of error.

Table 2. Chart review results of BDVA algorithm.

Total number of patients reviewed	100
Total number of eyes	200
Right eye accuracy	99%
Left eye accuracy	99%
Overall accuracy	99%

[a]*BDVA:* best documented visual acuity.

Figure 4. Graph depicting frequency of visual acuity detected within EHR notes by ranges (CF=Count Fingers, HM=Hand Motion, LP=Light Perception, NLP=No Light Perception).

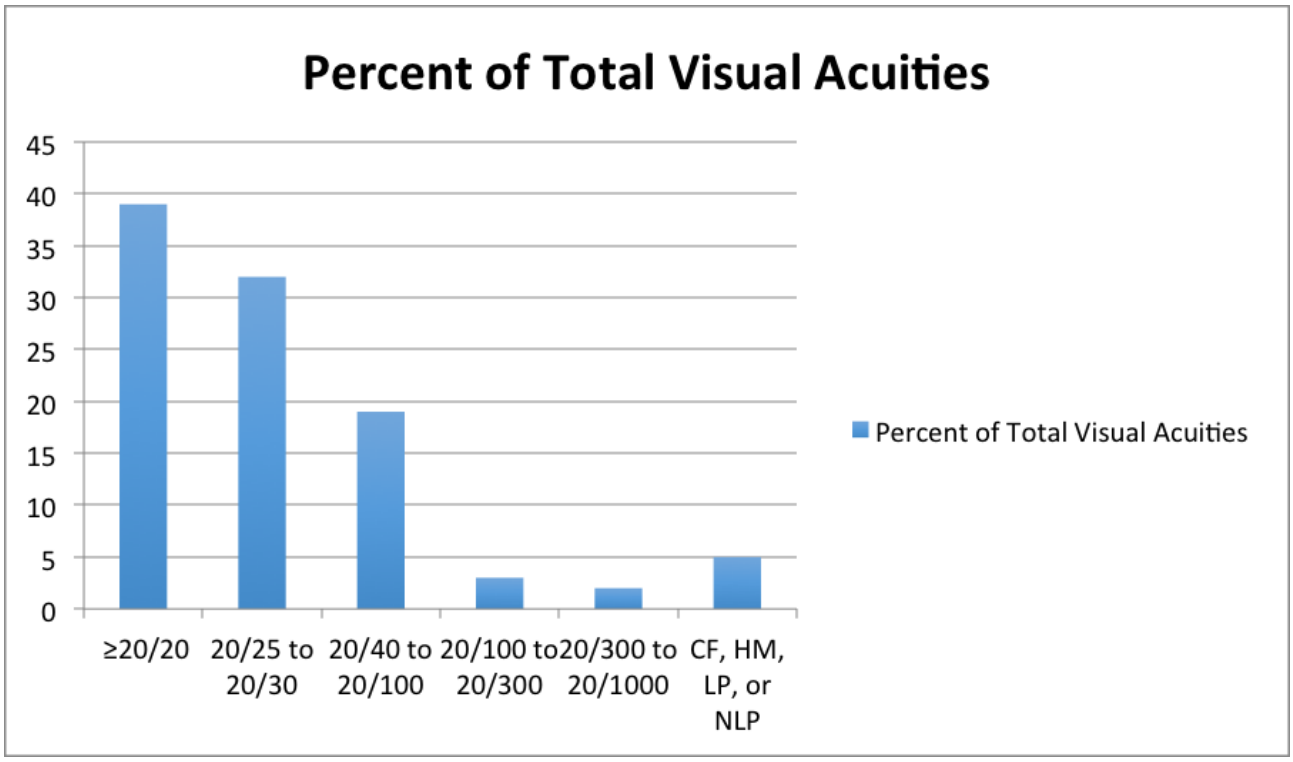
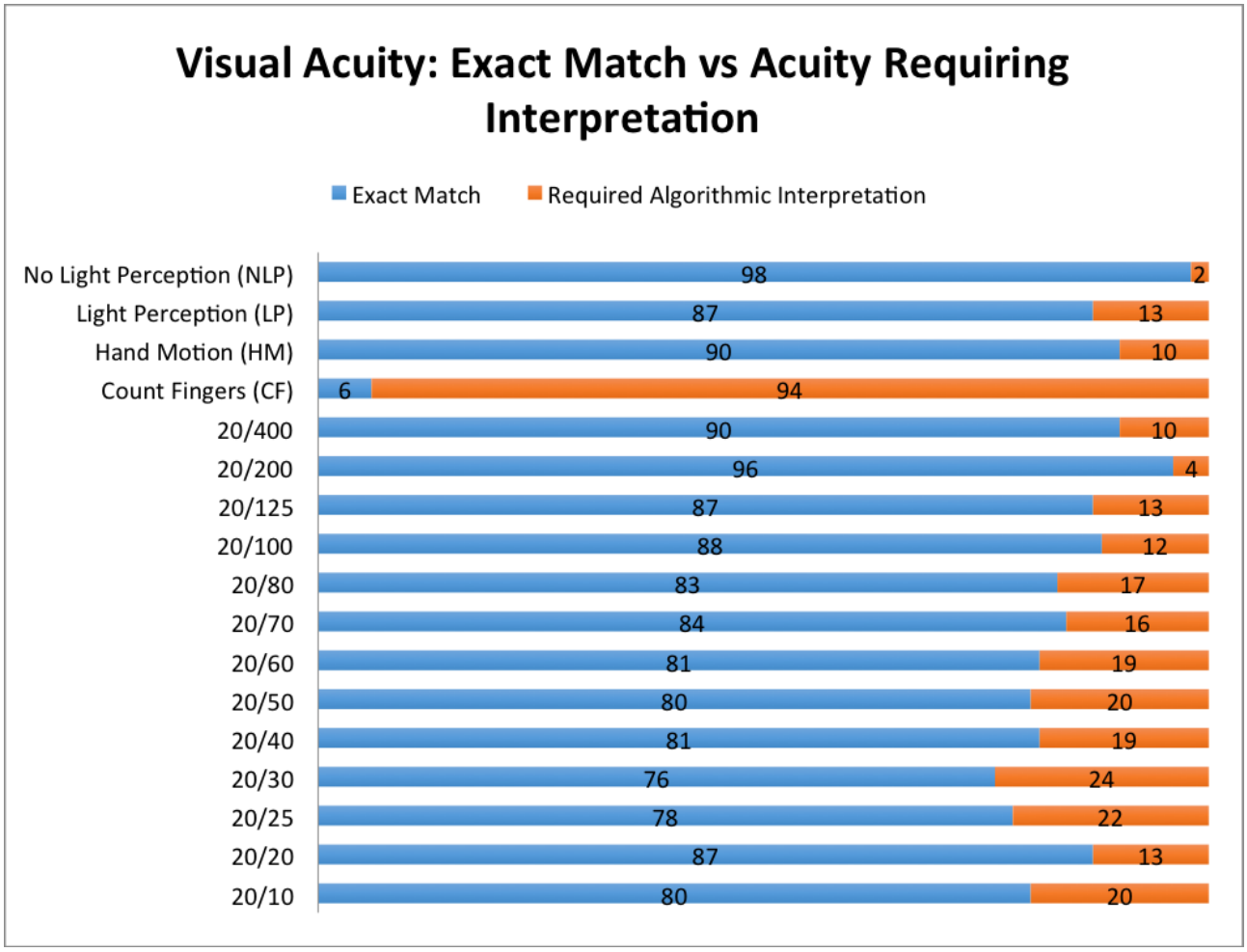


Figure 5. Visual Acuity as detected by algorithm.



Discussion

We created a unique algorithm to accurately determine best documented distance Snellen visual acuity data from EHR systems using electronic ophthalmology clinical notes. This algorithm was used on a large-scale data repository of 295,218 notes and was validated comparing the results to a manual chart review of 100 clinical notes. The algorithm accurately detected visual acuity in 99% of cases.

Principal Findings

Just as with visual acuity, there are numerous components of the medical record note (such as chief complaint, smoking status, allergies, and so forth) that may or may not contain completely "structured data," and are not easily captured. The accurate representation of quantitative traits from EHR notes is often overlooked due to difficulty with how they are documented within the EHR (often in free text), or assumption that these data are implicit within a clinical diagnosis. Given these challenges, related methodology to our work has necessarily been developed for other measures, such as detection of cataract cases [10] and adult height [4] from EHR notes. Numerous studies attempt to capture these in accurate and efficient ways, with varying results [11-14]. Our work, to the best of our knowledge, represents the first attempt at analyzing and capturing best documented visual acuity from electronic ophthalmology notes. This effort will allow us to perform patient centered outcomes research from the electronic health record. Our future work will center on comparative effectiveness research with BDVA changes for various treatments of macular degeneration, diabetic retinopathy, and cataract surgery just to name a few. Additional work to define EHR-based phenotyping of quantitative traits like BDVA can enable higher throughput association studies [15-20].

Limitations

There are limitations to our algorithm. First, with this method, it is only possible to categorize responses retrospectively and maintain complete confidence that they will be properly categorized. Any algorithm that searches free text may have difficulty deciphering it (eg, transposing the letter "O" for a "zero"). As visual acuity is captured as free text, a physician could enter a result that has never been used before and would not be captured by the current grouping method. We added more flexible rules, such as our alternative detection method, which could be put in place to attempt to categorize results prospectively but there is a potential for it to be inaccurate. Instead, it is likely that this method will require ongoing maintenance to maintain complete confidence.

Second, this algorithm was developed and tested using visual acuity values found in NMEDW and based on one EHR system. The algorithm currently searches in the "visual acuity" section of the EPIC EHR note. Should visual acuity be documented

elsewhere, such as a descriptive phrase in the history or assessment, it will not return a result; however, in our study this occurred in less than one percent of visual acuity notes audited. While this is a potential limitation, other EHR systems are known to store data in a similar defined fields fashion, increasing the potential generalizability of our algorithm at other institutions and EHRs [21,22]. The application and use of our algorithm at different clinical sites, as well as on different EHR platforms, will be the focus of future work.

While this is a representative sample of the Snellen distance visual acuity measurements, it may be necessary to adjust the algorithm for other types of visual acuity measurement systems (such as logMAR, ETDRS, metric scales, and so on), or when serving different patient populations such as pediatric populations or low vision patients. Our algorithm is flexible and can be easily modified by incorporating results from site-specific chart reviews. All codes used for this study are currently available upon request to the corresponding author. As visual acuity is a primary marker of assessing visual health, this research represents a pivotal first step in making ophthalmology electronic medical notes easily accessible for research purposes.

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Conflicts of Interest

None declared.

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Original Paper

Use and Uptake of eHealth in General Practice: A Cross-Sectional Survey and Focus Group Study Among Health Care Users and General Practitioners

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Abstract

Background: Policy makers promote the use of eHealth to widen access to health care services and to improve the quality and safety of care. Nevertheless, the enthusiasm among policy makers for eHealth does not match its uptake and use. eHealth is defined in this study as "health services delivered or enhanced through the Internet and related information and communication technologies."

Objective: The objective of this study was to investigate (1) the current use of eHealth in the Netherlands by general practitioners (GPs) and health care users, (2) the future plans of GPs to provide eHealth and the willingness of health care users to use eHealth services, and (3) the perceived positive effects and barriers from the perspective of GPs and health care users.

Methods: A cross-sectional survey of a sample of Dutch GPs and members of the Dutch Health Care Consumer Panel was conducted in April 2014. A pre-structured questionnaire was completed by 171 GPs (12% response) and by 754 health care users (50% response). In addition, two focus groups were conducted in June 2014: one group with GPs (8 participants) and one with health care users (10 participants).

Results: Three-quarters of Dutch GPs that responded to the questionnaire (67.3%, 115/171) offered patients the possibility of requesting a prescription via the Internet, and half of them offered patients the possibility of asking a question via the Internet (49.1%, 84/171). In general, they did intend to provide future eHealth services. Nonetheless, many of the GPs perceived barriers, especially concerning its innovation (eg, insufficient reliable, secure systems) and the sociopolitical context (eg, lack of financial compensation for the time spent on implementation). By contrast, health care users were generally not aware of existing eHealth services offered by their GPs. Nevertheless, half of them were willing to use eHealth services when offered by their GP. In general, health care users have positive attitudes regarding eHealth. One in five (20.6%, 148/718) health care users perceived barriers to the use of eHealth. These included concerns about the safety of health information obtained via the Internet (66.7%, 96/144) and privacy aspects (55.6%, 80/144).

Conclusions: GPs and health care users have generally positive attitudes towards eHealth, which is a prerequisite for the uptake of eHealth. But, general practitioners in particular perceive barriers to using eHealth and consider the implementation of eHealth to be complex. This study shows that there is room for improving awareness of eHealth services in primary care. It will take some time before these issues are resolved and eHealth can be fully adopted.

(JMIR Med Inform 2016;4(2):e11) doi:10.2196/medinform.4515

KEYWORDS

eHealth; technology; GPs, general practice; implementation; survey; health care users

Introduction

Support among national policy makers and health officials for eHealth in many Western countries is considerable, and efforts are focused on national strategies to expand its use [1]. Active promotion of eHealth arises from the belief that eHealth widens access to health care services and has considerable potential to increase service efficiency [1-3]. Furthermore, the use of eHealth has the potential to support patients' self- management, especially in those with chronic diseases such as asthma [4]. eHealth also has a potentially considerable impact on the use of health systems and patient-doctor roles [5].

There are many different definitions of eHealth in the literature [6,7]. A commonly used definition of eHealth is "health services and information, delivered through the Internet and related information and communication technologies, to improve or to enable health and health care" [8]. We use this definition in our study, which focuses on the use of patient online services in primary care for example, making an appointment with the general practitioner (GP) via the Internet and asking the GP a question via the Internet.

The global use of Internet has expanded dramatically in the last 10 years [9]. More than 90% of GPs offer Internet services that can be used by patients to communicate with their practice [10]. In European primary care, positive evolution in the use of eHealth is clearly observable. For example, the use of electronic networks for the transmission of medical patient data is well established and widespread. But the enthusiasm for eHealth among national policy makers is generally not matched by uptake and use in primary care among GPs and health care users [10,11].

From previous research, we know that the introduction of eHealth services is often seen as disruptive in relation to existing practice, rather than being supportive [2,3,12,13]. New systems and technologies also arrive with a set of assumptions of user needs, and they may not match user views and expectations [14,15]. We also know that beliefs and attitudes play an important role in the adoption of technology [16-18].

There is considerable literature available about the adoption of innovations in general, and in many disciplines such as public health [19]. However, to our knowledge, less is known about more specific areas, such as the process of adopting eHealth services in general practice, which is the focus of our study. The implementation of Internet communication services in primary care by GPs is expected to have positive effects because these services can increase the efficiency of care, patient satisfaction, and quality of care. Studying eHealth use in the area of primary care is important, as this may generate invaluable knowledge, for instance about access to primary care. Information about access is also important because of the clear gate-keeping role of GPs for (more expensive) medical specialists in the health care system. For example, the use of online communication (e-consults) by GPs in primary care practice can reduce the number of office visits and can enlarge primary care access [10]. This is the case in the Netherlands, where the GP is the entry point to the system.

The aim of this descriptive study is to gain insight into the current use of eHealth services by GPs and health care users and to identify the needs and perceived barriers of GPs and health care users using eHealth. This paper addresses the following questions for GPs: (1) What eHealth services do GPs currently provide? (2) What eHealth services do GPs intend to provide in future? (3) What are the needs and barriers that GPs face in providing current/future eHealth services? We also address similar questions for health care users: (1) What services do health care users currently use? (2) What services are health care users willing to use in future? (3) What are the needs and barriers that health care users face in using current/future eHealth services? The findings from the perspective of both GPs and health care users will enable us to compare both perspectives. This examination can contribute to the implementation of eHealth and the uptake of eHealth use in general practice.

Methods

Survey

This study is part of an annual, national survey about eHealth in the Netherlands, "The eHealth-monitor", financed by the Dutch Ministry of Health, Welfare and Sport [20]. In 2014, the monitor study was performed for the second time and these data are used in this paper [21].

Recruitment

General Practitioners

In April 2014, we sent an online questionnaire to a sample of 1402 GPs. These GPs were drawn from the members of the Royal Dutch Medical Association, which is representative of Dutch GPs in age and gender. At the time of the study, about 12,400 GPs were members of the Royal Dutch Medical Association. We sent an email reminder at 2 weeks and 4 weeks. In total, 171 GPs completed the questionnaire.

Health Care Users

In April 2014, a sample of 1500 panel members of the Dutch Health Care Consumer Panel run by NIVEL (Netherlands Institute for Health Research) was drawn. This sample was representative of the Dutch population aged 18 years and older regarding gender and age. This consumer panel is an access panel that consists of a large number of individuals who have agreed to answer questions on a regular basis. At the time of the study, the panel comprised approximately 6750 members [22]. The collected data are protected by registration with the Dutch Data Protection Authority (No. 1262949). In addition, the panel has privacy regulations.

We sent questionnaires by post or email, according to the respondents' previously stated preference. After 2 weeks, a postal reminder was sent. Those respondents who preferred to

fill in an online questionnaire received a reminder after 1 week and again after 2 weeks by email. A total of 754 health care users filled out the questionnaire.

Focus Groups

In June 2014, two focus groups were set up: one with GPs and one with health care users. The GPs were recruited from the respondents who gave permission in the questionnaire to receive an invitation for a focus group. The health care users were recruited from the respondents who gave permission in the questionnaire to receive an invitation for a focus group. Eight practicing GPs attended the focus group (2 women, 6 men). The focus group of health care users consisted of 10 individuals (5 women and 5 men). We did not ask the participants for their age.

The goal of the focus groups was to obtain feedback on the results of the survey and was meant to complement the quantitative part of the study. The goal of the focus groups was to gain more insight into the motives and underlying reasons for the participants to use (or not use) eHealth services and examine which positive effects and which barriers they perceive regarding the use of eHealth.

Questionnaire

General Practitioners

We asked GPs how often they use the Internet in their daily work and which device they use to access the Internet. We also asked the GPs (1) which eHealth services they currently offer in their general practice (eg, making an appointment with the GP via the Internet, (2) their plans to offer eHealth services in future, and (3) their perceived barriers to offering eHealth services.

Health Care Users

The questionnaire for health care users addressed the same eHealth-related topics as those in the questionnaire for GPs. Questions were asked about the use of Internet at home, for example, for gathering information about health and health care: (1) familiarity with eHealth services, offered by their GP, (2) usage and willingness to use eHealth services, and (3) perceived barriers to using eHealth. Only the respondents who had contact with their GP during the past year were asked to answer the questions about familiarity with eHealth and willingness to use eHealth.

Analysis

Questionnaire

To describe the use and the perceived barriers of eHealth services by health care users and by GPs, we used descriptive statistics. The analyses for the GPs were performed with the statistical program SPSS, version 19.0. The analyses for health care users were performed with the statistical program Stata, version 13.0.

For questions asked to all health care users, we weighted the descriptive analyses for age and gender in such a way that it resembled the distribution of age and gender within the Dutch population from 18 years, based on data from Statistics Netherlands. We applied a weighting factor ranging from 0.6 to 1.5.

The GP sample is representative of the Dutch population of GPs regarding gender, but the response is not representative for age: GPs younger than 35 years and GPs aged 50 years and older responded more often. Nevertheless, we did not use a weight factor to correct for this because applying the weight factor did not affect the results.

Focus Groups

In the two focus groups, the main results of the survey were discussed with the participants (GPs and health care users). The focus group feedback was recorded, transcribed, and coded in relevant topics.

Results

General Practitioners

The questionnaire was completed by 171 GPs, which is a 12% response rate (52.0%, 89/171 male; mean age 46 years, range 31-68 years). All the GPs in this study accessed the Internet in their daily work, using a computer or laptop (100.0%, 171/171), smart phone (80.7%, 138/171), or tablet (39.2%, 67/171). GPs used the Internet mostly to gather medical information (90%) or to show information to patients (78.9%, 135/171).

In this section we discuss the three research questions regarding GPs.

What eHealth Services Do GPs Currently Provide?

The possibility of requesting a prescription via the Internet was the most common eHealth service offered by GPs (see Table 1; 67.3%, 115/171). In second place, half of the GPs (49.1%, 84/171) stated that they offer patients the opportunity to ask them a question via the Internet. Other eHealth services, such as making an appointment via the Internet, receiving a reminder for an appointment, and screen-to-screen contact between GP and patient, were scarce (0.6%, 1/171 to 18.1%, 31/171).

What eHealth Services Do GPs Intend to Provide in Future?

GPs who do not have plans for offering eHealth services, often reported that they would like to offer these services. For example, four out of ten GPs (41.5%, 71/171) would like to offer patients the possibility of receiving a reminder for an appointment via the Internet or by text message (see Table 1). Looking at the plans and the willingness of the GPs to offer more eHealth services in the near future, we found that almost a quarter of the GPs plan to offer patients the opportunity to make an appointment via the Internet within 1 year (22.8%, 39/171).

What Are the Needs and Barriers Facing GPs in Providing Current or Future eHealth Services?

Most of the GPs (79.5%, 136/171) who completed the questionnaire experienced barriers regarding eHealth (see Table 2). About half of the GPs mentioned that communication with patients via the Internet is not explicit enough (48.5%, 66/136). They also noted that implementation of eHealth is

time-consuming and that there is no funding or financial compensation for the effort and time they spend on it (48.5%, 66/136). GPs also perceived that contact by telephone or face-to-face contact is more efficient than contact via the Internet (42.6%, 58/136) and that they do not have the time for training or upskilling regarding eHealth (40%, 54/136).

The general experience of GPs in the focus groups was that the implementation of eHealth is inevitable. One GP stated that "eHealth is becoming more and more important, so I had better prepare for it." All the participating GPs in the focus groups were familiar with eHealth, but they were also reluctant to use eHealth. "There is no triage when patients make an appointment via the Internet and there is no patient information available" (GP1). GPs who attended the focus group also "fear loss of control of their agenda" (GP2) and "fear huge increase of patient appointments" (GP3). Providing patient online communication is also perceived as "time-consuming and expensive" (GP4), and "the reimbursement for an e-consult is not sufficient to compensate the investments" (GP5).

Table 1. GPs who offer and are willing to offer eHealth-services in their general practice (N=171).

According to GPs	n (%)				
	This is offered	There are plans to offer within 1 year	There are no plans, but I would like to offer	There are no plans, and I do not know if I would like to offer	There are no plans, and I would not like to offer
To make an appointment with my GP via the Internet	31 (18.1)	39 (22.8)	44 (25.7)	40 (23.4)	17 (9.9)
To receive a reminder for an appointment with my GP via the Internet or text message	13 (7.6)	12 (7.0)	71 (41.5)	50 (29.2)	25 (14.6)
To ask my GP for a requesting prescription via the Internet	115 (67.3)	16 (9.4)	28 (16.4)	7 (4.1)	5 (2.9)
To ask my GP a question via the Internet	84 (49.1)	13 (7.6)	17 (9.9)	39 (22.8)	18 (10.5)
To talk with my GP screen to screen via the Internet, for example via a tablet	1 (0.6)	4 (2.3)	33 (19.3)	78 (45.6)	55 (32.1)

Table 2. Barriers to using eHealth, perceived by GPs (N=171).

Barriers	n (%)
Perceived barriers (N=171)	
Yes	136 (79.5)
I do not know	27 (15.8)
No	8 (4.7)
Type of barriers (N=136)	
The communication is not explicit enough, when contacting via the Internet	66 (48.5)
Lack of financial fees for the time spent to implement eHealth	66 (48.5)
Less efficient than contact by telephone or face-to-face contact	58 (42.6)
Lack of time to delve into this	54 (39.7)
Lack of sufficient safe systems	52 (38.2)
Fear of criticism about privacy aspects	49 (36.0)
Fear of increase in patients' care demands	48 (35.3)
Lack of clarity about laws and regulation regarding eHealth	46 (33.8)
Doubts about the benefits for my general practice	46 (33.8)
Lack of clarity about a good way to set up the system	40 (29.4)
Fear that patients have higher expectations	38 (27.9)
Lack of standards for the right set-up of systems	32 (23.5)
Doubt about the benefits for patients	33 (24.2)
Lack of knowledge and skills to apply eHealth in my general practice	32 (23.5)
Lack of technical support	28 (20.6)
Patients are unfamiliar with eHealth	24 (17.6)
Resistance of employees in my general practice to expand the possibilities of eHealth	19 (13.9)
Lack of opportunities for training	17 (12.5)
No access to the right technique	14 (10.3)
Patients' resistance to expanding the possibilities for using eHealth	3 (2.2)

In the focus groups, GPs also reported that they "have a need for information about the do's and the don'ts of eHealth, such as how to deal with privacy aspects or with triage when using electronic appointments" (GP6). Also, GPs in the focus groups mentioned that they "have an urgent need for information from a colleague GP" (GP7) so that they can learn from each other about how to deal with technical, financial, or organizational problems.

According to the focus groups, most of the GPs had plans to offer eHealth services in general practice because of the opportunities to widen access to their practice and to improve the service to patients. "The added value of providing online patient services is that the telephone of the general practice rings less often." Another advantage for GPs was convenience: "I can answer patients' online questions at a moment I prefer" (GP8).

Health Care Users

The questionnaire was completed by 754 members of the Dutch Health Care Consumer Panel, which is a response of 50% (51.1% male, 385/754; mean age 52 years, range 20-84 years). We also asked health care users questions about their Internet use at home because the availability and use of Internet is an important prerequisite for using eHealth. Almost all health care users (93.0%, 676/727) used the Internet at home, on various devices, such as a computer or a laptop (97.6%, 644/660), a smart phone (51.2%, 338/660), or a tablet (48.8%, 322/660). Many health care users (70.0%, 465/664) stated they find using the Internet easy, 20.0% (133/664) were neutral, and 9.9% (66/664) had the opinion that using the Internet is difficult. Health care users used the Internet especially for gathering information about health and health care (64.4%, 463/719), to look up information about nutrition and health (50.5%, 350/693), and to search for relevant information in deciding whether or not they should visit their GP (38.8%, 279/719).

In this section we answer the three research questions regarding health care users.

What eHealth Services Do Health Care Users Currently Use?

Table 3 shows that about half of health care users (48.6%, 282/580 to 60.0%, 352/587) who visited their GP last year at

least once, did not know whether or not the above-mentioned eHealth services are offered by their GP. For example, 55.0% (323/587) did not know if it is possible to make an appointment via the Internet. Health care users were most familiar with the possibility of requesting a prescription from the GP via the Internet (30.5%, 177/580).

When we look at the frequency of eHealth use, 17.8% (102/573) of the health care users who visited their GP last year at least once used this eHealth service (see Table 4). Other eHealth services, such as making an appointment with the GP via the Internet and screen-to-screen contact between patient and GP, were hardly used in general practice, according to health care users (4.3%, 25/573 and 1.2%, 7/563, respectively; see Table 4).

What eHealth Services Are Health Care Users Willing to Use in Future?

About half of the health care users that did not use eHealth services reported that would like to use these services if offered by their GP (43.7%, 246/563 to 50.3%, 288/573; see Table 4). An exception is the possibility of talking with the GP via the Internet, for example a tablet. Only one out of five (19.0%, 107/563) would like to use this service if offered by their GP.

What Are the Needs and Barriers Facing Health Care Users in Using Current or Future eHealth Services?

One fifth of all the health care users (20.6%, 148/718) perceived barriers to using the Internet for their health and health care (Table 5). Health care users who perceived barriers mostly had "concerns about the validity of the information obtained via the Internet" (66.7%, 96/144) and "concerns about privacy aspects" (55.6%, 80/144). Barriers to eHealth use also had to do with beliefs. In this study, we found that half of the health care users thought that using the Internet was not suitable for personal contact (49.3%, 71/144). Health care users also needed more knowledge and skills in using eHealth (36.1%, 52/144), and they had doubts about the benefits of eHealth for themselves (35.4%, 51/144).

According to the focus groups, health care users also perceived benefits using eHealth. They were motivated to use eHealth for reasons of convenience, such as the possibility of contacting their GP at any time. Some members of the focus groups commented that "The use of Internet for health care is nice, but personal contact with the GP is also important" (PT1). "Internet is no substitute for personal care. Sometimes you want to speak your GP face-to-face" (PT2). Another member of the focus groups noted: "Change will occur slowly, because the privacy aspect and safety are also issues that should be addressed" (PT3).

Table 3. Familiarity of eHealth in general practice by health care users, who visited their GP at least once last year (N=580-587).

According to health care users	n (%)		
	This is possible	I do not know if it is possible	This is not possible
To make an appointment with my GP via the Internet	77 (13)	323 (55)	187 (32)
To receive a reminder for an appointment with my GP via the Internet or text message	31 (5)	352 (61)	197 (33)
To ask my GP for a requesting prescription via the Internet	177 (30)	282 (48)	127 (22)
To ask my GP a question via the Internet	84 (14)	340 (58)	159 (27)
To talk with my GP screen to screen via the Internet, for example via a tablet	8 (1)	348 (60)	225 (39)

Table 4. Use and willingness to use eHealth by health care users who visited their GP at least once last year (N=563-573).

According to health care users	n (%)			
	I used it, at least once last year	I did not use, but I would like to use	I did not use, and I do not know if I would like to use	I did not use, and I would not like to use
To make an appointment with my GP via the Internet	25 (4)	262 (46)	139 (24)	145 (25)
To receive a reminder for an appointment with my GP via the Internet or text message	13 (2)	261 (46)	125 (22)	166 (29)
To ask my GP for a prescription via the Internet	102 (18)	288 (50)	90 (16)	93 (16)
To ask my GP a question via the Internet	22 (4)	246 (44)	135 (24)	161 (29)
To talk with my GP screen-to-screen via the Internet, for example via a tablet	7 (1)	107 (19)	183 (32)	270 (48)

Table 5. Barriers to using eHealth, perceived by health care users (N=718).

Barriers	n (%)
Perceived barriers by health care users (N=718)	
Yes	148 (20.6)
I do not know	184 (25.6)
No	386 (53.8)
Type of barriers (N=144)	
Concerns about the validity of health information obtained via the Internet	96 (66.7)
Concerns about privacy aspects	80 (55.6)
Using the Internet is not suitable for personal contact	71 (49.3)
Lack of knowledge and skills to adjust eHealth	52 (36.1)
Doubt about the benefits of eHealth for myself	51 (35.4)
Unfamiliarity with the possibilities of eHealth	45 (31.3)
Lack of technical support	20 (13.9)
Lack of time to delve into eHealth	18 (12.5)
My care provider does not offer the opportunity	13 (9.0)
I have no access to the Internet	7 (4.9)

Discussion

Principal Results

The results of the 2014 eHealth monitor show that three-quarters of the GPs that responded (67.3%, 115/171) offered patients the possibility of requesting a prescription via the Internet and half offered patients the possibility of ask them a question via the Internet (49.1%, 84/171). eHealth services for patients such as making an appointment via the Internet, receiving a reminder for an appointment, and screen-to-screen contact are much less likely to be offered by GPs. In general, the GPs in our study did have plans to offer eHealth services or at least they were willing to offer eHealth. Thus, the potential for further growth of eHealth services in general practice exists. However, we found that over three-quarters of respondents experience barriers to successful use eHealth. The main barriers they cited are communication problems, lack of financial compensation, and lack of time and technical skills to implement eHealth in daily practice. Accordingly, these barriers could hinder the further development of eHealth services.

The results of this survey also showed that eHealth services offered by GPs are not well known to health care users who had contact with their GP at least once last year. But nearly half of health care users are willing to use eHealth services, if offered by their GP, which means there is great potential for eHealth in the future.

It is worth pointing out the differences in perception of eHealth services between health care users and GPs. When we compare health care users and GPs, we may conclude that GPs often report that they offer eHealth services, while many health care users are not aware of these services being offered. That said, we have to keep in mind the low response rate of GPs. Accordingly, there appears to be a substantial gap between the availability of eHealth services in general practice and health care users' familiarity with the possibility of using eHealth offered by their GP. To increase familiarity with eHealth services, websites such as National Health Services Choices in England is an example of altering health care seeking behavior, attitudes, and knowledge among health care users [23].

When we compare the findings of our study about barriers perceived by GPs with those perceived by health care users, it is remarkable that only one fifth of health care users perceive barriers to using eHealth versus the majority of GPs. A possible explanation for this gap in perceived barriers is that health care users scarcely use eHealth services, so it is plausible that they do not know whether or not they perceive barriers.

Comparison With Previous Studies

Earlier studies showed that, in a European primary care setting, positive evolution is clearly observable in GPs' use of the Internet, mainly with regard to online medical information searches, use of electronic health care records, and to a lesser extent, electronic transfer of patient data [24].

GPs are also increasingly seeking out eHealth services, such as digital prescribing and email consultations, to improve patients' access to health care, patients' quality of care, and service efficiency [2,25]. For example, a recent study of electronic prescribing suggests that after the implementation, the appropriate prescribing in polymedicated patients improved [26]. This is in line with our findings that GPs are optimistic about the potential of eHealth to increase access to primary care and improve quality of care. Our findings that GPs and health care users experience barriers are also in line with research about health care innovation in general [19] and with the results of other reviews and longitudinal studies regarding factors that promote or inhibit the implementation of eHealth [2,3,24,27].

Strengths and Limitations

The main strength of this study is that we used a large number of health care users, with a subsample of health care users who visited their GP last year, and a large sample of GPs. The combination of a survey and focus groups is also a strength. In the focus groups, the results of the survey were discussed and we obtained important background information in the respondents' motives for (not) using and offering eHealth as well as insight into facilitators and barriers to eHealth implementation. Thus, we have gathered valuable information about eHealth services, through the eyes of GPs and health care users as well.

A limitation of this study is the low response by GPs, which might have influenced the results and which means that the results cannot be generalized to the whole population of GPs in the Netherlands. The reason for the low response is that in 2014 we could not approach the panel members of the Royal Dutch Medical Association, due to the transition to another information system. Our solution was to approach a large, representative sample of members of this association. But because these members are not members of a panel (available for participation in research), we expected a lower response than in 2013 (it was 49%). The low response rate of 2014 was disappointing. In addition, we asked non-responders why they did not fill in the questionnaire. The main reasons were that GPs are very busy and that they often get requests by email to complete questionnaires.

We want to stress that a bias in the sample may have occurred, namely that responses may have mainly come from those health care users and GPs who are very positive about using the Internet and eHealth, as well as respondents who are very negative about this topic. Nevertheless, we also conducted focus groups with GPs to reflect on the results. This was very informative, shedding more light on GPs' attitudes about eHealth and their reasons for offering, or not offering, eHealth services. In the focus groups, we asked the participants to clarify their attitude to eHealth. Both focus groups represented participants with a positive attitude as well as participants who were negative about eHealth. Thus, we may conclude that both proponents and opponents are at represented in the focus groups in this study.

Conclusions

This study showed that many GPs want to offer eHealth services in the near future because of the positive effects they expect when offering eHealth, for example, to expand access to their general practice. By contrast, health care users are not aware of the existing eHealth services their GPs offer. Nevertheless, most of the health care users are willing to use eHealth services, when offered by their GP, but they are not actively looking for eHealth services. In general, health care users and GPs have positive attitudes regarding eHealth. Therefore, the results imply that there are opportunities to further expand eHealth in general practice.

In our study, GPs perceived barriers to offering eHealth, such as communication problems, insufficient technical support, lack of financial compensation for the extra time spent on the implementation of eHealth, and their lack of knowledge and skills to implement eHealth properly. Health care users also had concerns about the safety of the health information via the Internet and about privacy aspects regarding the use of eHealth. Offering eHealth services in general practice is complex. Until now, widespread adoption of eHealth in general practice has been challenging because many problems have to be overcome. Thus, there are also many conditions that should be fulfilled to implement eHealth successfully and there is still a long way to go before eHealth is fully integrated in primary health care.

According to the results of this study, there is room for improving awareness of eHealth services in primary care. Increasing user awareness might result in more insight into the perceived benefits to health care users. To promote and further increase the use of eHealth services in general practice, best practices should be widespread. GPs could act as ambassadors to promote the knowledge of GPs and health care users about eHealth services and show how to use eHealth in general practice.

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Authors' Contributions

JP drafted the manuscript, conducted the survey for health care users, acted as discussion leader of the focus group with health care users, and revised the manuscript. JK conducted the survey for GPs, was discussion leader of the focus groups with GPs, and gave critical comments on the manuscript. AB contributed to the statistical analyses, the acquisition of the data, and reviewed the draft of the manuscript. JdJ was involved in drafting the manuscript and the critical revision of the manuscript. RF critically commented on the draft manuscript. All authors have given their final approval of the submitted manuscript.

Conflicts of Interest

None declared.

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Abbreviations

GP: general practitioner

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Original Paper

Adoption Factors of the Electronic Health Record: A Systematic Review

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Abstract

Background: The Health Information Technology for Economic and Clinical Health (HITECH) was a significant piece of legislation in America that served as a catalyst for the adoption of health information technology. Following implementation of the HITECH Act, Health Information Technology (HIT) experienced broad adoption of Electronic Health Records (EHR), despite skepticism exhibited by many providers for the transition to an electronic system. A thorough review of EHR adoption facilitator and barriers provides ongoing support for the continuation of EHR implementation across various health care structures, possibly leading to a reduction in associated economic expenditures.

Objective: The purpose of this review is to compile a current and comprehensive list of facilitators and barriers to the adoption of the EHR in the United States.

Methods: Authors searched Cumulative Index of Nursing and Allied Health Literature (CINAHL) and MEDLINE, 01/01/2012–09/01/2015, core clinical/academic journals, MEDLINE full text, and evaluated only articles germane to our research objective. Team members selected a final list of articles through consensus meetings (n=31). Multiple research team members thoroughly read each article to confirm applicability and study conclusions, thereby increasing validity.

Results: Group members identified common facilitators and barriers associated with the EHR adoption process. In total, 25 adoption facilitators were identified in the literature occurring 109 times; the majority of which were efficiency, hospital size, quality, access to data, perceived value, and ability to transfer information. A total of 23 barriers to adoption were identified in the literature, appearing 95 times; the majority of which were cost, time consuming, perception of uselessness, transition of data, facility location, and implementation issues.

Conclusions: The 25 facilitators and 23 barriers to the adoption of the EHR continue to reveal a preoccupation on cost, despite incentives in the HITECH Act. Limited financial backing and outdated technology were also common barriers frequently mentioned during data review. Future public policy should include incentives commensurate with those in the HITECH Act to maintain strong adoption rates.

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KEYWORDS

electronic health record; information technology; HITECH Act; health information technology

Introduction

Background

Currently in the United States, expenditures associated with health care average 17.5% of the gross domestic product (GDP) [1]. The Health Information Technology for Economic and Clinical Health (HITECH) Act was initiated in 2009 and, as described by Samuel (2014), implemented goals of "widespread" adoption of Electronic Health Records (EHRs) that should realize nationwide savings in the health care industry [2]. Although much research exists in support of the policy makers' agenda tied to the HITECH Act, the widespread adoption process leaves many providers reluctant to move forward due to concerns of financial pressures, technology limitations, and potential unintended errors related to limited knowledge of the EHR [3]. There is plenty of literature that supports the idea that adoption of Health Information Technology (HIT), specifically the EHR, presents great potential value to the health care industry in our nation [3]. Through the implementation of HIT, patients, providers, and intermediaries can expect "efficiency, effectiveness, and safety of health care" [4]. The potential for great savings, efficiency, and quality through the adoption of the EHR created high expectations from the federal government, and President Bush even expected ubiquitous adoption by the year 2014 [5]. However, only 55% of nationwide providers had fulfilled the HITECH Act requests by the end of 2014 [5]. With financial-savings estimates ranging from $77-$371 billion throughout the country following broad implementation, adoption of the EHR is essential for all who are involved [6]. A thorough review of EHR adoption facilitator and barrier factors provides ongoing support for the continuation of EHR implementation across various health care structures, possibly leading to a reduction in associated economic expenditures. Several researchers have examined adoption factors and barriers, but a gap in the literature exists that places these factors into an affinity diagram to identify those facilitators and barriers to adoption most often cited [7].

Objective

The purpose of this review is to compile a current and comprehensive list of facilitators and barriers to the adoption of the EHR in the United States, and create an affinity diagram that orders these items by frequency of occurrence. Although frequency of occurrence in the literature does not necessarily identify the most important factors, it may help policy makers prioritize levels of effort for maximum effectiveness and the results of this review should enable future studies to explore the significance and order of importance.

Methods

Search

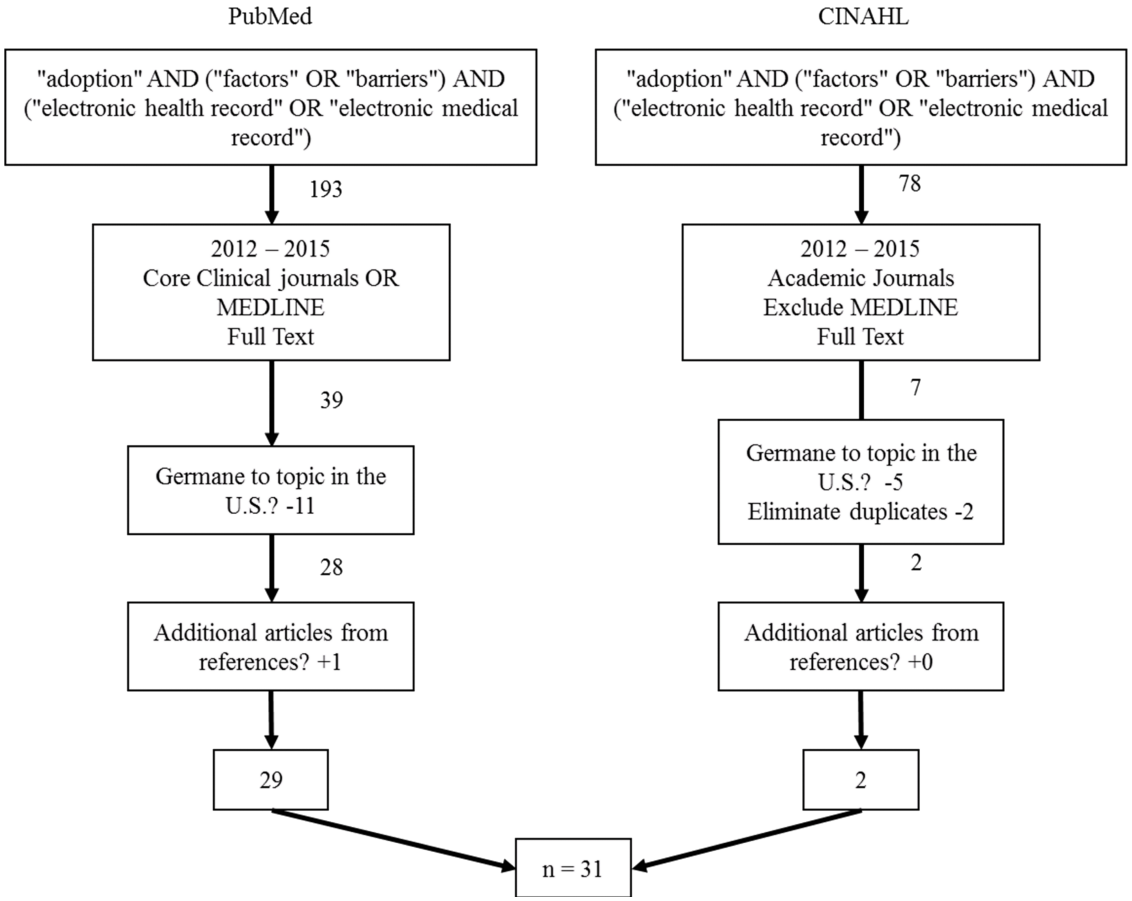
We searched for research on the topic of both facilitators and barriers to adoption of the EHR. A quick look at the Medical Subject Heading (MeSH) in PubMed terms shows no clear association with the term "adoption" in the sense of "selection". As a result, a combination of Boolean operators and several similar terms were employed in a manner that would be likely to capture of the desired articles. Additionally, two terms are closely associated with the electronic records: the electronic health record, and the electronic medical record (EMR). While these terms are distinct in the HIT field, they are often used interchangeably throughout the literature, so both were included in the search terms. We also accepted studies and reviews on the topic, but only if they were published in academic journals or indexed in MEDLINE.

Data

Articles for this review were gathered from two separate databases: Cumulative Index of Nursing and Allied Health Literature (CINAHL) Academic Search Complete via Ebson B Stephens Company (EBSCO Host), and PubMed (MEDLINE Complete). Search criteria were not limited to any specific focus. Instead, we searched for EHR or EMR adoption factors and barriers to adoption in patient care facilities in general. An iterative, nonlinear search string was created through PubMed and a similar string was used with Boolean operators in CINAHL.

Figure 1 illustrates the search process, with the associated inclusion and exclusion criteria. As depicted, we narrowed the focus of the review to 1/1/2012–9/1/2015, core clinical/academic journals, full text. From this process, 60 articles were identified. The beginning of 2012 was chosen because it is one year after incentives for Meaningful Use incentives became available. The entire process of article selection is illustrated in Figure 1 (Literature review process). Authors agreed ahead of time on acceptable criteria for articles included in the review in an effort to increase the inter-rater reliability.

Figure 1. The search process with inclusion and exclusion criteria.



Using the criteria agreed upon, we independently read abstracts of these articles to determine if the research was germane to our topic, then we discussed our findings to reach consensus. Once consensus was reached, we examined the references in the remaining 30 articles to identify additional research that was not captured with our search string; one additional article was identified for the sample through this process. The final sample included 31 articles. The inter-rater reliability for the initial selection of titles was very good (kappa=.789). Our group of five divided the articles into sets that overlapped. We met again to discuss the merits of these articles, and through this meeting, we identified common themes in the literature of both facilitators and barriers to adoption. Consensus was reached on all 31 articles (kappa=1.0, excellent).

We decided to include systematic reviews in the sample because the data in the reviews would help validate our review. A total of three reviews were included and integrated into a literature matrix with the other articles. The literature matrix consisted of date of publication, journal, authors, titles, study designs, data sources, and pertinent details on both facilitators and barriers to the adoption of the EHR. Studies and reviews were sorted by date of publication (newest to oldest), by author (alphabetical), and they were assigned numbers that correspond to those in the references. The numbers are not sequential in Table 1 because several of the articles were used in the background section, so their numbers are lower than the start of those called up in the review. From this matrix, multiple affinity diagrams were created that illustrate the frequency of facilitators, barriers, study designs, and sources of data.

Results

Summary of Findings

We identified 31 unique publications that addressed facilitators and/or barriers to adoption of the EHR. Our analysis identified 25 facilitators for and 23 barriers to adoption. A portion of our literature matrix is included in Table 1. Many factors that some studies listed as facilitators were listed by others as barriers.

Table 1. Summarized facilitators and barriers.

Authors	Facilitators	Barriers
Kruse CS, et al [8]	Access to information	Initial cost
	Error reduction	User perceptions
	Transfer of information	Implementation problems
	Long-run cost savings	External factors
	Clinical and administrative efficiency	Training
	Project planning	Cultural change
	Security	Future upgrades
	Time savings	Necessary maintenance
	Staff retention	
Cucciniello M, et al [9]	Commitment promotion	Change processes
	Role defining	
	System impacts assessments	
McCullough JM, et al [10]	Availability of clinical data	Competition
	Support from management	
	Competition	
Tang, et al [11]	Availability of RECs	none specified
Abramson EL, et al [12]	Size of hospital (bed size)	Cost
		Lack of incentive
		Lack of interoperability
		Competitiveness
		Ongoing cost of maintenance
Ben-Zion R et al [13]	Executive management support	Cost-benefit asymmetry
	Alignment with firm strategy	Lack of standard protocols for data exchange
	Economic competiveness	Uncertainty over implementation cost
	Knowledge management	User resistance
	Patient empowerment	Breaches in security
		Patient privacy
D'Amore JD, et al [14]	Continuity of care document	Omission or misuse of LOINC
		Excess precision in timestamps
		Omission or misuse of UCUM in meds
		Omission or misuse of RxNorm
		Omission or misuse of dose amount
		Omission or misuse of allergic reactions
		Omission or misuse of allergy severity
		Omission or misuse of dose frequency
		Omission of result interpretation
		Omission of result reference range
Jones EB, Furukawa MF [15]	Engage patients and family in their care	Health centers with large share of Hispanics and Blacks had lower adoption rates
	Improve care coordination	
	Improve population and public health	Centers located in rural areas
	Quality recognition	Health center size, income status and region
		Health centers with larger share of patients whose family incomes were below poverty level had lower rate of EHR adoption
Kruse CS, et al [7]	Size of hospital (bed size)	Patients' age
	Competiveness	Rural locations
	Urban locations	Computer anxiety
	Users cognitive ability	
	User attitude toward information	
	Workflow impact	
	Communication among users	

Authors	Facilitators	Barriers
Samuel CA [2]	Patients enrolled in Medicare or Medicaid Metropolitan status Increased financial incentives	Health professional shortage areas Minority concentration
Sockolow PS, et al [16]	Increase in productivity Improved clinical notes Reduced time to reimbursement Improved communication among staff	Incomplete medication information Incomplete hospital-stay information
Ancker JS, et al [17]	Monetary incentives Efficiency (fewer providers needed) Efficiency (practice sites) Effectiveness (fewer patients) Practice size	Cost Lack of tech assistance
Audet AM, et al [18]	Size of practice Ability to search for patients by diagnosis Ability to list patients overdue for preventative care Sort patients by specific laboratory results	Cost lack of experience Lack of tech-support infrastructure
Baillie CA, et al [19]	Reduce readmission rates	Existing data may not serve well in a predictive model
Cheung SK, et al [20]	Efficiency Reduction of medical errors Ability to share patient information in public sector Eliminate need to store paper records Eliminate illegibility of practice partners	Patient unfriendliness Limited consultant time Cost concerns Computer use more time consuming Concerns on data migrations from paper to system Insufficient space for computer installation
Georgiou A, et al [21]	Laboratory order forms contained bar codes for easier ordering A unique bar code for patient details Unique bar codes for each test A test order episode barcode	EMR test order problems Handwritten request on an EMR order Order number problem Multiple forms EMR order incorrect Change of test Add-on test No information provided Longer data entry time
Hamid F, Cline TW [5]	EHR satisfaction increased when users understood the benefits Supportive management Training programs	Cost Perceived lack of usefulness and provider autonomy Time consuming
Iqbual U, et al [22]	Perceived usefulness Perceived ease to use Computer self-efficacy Security Intention to use	Clinics with high number of outpatient visits Subjective norm
Kirkendall ES, et al [23]	Communication Job satisfaction Quality and patient data Quality and safety of patient care Employee understanding and support Organizational support The “Rights” of patient care	Transition of data

Authors	Facilitators	Barriers
Middleton B, et al [24]	Monetary incentives Improve effectiveness Improve efficiency	Increased training burden Alert fatigue
Patel V, et al [25]	Financial incentives Size of practice	Lack of interoperability standards
Shen X, et al [26]	Size of practice	Cost Lack of integration with other systems Lack of national guidelines for implementation
Xierali IM, et al [27]	Health maintenance organizations more likely to adopt EHR Those with faculty status more likely to adopt EHR	Medically underserved locations less likely to adopt EHR Geographic health professional shortage areas less likely to adopt EHR International medical graduates less likely to adopt EHR Group practice/solo practice and small practice physicians less likely to adopt EHR
Menachemi N, et al [28]	HMO penetration into market	Competition Low income patients
DesRoches CM, et al [29]	Size of facility Incentives	Cost Size of facility
Decker SL, et al [30]	Size of organization	Age
Hudson JS, et al [31]	Hospital setting Improved outcomes Reduce duplicative tests Integrate levels of care Improve communication Greater readability	Cost
Jamoom E, et al [32]	Age Size of practice Enhanced patient care	none specified
Leu MG, et al [33]	Size of practice	Cost Productivity Customizability (right fit)
Linder JA et al [34]	Better for structured documenters Better for free text documenters	Decrease in quality of care for dictator note takers
Ramaiah M, et al [35]	Workflow can be optimized Access to electronic information e-prescriptions	Workflow often ad-hoc in nature Check-backs of scripts still time consuming Medical literacy of clerks inhibits smooth scheduling Information must still be verified Lack of IT experience of staff Uncertainty of time Uncertainty of cost
Rea S, et al [36]	Secondary use of data Natural language processing	Privacy and security
Ronquillo JG [37]	Genome-associated care Reduce error More efficient care More effective care Control costs	Privacy and security

Authors	Facilitators	Barriers
Wang T, Biederman S [38]	Reduce error	Cost
	Improve quality of care	
	Deliver more effective care	
Soares N, et al [39]	Improve clinician satisfaction	Cost
	Improve clinical efficiency	Technical assistance
	Improve parent satisfaction	Organizational barriers
		No consensus among peer organizations
Hacker K, et al [40]		Disruption of care
		Lack of interoperability
		Disruption of workflow
		Increased patient-cycle time
		Breakdown in communication
		Fragmentation of information
		Inflexible processes
		Physician overload

Facilitators

As depicted in Table 1, various articles used similar, but not exact terms. While compiling the results into Table 2, several factors were similar enough to be combined. *User perception/perceived usefulness* [5,9,27,31], was combined with *user attitude toward information* [7,22,23,36]. Table 2 is organized to rank order each factor that serves as a facilitator for EHR adoption. The center column identifies the article in which the factor was observed–the numbers correspond to the number assigned in order of mention (Introduction), followed by the order analyzed (Table 1), and the numbers match those assigned to these articles in the references. The last column numbers the occurrences. There were a total of 25 facilitators, and they were found a total of 109 times in the literature.

From the facilitators listed, *efficiency, organization size, and improved quality* were listed 12%, 9%, and 9% of the total occurrences of all facilitators mentioned in the literature, respectively. *Access to patient care, user perception/perceived usefulness, ability to transfer information* and *incentives* were identified in the literature 7%, 6%, 6%, and 5%, respectively. *Error reduction, time savings*, and *competitiveness* were all listed 4% of all occurrences. The rest of the barriers were mentioned three or less times, so we grouped them into a category of miscellaneous.

Barriers

As depicted in Table 1, various articles used similar, but not the exact terms. While compiling the results into Table 3, several barriers were similar enough to be combined. This occurred more often in the barrier table than the facilitator table. *Interoperability* was combined with *no standard protocol for data exchange* [12,22,26,40]. *Training* was combined with *maintenance and upgrades* [8,12,21,24]. The barrier of *Staff shortages* was combined with *overworked* [2,27,40]. *Privacy* was combined with *security* [10,36,37]. *Lack of infrastructure* was combined with *lack of space* [18,20]. Finally, *missing data* was combined with *omission of result, interpretation*, and *omission of result reference range* [14,16,21]. There were a total of 23 barriers, and they were found a total of 95 times in the literature.

Table 2. Facilitators identified in the literature.

Facilitators	Occurrences by article reference number	Total occurrences
Efficiency	2,7,8,15,16,17,19,20,23,25,29,31,33	13
Hospital size[a]	7,12,16,24,25,26,28,29,31,32	11
Improved quality	15,18,21,22,23,26,30,31,32,33	10
Access to patient data	8,10,15,19,20,22,28,29	8
User perception/perceived usefulness	5,7,9,21,22,26,30	7
Ability to transfer information	8,9,19,28,29,30	6
Communication	7,8,15,22,30	5
Executive management support	1,5,9,10,13	6
Incentives	2,16,21,23	5
Error reduction	8,19,31,32	4
Time savings	5,8,15,20	4
Competiveness[a]	7,10,13,27	4
Security	8,21,22	3
Improved population health	2,15,22	3
Continuity of care document	2,15,40	3
Urban/more developed locations/status[a]	2,7,26	3
Knowledge/IT management	11,13,15	3
Staff retention	8,16	2
Long run cost savings	8,31	2
Alignment with strategy	1,13	2
Project planning	8	1
Patient empowerment	1	1
Patient engagement	14	1
Effectiveness	32	1
Genome associated care	31	1

[a]Statistical association identified through retrospective studies, rather than answers to “why” in a survey or interview.

Table 3. Barriers identified in the literature.

Barriers	Occurrences by article reference number	Total occurrences
Cost	5,8,12,13,16,17,19,25,28,30,32, 33,34,37,38	16
Time consuming	5,19,20,32,34,39	6
User perception/perceived lack of usefulness	5,8,13,17,19,34	6
Transition of data	13,19,20,22,28,34	6
Facility location (rural areas)/characteristics[a]	2,7,14,21,28	6
Implementation issues	8,13,19,20,25	5
User/patient resistance	7,9,13,19,20	5
Lack of tech assistance/experience	13,16,29,33,38	5
Interoperability/no standard protocols for data exchange	12,21,25,39	4
Medical error	15,20,23,40	4
Training, maintenance, upgrades	8,12,20,23	4
Lack of agility to make changes	20,32,39	3
Staff shortages/overworked	2,26,39	3
Privacy and/or security	13,35,36	3
Missing data	15,20,40	3
External factors[a]	8,26,38	3
Competiveness	12,10,27	3
Provider or patient age[a]	7,29	2
Race & income disparities[a]	2,15	2
Lack of infrastructure and/or space for systems	17,19	2
Need organizational cultural change	8,38	2
Lack of incentives	12	1
IMGs less likely to adapt	26	1

[a]Statistical association identified through retrospective studies, rather than answers to "why" in a survey or interview.

The barrier most often identified in the literature was cost (17%, 16/95). This factor included the following: *initial cost*, *implementation cost*, *maintenance cost*, and *training cost*. The barriers of *too time consuming*, *user perception/perceived lack of usefulness*, *transition of data*, and *facility location* were each identified 6% of the time (6/95). *Implementation issues*, *user/patient resistance* and *lack of technical assistance or experience*, were listed 5% of all occurrences (5/95). *Lack of interoperability*, *medical error*, *training*, *maintenance*, *and upgrades* were all listed 4% of all occurrences (4/95). The rest of the barriers were mentioned three or less times, so we grouped them into a category of miscellaneous.

As depicted in Tables 2 and 3, two facilitating factors and four barriers to EHR adoption are followed by a superscript letter. These factors appeared in the literature, but they were identified through statistical associations by researchers conducting retrospective studies. We included these factors in the review because the retrospective studies add value overall, but they are set apart because they are factors that really cannot be easily changed; therefore, they do not offer administrators and policy makers much actionable information.

From the 31 articles included in the review, 3 (10%) were reviews, and 9 (29%) were mixed methods. The remaining articles were a combination of retrospective, observational, cross-sectional, or descriptive. Of the articles reviewed, 17 (55%) analyzed secondary data, 12 (39%) collected primary data, and 4 (13%) used a mixture of sources. Thirteen (42%) of the articles in the review collected primary data through a survey, interview, or combination of both.

Discussion

Principal Findings

We found it interesting how often perception plays into interviews and surveys, and in the case of this review, resulted in one or more factors appearing as both an enabler and a barrier, based on the perception of the interviewee. Error is one example of that phenomenon. It is listed as a facilitator (mentioned 4% of the time), *using the EHR to prevent error* [8,20,32,33] and as a barrier (mentioned 4% of the time), *use of the EHR can cause error* [14,16,21,24]. User perceptions were also listed on both sides for monetary factors: the cost-related facilitator was

incentives (mentioned 5% of the time), and the cost-related barrier was *cost* (mentioned 17% of the time). One more dichotomy was time-related factors: the facilitator factor, *efficiency* (mentioned 12% of the time), and the barrier, *time consuming* (mentioned 6% of the time). Some interviewees listed *ability to transfer information* (6%) as a facilitator, while others listed *interoperability/no standard protocols for data exchange* (4%) as a barrier.

Results from this review are in line with others performed along the same lines. Cost is repeatedly a primary barrier to the adoption of the EHR [5,8,12,13,17,18,20,26,28,31,33,34,35,38,39]. Several factors were reinforced by this review that highlight organizational characteristics such as size and location [7,8]. Location is a difficult barrier to overcome. It is not a mystery to anyone that rural communities often struggle to overcome barriers such as cost, bandwidth, and user/patient acceptance, a point supported by the literature [2,7,15,22,29]. Unfortunately, very few solutions are offered to this group; at a minimum policy should look to assist those who lag behind the rest of the adopters [29]. Small, rural communities are the slowest to adopt, and their size is a major disadvantage in terms of budget and technical agility. Policy should look to a range of factors to lever, such as organizational, cultural, technological, and financial considerations [9].

Many factors play a role in establishing an environment conducive to the adoption of the EHR. This review was not intended to establish causality, but instead, it was designed to identify the frequency with which facilitators and barriers are discussed in the literature. It is hoped that by this review, data-driven studies can be developed to strengthen the validity of the factors listed.

Limitations

This paper provides a review of the factors associated with adoption of EHR systems. Interrater reliability was calculated for both the search terms and titles selected, as well as the consensus-building activity surrounding the final selection of the 31 articles. In that regard, reliability of the results are strong.

Validity was strengthened by these results aligning with those of previous reviews. This addresses internal validity, but external validity would be limited to the United States because articles that focused on other countries were excluded from the review. Another limitation is that EHR adoption and usage were often self-reported by physicians, and social-desirability bias may have led physicians to overestimate actual usage.

Conclusion

Users and nonusers alike are concerned about similar topics such as efficiency, quality, and interoperability. This review supports the findings of other reviews. Additional research remains necessary to assess the EHR system adoption factors in health care organizations in future years. Within the constantly changing environment of health care in the United States, health care decision makers are gradually adopting the EHRs, but adoption is far from ubiquitous. Country-level advantages will likely not emerge until everyone adopts a fully interoperable EHR.

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Conflicts of Interest

None declared.

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Abbreviations

CINAHL: Cumulative Index of Nursing and Allied Health Literature
EBSCO Host: Ebson B Stephens Company
EHR: electronic health records
EMR: electronic medical records
GDP: gross domestic product
HITECH: The Health Information Technology for Economic and Clinical Health
MeSH: Medical subject headings from the American National Library of Medicine

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Original Paper

A Legal Framework to Support Development and Assessment of Digital Health Services

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Abstract

Background: Digital health services empower people to track, manage, and improve their own health and quality of life while delivering a more personalized and precise health care, at a lower cost and with higher efficiency and availability. Essential for the use of digital health services is that the treatment of any personal data is compatible with the Patient Data Act, Personal Data Act, and other applicable privacy laws.

Objective: The aim of this study was to develop a framework for legal challenges to support designers in development and assessment of digital health services.

Methods: A purposive sampling, together with snowball recruitment, was used to identify stakeholders and information sources for organizing, extending, and prioritizing the different concepts, actors, and regulations in relation to digital health and health-promoting digital systems. The data were collected through structured interviewing and iteration, and 3 different cases were used for face validation of the framework.

Results: A framework for assessing the legal challenges in developing digital health services (Legal Challenges in Digital Health [LCDH] Framework) was created and consists of 6 key questions to be used to evaluate a digital health service according to current legislation.

Conclusions: Structured discussion about legal challenges in relation to health-promoting digital services can be enabled by a constructive framework to investigate, assess, and verify the digital service according to current legislation. The LCDH Framework developed in this study proposes such a framework and can be used in prospective evaluation of the relationship of a potential health-promoting digital service with the existing laws and regulations

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KEYWORDS

digital health; legal aspects; technological innovations

Introduction

Through the use of wireless devices, sensor technologies, the Internet, social networks, health information technology (IT), and personal health data, digital health services empower people to track, manage, and improve their own health and quality of life. At the same time, these services provide a more personalized and precise health care delivery, at a lower cost and with higher efficiency and availability [1]. An emerging area at the intersection of informatics, health care, and business is electronic health (eHealth) [2], which encompasses the mediation and interaction between health care and the individual via information and communication technology (ICT) [3]. Although the extent of implementation and application of eHealth systems vary, the overall goal is the same: using ICT to provide better care more efficiently at a lower cost [4]. Mobile health (mHealth), as a component of eHealth, involves the use and capitalization on mobile devices [5] and encompasses any use of mobile technology to address health care challenges such

as access, quality, affordability, matching of resources, and behavioral norms [6]. The use of mHealth offers great opportunities by allowing asynchronous and remote care [7] to an extensive number of potential users [5]. Applications for mHealth serve a variety of functions: providing easy access to medical information about the symptoms and treatment of various diseases or allowing patients to track clinical measurements that can be sent to the care provider [6]. These applications could change the nature of health care [8] by using technology to increase patient engagement, improve care quality, transform care processes [6], reduce health care costs, and minimize human error [9].

Essential for the use of all digital health services is that the treatment of any personal data is compatible with the Patient Data Act, Personal Data Act, and other applicable privacy laws. The European Commission has declared its intention to drive greater legal certainty in the digital health domain, and through the Directive 2011/24/European Union (EU), for the first time, it has placed eHealth in a legal context, requiring member states to cooperate with interoperability standards to allow full use of eHealth services across EU borders [10]. Although some significant steps have been taken toward attaining this goal, the questions of liability for eHealth goods and services are still not fully addressed on EU level legislation. The lack of a fully worked out EU level framework illustrates the difficulties in pinpointing key concepts in relation to this rapidly evolving market. In response to this, the eHealth Authority was formed in Sweden in 2014 with responsibility for registries and the heterogeneity and variety of IT functions developed within Swedish health care.

While the authorities investigate and consider the technological capabilities of eHealth services in the intersection of health care quality, patient safety, ethics and legal matters, new IT services, and mobile applications are advancing dramatically. The focus for the regulatory authorities should be to streamline the regulatory processes and promote innovation [11], but because regulation and legislation are still behind, governmental authorities are forced to handle many issues in this domain case by case [10]. This implicates that designers of digital health services need to acquire knowledge about relevant regulation and legislation and how to relate to and act on such regulation [12]. A legal framework that could guide designers through these legal challenges, together with an understanding of the definitions of the concepts [13], would both simplify and speed up development of digital health solutions [14] and promote involvement of designers with experience from digital service design [15] in the development of new digital health services. The aim of this study was to develop such a framework to support designers in development and assessment of digital health services.

Methods

The study design was based on a stakeholder analysis approach for generating knowledge about actors to understand their intentions, interrelations, and interests and for assessing their influence on legal challenges in development of digital health services [16]. Data obtained from interviews with relevant authorities and organizations together with information about concepts and regulations in relation to digital health services were analyzed and structured to create a framework for legal challenges.

Case and Framing

A framing of the questions about legal challenges and key concepts relevant to development of digital health services was discussed in the project group and with a consulting firm (Carmona AB) with expertise in the field of Web-based services and information solutions for handling of patient data and quality control. The consulting firm is in the forefront of developing such services in accordance with current legislation and in development of new practices and legislation. In this communication, we used data from our development of a digital service for play and interaction between children, aged 8-12 years, who have survived from childhood cancer treatment to frame legal challenges and key concepts [17]. The case was described by a concept description [18] and use experience descriptions through Persona characters and use scenarios [19].

On the basis of this, a basic understanding of the domain was formed, and a major law firm, with experience of legal issues in health care and a jurisconsult responsible for privacy and patient safety issues at the county council, was consulted with the intention to extend knowledge and our preunderstanding of the legal challenges and key concepts in this domain. A first draft was conceived, of a legal framework with relevant concepts, laws, and agencies or organizations involved in the care of the target group, or with regulatory or supervisory responsibility.

Information Sources

A purposive sampling [20] was used to identify stakeholders and information sources for organizing, extending, and prioritizing the different components of the framework guided by the case. The first contacted stakeholders referred to other stakeholders, that is, a snowball recruitment [21]. The information sources identified and used are listed in Table 1.

Table 1. Identified actors, organizations, and authorities, and their area of expertise, to be considered in the following investigation.

Actor	Area of expertise
The project group	Researchers focused on development of digital health services for children using a participatory design where researchers collaborate with children from the target group.
A local consulting firm	Specialized in development of Web-based services and information solutions
Data Inspection Authority	Works to secure the individual's right to integrity in society
Inspection Authority for Health Care	Supervises the activities in the social area and health care, as well as of health care professionals; the Authority is also responsible for certain permits.
The National Board	Works for all citizens' equal access to good health and health care
Ministry of Social Affairs	The different disciplines within the overall responsibility: health care, health, social issues, social security features news about the government's policy initiatives or decisions; they also contain current objectives and the government's priorities in the field.
County Council	Responsible for many aspects of development in the county; the County Council has the mission to promote development and growth and to provide good health care.
eHealth Authority	Works with the development of national eHealth to contribute to better health care and health; the business is focused on creating participation for residents and providing support to practitioners and policy makers.
European Commission	Represents interests of the EU[a]; the commission proposes new legislation to Parliament and the Council of Ministers and ensures that EU countries apply EU law correctly.
Medical Products Agency	Government agency under the Ministry of Social Affairs; it has the mandate to promote the Swedish public and animal health.

[a]EU: European Union.

Data Collection

Identified websites of organizations, authorities and different operators or actors, and functions were screened for information about concepts and regulations in relation to digital health services. Stakeholders were interviewed about their relationship to eHealth and digital health services (Table 1). Interviewees were representatives from the County Council Board on Coordination of Information Safety, The National Board, The Data Inspection Authority, eHealth Authority, and Inspection Authority for Health Care. Interviews were performed, with 1 person from each of the aforementioned organizations, over phone (approximately 30 minutes) and repeated if new questions appeared. The topics in the semistructured interview guide were as follows: (1) Relationship to digital health services; (2) the authority's function, assignment, and work for digital health services; (3) regulations that govern the work; and finally (4) other relevant information sources we should approach. In cases where we wanted to get the data confirmed in writing, follow-up questions were sent by email to the respective informant.

Data Analysis

The meaning out of the data was made in a systematical way to discover the relevant concepts and relationships among the input [22]. All data inputs, such as questions, concept descriptions, laws and regulations, and functions, were put on post-it notes by the main author and structured on different levels and in relation to each other, and an affinity diagram was formed and discussed between all authors. The insights gained were used as a starting point for a framework for assessing the legal challenges in developing health-promoting digital services. The framework was iteratively verified against the project group and stakeholders (the Data Inspection Authority and eHealth Authority) and finally validated against three cases of digital health services.

Results

Identification of Concepts and Regulations

The identified concepts to consider in this domain are: medical device, eHealth, medical responsibility, care damage, personal data, and consent. The concepts, their definitions, and relevant regulations identified during data collection and the subsequent analysis are listed in Table 2. Concepts and regulations that were identified during data collection but were not found to be relevant for framing of legal challenges from the perspective of development of digital health services are not included in this compilation, such as: health care quality registries, the law on drug lists, and the regulations of The National Board of Health and Welfare.

Table 2. The Legal Challenges in Digital Health (LCDH) Framework for exploring a prospective health promoting digital service's relationship to valid regulations.

#	Concept	Definition	Question	The following is valid for "yes"	The following is valid for "no"	Regulation
1	Medical device	A product is a medical device if it has a medical purpose as to: - Prove, prevent, monitor, treat, or mitigate a disease. - Prove, monitor, treat, mitigate, or compensate an injury or disability. - Examine, change, or replace anatomy or a physiological process. - Control fertilization.	Is the product a medical device?	The manufacturer must handle security aspects. Medical Products Agency is responsible for supervision of products and manufacturers. Inspection Authority for Health Care audits healthcare usage. *Proceed to No. 2.*	The manufacturer cannot claim anything, which is covered by the definition of a medical device, for example, that the product may mitigate a disease. *Proceed to No. 2.*	The law of medical devices (SFS[a]1993:584). Council Directive 93/42/EEC[b]concerning medical devices.
2	eHealth	An eHealth service has a purpose to: - Mediate health service or information and interaction between health care and an individual. - Mediate information exchange between patients and health care professionals, hospitals, and other professionals within health care and networks for health information and telemedicine. - Use ICT[c]to improve the preventive work, diagnoses, health care, monitoring, or administration.	Is the product an eHealth service?	*Proceed to No. 4.*	*Proceed to No. 3.*	The Health Care Act (SFS 1982:763).
3	Medical responsibility	Usually referred to health professionals' medical professional liability in the care and treatment of a patient and the medical responsibility in a comprehensive organizational plan.	Is the service recommended/supplied by the health care? The health care recommends a service if they encourage or call for usage. It is not enough to only inform that the service is available.	The health care vouches for the safety and security of the technology and that the risk of care damage is low. The service is examined and evaluated by a number of criteria. *Proceed to No. 4.*	The health care has no responsibility. *Proceed to No. 5.*	The Health Care Act (SFS 1982:763).
4	Care damage	A damage that could have been avoided if adequate arrangements were taken in contact with health care. If medical device or eHealth service: The risk of care damage is determined by the level of care, the vulnerability of the target group, and how the usage is being monitored or followed up by the health care.	Is there any risk of care damage?	If the service provides monitoring/data logs that register threshold values or personal controls to prevent care damage, the responsibility of the health care is restricted. If no monitoring, the health care is responsible for preventing formation of care damage. *Proceed to No. 5.*	The healthcare has no responsibility. *Proceed to No. 5.*	Patient Safety Act (SFS 2010:659).

#	Concept	Definition	Question	The following is valid for "yes"	The following is valid for "no"	Regulation
5	Personal data	Definition personal data: All information that can directly or indirectly be assigned to a physical person who is alive. Definition handling of personal data: Every action or series of actions taken regarding personal data (automatically or not). For example, collection, registration, usage, storage, organization, processing, and distribution.	Are personal data handled?	*Proceed to No. 6.*	To completely stay out of Privacy Act, the outcome measures of the patients must be anonymized. The health care has no responsibility.	Privacy Act (SFS 1998:204). Patient Data Act (SFS 2008:355).
6	Consent	Consent is defined as any freely given specific and unambiguous expression by which the registered person, after receiving information, accepts handling of personal data relating to him or her.	Does the service lack user agreement? An agreement in which the purpose with the service, privacy, terms of use, responsibilities, and similar are regulated.	The responsibility of the health care should be investigated/examined.	A responsibility agreement signed by adult or parent/advocate may disclaim the health care from responsibility.	Privacy Act (SFS 1998:204).

[a]SFS: Swedish Code of Statutes

[b]EEC: European Economic Community

[c]ICT: information and communications technology

Structure of Concepts and Regulations Into a Framework

On the basis of the identified concepts, regulations, and stakeholders, we designed a framework for assessing the legal challenges in developing digital health services (Legal Challenges in Digital Health [LCDH] Framework) consisting of 6 key questions to be used in prospective evaluation of the relationship of a digital health service to existing laws and regulations (Table 2). The questions are sequentially arranged so that affirmative responses gradually delineate which parts of the law apply to a certain digital health service. Negative responses to the same questions show which laws and regulations that each service is exempt from.

Validation of the Framework

The accuracy and quality of the LCDH Framework were assessed by the Swedish Data Inspection Authority and eHealth Authority and, finally, by the consulting firm, the law firm, and the jurisconsult involved in the framing of the data collection. The reviewed and iteratively revised framework was confirmed to be in accordance with current regulation, law and practice, and experience of these stakeholders. Because the stakeholders, during data collection, did not identify additional stakeholders or sources of information than those already included in our dataset (which means that saturation was achieved), the quality assessment of our framework indicated that it was valid and in line with current law and practice.

To assess the usability, and hence the face validity, for using the framework for development and assessment of products and services, we applied the framework for evaluation of the legal challenges in 3 cases entailing development of digital health services. The questions in the framework (Table 2) were used to systematically evaluate and frame the legal challenges for the development and implementation of the digital services, *Give Me a Break*, *Sisom* and *DELTA* (Multimedia Appendix 1).

Is the Product a Medical Device?

A medical device is a product with a medical purpose; as to prove, prevent, monitor, treat or mitigate a disease, and to prove, monitor, treat, mitigate, or compensate an injury or disabilities (Table 2). The 3 digital services *Give Me a Break*, *Sisom*, and *DELTA*, were developed to facilitate child peer support, communication between children and their care providers, and adolescent's participation in schools related to their health, respectively. None of the services has medical functions such as handling, treating, or preventing disease or illness and should therefore, according to the definitions outlined in Table 2 , not be considered as medical devices.

Is the Product an eHealth Service?

An eHealth service mediates health information or service or interaction between health care and the individual (Table 2). The system owner and system administrator of each of the 3 services, as well as the support and maintenance from the operation manager who is responsible for all data, will be independent from health care providers and schools. In one case though, *Sisom*, the services by the health care providers will be mediated through the digital service and information about the users' personal data will be shared with the health care providers. This service should therefore be considered as an eHealth

service. The other 2 services, *Give Me a Break* and *DELTA*, do not mediate any communication of personal data or sensitive interaction at all between health care providers and users and should therefore not be considered as tools or services that use ICT to improve the preventive work, diagnoses, health-care monitoring, or administration and hence therefore not be defined as eHealth services.

Is the Service Recommended/Supplied by the Health Care?

Two of the services, *Sisom* and *DELTA*, are recommended and supplied by the health care services who therefore have medical responsibility for the usage of the services and any potential consequences of usage. This responsibility is independent of whether the services are to be considered as eHealth services. The other service, *Give Me a Break*, is neither part of regular treatment nor used to improve health care according to the definition of an eHealth service. It is neither recommended nor supplied by the health care, and there is therefore no medical responsibility for the activities or the consequences of the interaction on the service that can be imposed on the health care providers.

Is There Any Risk of Care Damage?

According to the definition in Table 2 , care damage is a damage that could have been avoided if adequate measures were taken by health care. The 2 services recommended and supplied by the health care, *Sisom* and *DELTA*, are not associated with medical treatment but involve sharing of potentially sensitive personal information. Although the risk of care damage is limited to sharing of personal information, this entails privacy risks for which the health care is responsible. To prevent this, there is no follow-up or surveillance system in the services that automatically transfers personal information or use data to the health care. To protect the users, the services has well-ordered procedures for registration and login. All information transfers are performed by web encryption technology, and professionally trained personnel monitor all real-time activities and use logs. Moreover, in *DELTA*, abuse or misconduct can be reported by the users to be handled by the involved school personnel. Both systems thus have significant infrastructure for monitoring safety and security of the users without interfering with their integrity. For the other service, *Give Me a Break*, the health care will not have any medical responsibility, as it neither has a medical purpose nor is seen as health care or treatment. Consequently, although problems can arise, there can be no care damage per se.

Are Personal Data/Personal Information Handled?

Personal data are handled in all the 3 services and in some cases, such information is of sensitive nature as it relates to health and is coupled to the users identity through a personal code number, name, or photo. In *Sisom*, health care handles sensitive personal data coupled to health and the users' identity. In *Give Me a break* and *DELTA*, the personal data are however not of sensitive nature (not coupled to sensitive information about the users) but deal with their identities and therefore still must be handled with care. In all the 3 services, the users provide all data added into and shared in the system, and the users are the sole owners of the information that they share. In *Give Me a Break*, the personal and shared user profile is stored but can be deleted by the users themselves if they decide to no longer make it available to others on the service. The provider of each of the 3 services has complete responsibility for all personal data stored or shared. This includes responsibility to: inform about the purpose and use of the service; not publish or share sensitive personal data, if applicable, regularly monitor posts to discover offensive personal data; and promptly remove any offensive personal data.

Does the Service Lack User Agreement?

At registration and the first logon to all the 3 services, the users and their parents must approve an agreement in which the purpose of the service is outlined. The user agreement regulates privacy issues, terms of use, and responsibilities. Specifically, they state to what extent and how the services are a part of the user's health care. For *Give Me a Break*, the user agreement also states that all use takes place on the users' own initiative and under own responsibility.

Discussion

The aim of this study was to develop a framework for legal challenges to support designers in development and assessment of digital health services. The LCDH Framework presented herein was created based on concepts and regulations identified through interviews with authority representatives, and a process of stakeholder review and iterative revision of the developed framework confirmed that it was in accordance with current regulation, legislation, and practice. Usability evaluation against real cases of digital health services revealed how the definitions in the framework feasibly guided identification of distinctive and appropriate regulation to be considered and legal challenges to relate to given the nature of each of the evaluated services.

The work of government regulation and legislation of digital health services have not so far kept pace with the digital development. Digital health services in various forms are under rapid development and are involving several stakeholders and actors. Game and app developers, for instance, with innovative ideas for digital health may experience obstacles in implementation of digital health services in the interface between health care and individuals [23]. One problem can in many cases be the indistinct legislation.

This slow and perhaps circumspect legislation under construction may cause difficulties to developers of digital health services to acquire knowledge about relevant regulation and how to relate to and act on the regulation. Implications of this can be: (1) inaccuracies due to misinterpretations and (2) omitted development of digital health services owing to complexity in understanding the regulations. It would be desirable in the future that this type of regulation and legislation would be prepared in cooperation between the authorities, the developers, and the health care experts [12]. However, until then, there is a need for a dynamic tool, a framework, guiding designers and developers through the legal challenges in development work in the digital health domain, together with an understanding of the definitions of the concepts [13]. This

is important both to simplify and speed up development of digital health solutions [14] and to promote involvement of developers experienced in digital service design [15]. There is a need for approaching and proceeding with legal challenges adjacent health care in the design development to facilitate the forthcoming implementation.

The LCDH Framework presented in this article has the qualifications to be a useful tool in guiding designers and developers through the legal challenges in development work in the digital health domain. The framework: (1) considers the current regulation and legislation that apply in the EU; (2) presents the definitions of relevant legal concepts; (3) is verified by the Swedish Data Inspection Authority and eHealth Authority; and finally, (4) is easy to use. The framework merely aims to guide development by identifying legal dividing lines between different digital health services in their product design. It has no legal power to determine guidelines, and a jurisconsult may need to confirm the legal application in case of uncertainties. Although the concepts used in the framework are based on legislation in the EU, it can be used in other contexts to understand the legal challenges and the hierarchy of the various concepts governing legislation within the digital health domain.

Strengths and Limitations

As with all methods and studies used in research, certain limitations apply. The interviews were performed with 1 person from each organization or authority over the phone. Performing the interviews over phone was convenient and time-saving, and if the informants had text material to share, it was sent by email. Important information sources and stakeholders can be identified by using snowball recruitment [21]; however, there is a risk that important informants are missed by this approach. In our study, it is likely that we through this approach identified relevant informants as both the Swedish Data Inspection Authority and the eHealth Authority verified our report. The mapping was performed during the spring and summer of 2014 in accordance with the regulations prevailing in Sweden. The definition of eHealth is however taken from the European Commission's declaration of eHealth [3].

Conclusions

Consideration toward ethical aspects is a requirement for both performing and publishing research in relation to health and human subjects. However, as long as such ethical aspects are taken into account, no requirements are placed on that, and research should also be aligned with legal challenges that are relevant to the context of the research.

Structured discussion about legal challenges in relation to health-promoting digital services can be enabled by a constructive framework to investigate, assess, and verify the digital service according to current legislation. The LCDH Framework developed in this study proposes such a framework and can be used in prospective evaluation of the relationship of a potential health-promoting digital service to the existing laws and regulations. However, legislation regarding eHealth in general and health-promoting digital services in particular is under construction, and authorities' judgments are made from case to case. Further research is critical to expanding the knowledge base of cases, or products, using health-promoting digital service implemented and where current legislation is applied.

Acknowledgments

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Usability validation of The Legal Challenges in Digital Health (LCDH) Framework for exploring the relationship to valid regulations of 3 health-promoting digital services.

[PDF File (Adobe PDF File), 30KB - medinform_v4i2e17_app1.pdf]

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Abbreviations

eHealth: Electronic health
EU: European Union
ICT: information and communications technology
LCDH Framework: Legal Challenges in Digital Health Framework
mHealth: mobile health

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Original Paper

Facilitating Secure Sharing of Personal Health Data in the Cloud

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Abstract

Background: Internet-based applications are providing new ways of promoting health and reducing the cost of care. Although data can be kept encrypted in servers, the user does not have the ability to decide whom the data are shared with. Technically this is linked to the problem of who owns the data encryption keys required to decrypt the data. Currently, cloud service providers, rather than users, have full rights to the key. In practical terms this makes the users lose full control over their data. Trust and uptake of these applications can be increased by allowing patients to feel in control of their data, generally stored in cloud-based services.

Objective: This paper addresses this security challenge by providing the user a way of controlling encryption keys independently of the cloud service provider. We provide a secure and usable system that enables a patient to share health information with doctors and specialists.

Methods: We contribute a secure protocol for patients to share their data with doctors and others on the cloud while keeping complete ownership. We developed a simple, stereotypical health application and carried out security tests, performance tests, and usability tests with both students and doctors (N=15).

Results: We developed the health application as an app for Android mobile phones. We carried out the usability tests on potential participants and medical professionals. Of 20 participants, 14 (70%) either agreed or strongly agreed that they felt safer using our system. Using mixed methods, we show that participants agreed that privacy and security of health data are important and that our system addresses these issues.

Conclusions: We presented a security protocol that enables patients to securely share their eHealth data with doctors and nurses and developed a secure and usable system that enables patients to share mental health information with doctors.

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KEYWORDS

self care; telemedicine; privacy; computer security; information dissemination

Introduction

A new type of sociotechnical challenge has arisen with the advent of eHealth and big data technologies. For example, ubiquitous and wearable health systems collect data through sensors and mobile apps and store the data in the servers of multiple commercial service providers. Furthermore, a growing number of people share this sensitive medical information through social networks such as Facebook and Twitter. This is

significantly different from the traditional health service, where service providers kept tight control over patient data.

It has been argued that these new technologies can lead to positive health outcomes, as they are evidence of people self-managing their illness [1]. Some of the ways in which self-management can have a positive effect include supporting the patient's motivation to look after their health, greater levels of engagement, and understanding about the condition.

Furthermore, these new technologies may help improve population health by helping researchers learn about the drivers of different pathologies, or how people's behavior is affected by social influence and public health promotion campaigns [2]. The information posted to social networks can prove invaluable in assisting doctors and counselors to better understand patient behaviors and symptoms and can help to provide support and/or consultation. Social networks are now being leveraged to provide people with a better lifestyle and health, without the need to continually visit the doctor's clinic.

However, privacy [3], trust, and security issues associated with health data make patients hesitant to post sensitive health information and share it with health providers [4]. Data are not ephemeral and will be stored in servers and shared. All stakeholders need to worry about the lifecycle of the data; not just who can access and manage the data at a particular point in time, but also who will be able to do so in the future. There is a strong need to provide patients with a guarantee that their sensitive health information will only be visible to the doctors, counselors, or others they wish to share it with at a particular point in time.

A trivial solution to sharing data in the cloud involves the data owners first encrypting their data before storing to cloud servers. The data owner can then distribute encryption keys to every user in the group thereby keeping the data protected from the cloud provider and also malicious users. Authorized users in the group can then download the encrypted data from the cloud and decrypt the data using the encryption key provided. However, the main problem with this solution is user revocation. When the data owner wishes to revoke one of the users in the group, he must re-encrypt the data with a new encryption key and redistribute the new key to all the remaining users in the group. This renders the revoked user's key useless and he or she will thus not be able to access the data contents. This process of re-encrypting the data and redistributing keys to all the remaining users in the group every time a user is revoked access can place a huge burden on the data owner. This is especially the case when the group size is very large, in excess of thousands to hundreds of thousands (eg, everyone in an organization or online community).

There is a growing body of research on the trust, privacy, and security in information systems, most of which apply to health.

Trust and Privacy

These issues often arise from insider attacks. For example, malicious insiders to a cloud service provider (eg, employees) can steal data, because they have direct access to it. Insiders who are not happy with their job and who have recently been terminated may take revenge and destroy, corrupt, or sell all data owner's data [5]. Organizationally, cloud service providers may misuse data in order to sell to third parties [6,7]. Such privacy attacks affect the trust of users and make them skeptical of using cloud services for sensitive data storage. It has been argued that this is one of the main reasons why patients have a lack of trust for using the cloud for storage and sharing of highly critical medical information [8,9].

There have been multiple studies around privacy and trust in health systems in research [10-15]. One of the most effective ways of keeping data private in the cloud, and thus increasing the trust of the data owners, is keeping data encrypted when stored on untrusted servers, backup servers, and when in transit on untrusted public channels.

The THEWS (Trusted eHealth and eWelfare Space) architecture [16] provided privacy management to help data owners create and manage the network as well as maintain information privacy. As Ruotsalainen et al [16] pointed out, there is an asymmetric relationship between health information systems and their users because users rarely have the power "to force a system to put personal rules into effect." Our paper contributes a novel security architecture that can help balance this power difference.

Even when data are encrypted, it may still be possible for a malicious cloud provider to deduce information from the encrypted data. Zhang et al [17] propose a novel solution that adds noise obfuscation based on a time-series pattern to client data stored in the cloud. This can help protect the privacy of the owner's data because it prevents malicious service providers from deducing information from the encrypted data.

Little of this work has focused on private data sharing between patients and doctors using social networks. We present a new security model that would allow users to have a much more fine-grained control of their health data.

Security

One of the major issues with private sharing of health information, and hence the major focus of this paper, is encryption key management. As discussed above, the trivial solution is computationally inefficient when having to revoke users because of the burden on re-encryption and redistribution of keys.

Microsoft HealthVault [18,19] provides a next step to allowing patients to store and manage their health and fitness information, as well as share the data securely with their friends and family. The encryption is done within HealthVault and does not rely on the patient to generate and distribute keys. The patient can decide who specifically can view his health information. With our system, the patient has greater control over his health information and can choose to store his health data on any cloud service provider that he wishes. The patient himself distributes encryption keys to people he wishes to share the data with and does not rely on commercial services, which may be untrustworthy.

Proxy re-encryption and attribute-based encryption (ABE) [20] are two current techniques aimed at secure and private data sharing in the cloud [21]. Ming et al [22] use ABE for efficient

revocation for outsourced data sharing control. Liang et al [23] combine ABE with proxy re-encryption to achieve stronger security.

Silva et al [4] present a data encryption solution for mobile health apps and a performance evaluation comparing both symmetric and asymmetric encryption algorithms. Our work takes advantage of both symmetric and asymmetric cryptographic algorithms to achieve both strong security and high performance eHealth data using mobile phones.

Other Related Work

Tran et al [24] utilize the idea of a proxy re-encryption scheme where the data owner's private key is divided into two parts, where one is stored in the data owner's machine and the other on the proxy. We also use this concept in our work and apply it to data sharing with many users instead of just one user.

Huda et al [25] propose a privacy-aware patient-controlled personal health record system that provides the patient the ability to control who can access which part of the patient's health record as well as view health history. A shared key is used to control data access. In our work, we send key partitions to doctors as this allows for more efficient consumer revocation. We also use mobile apps because of their increased popularity.

In our previous work [26], we focused on secure sharing of electrocardiographic (ECG) data using a sensor, mobile phone, and the cloud. The sensor connects to the mobile phone via Bluetooth and streams encrypted ECG data to the cloud. Like Tran et al [24], we use a form of proxy re-encryption where keys are partitioned and shared with other doctors. Revoking a user would simply involve removing the corresponding doctor's key partition in the cloud.

Furthermore, we applied our key partitioning encryption solution in two studies [27,28]. In one [27], we developed a software object that will carry out background monitoring to hold data consumers accountable if they breach the policy set out by the data owner. In the other [28], we applied our solution to a big data analysis in the health domain.

Our work leverages existing encryption algorithms to help build a more secure protocol that allows health data to be shared between a patient and many doctors, where the patient is in full control over who can access his health data and who cannot.

Our contribution is a new way of protecting data, without revealing the full encryption key to both the user and the cloud provider. The encryption key is a string of digital information that defines what a cryptographic algorithm produces, that is, how data are encrypted/decrypted. This is in addition to users' passwords. The encryption key is used to generate a ciphertext of the original data and hence make the data illegible to ordinary users. The encryption key is used to decrypt or convert the ciphertext back to the original plaintext data.

We propose a system that is designed to be highly scalable, providing the ability to share data with many users, such as doctors and nurses, while allowing the simple revocation of a user without the need to re-encrypt the data every time a user revocation occurs. We focus on creating a secure and usable system that will enable patients to share mental health information with doctors and mental health specialists, from the comfort of their own home.

In this project, we evaluate the security model through a prototypical mobile phone app. We chose to recruit students and medical professionals to evaluate the security of our system because they were the most likely potential users of the system. Using a mobile phone app, patients can report and receive help, wherever they are. In the field of mental health, for example, studies have also shown that the use of mobile phone apps can support significant reductions in depression, stress, and substance use [29].

Methods

Our system is built upon a requirements-driven design methodology [30].

Figure 1 highlights the methodology we used to carry out our work. We first define the requirements of our work. That is, to develop a system that allows patients to share their personal health information securely and privately, while ensuring the system is usable. We use a fictitious scenario to assist in defining the requirements of the system. We then review state-of-the-art literature to explore the existing works or technologies that attempt to address this. We then build on these works and develop new technology. Finally, we test our developed system through performance and scalability tests and evaluate the system in terms of usability.

The secure encryption protocol has been developed over several projects at the Commonwealth Scientific and Industrial Research Organisation [21,26,28]. We also use the key partitioning technique in this work through the existing ElGamal encryption algorithm [15] because it is most suitable for efficient user revocation. In this paper, we leverage the key partitioning technique and mobile phones to provide patients with a new way of sharing their personal health information with doctors anywhere anytime while having the ability to control which doctor is able to access that information.

For the evaluation discussed in this study, we created a fictitious, but quite common, scenario: collecting data and providing support.

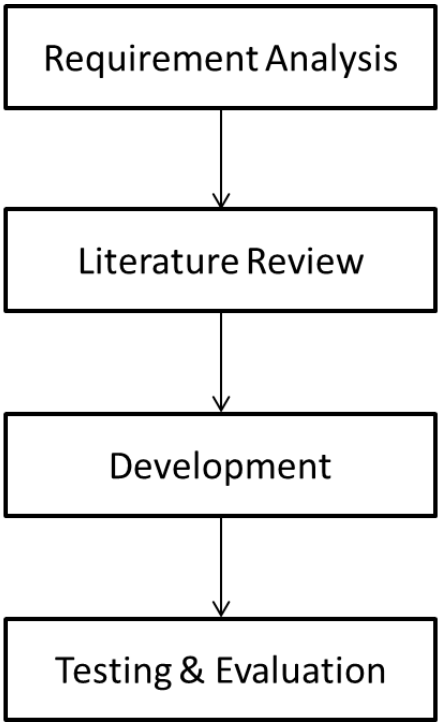
The best way of designing and then evaluating a security feature is through a minimum viable application in a realistic scenario. This security feature would be applicable in other scenarios, but the reification into concrete terms with users, and evaluate the design on scalability and nonfunctional requirements. Our application emulates one where data are collected to provide support to people at risk of mental health issues at the workplace.

We chose this scenario because it was relevant to our research and because of its significance. There is evidence of increased work stress, sleep disorders, and depression in the workplace [31]. As a result, there is a need for the means through which an organization can provide support and feedback in a convenient and secure manner. In order to detect people at risk, information is needed. This information may come from the people themselves or their friends, reporting problems at home

or at work that are affecting their lives and their mental state. It could also come from managers, occupational health and safety reports, or other sources such as other eHealth systems. Regrettably, in many cases, people fail to seek help when they need it because of a number of reasons, including the lack of time or access to resources, stigma, and trust. For example, regularly visiting a clinic can be costly for patients and doctors. For patients, this also involves the time and effort spent visiting the clinic, particularly for rural and disabled patients. For doctors, eHealth may allow them to prioritize differently and tend to patients who cannot travel. Others have highlighted the possibility of using eHealth services to reduce health care costs [32].

We also speculated that certain aspects, characteristic of mental health issues, would make the importance of trust and privacy more relevant to users. Trust and stigma also make it harder for people to seek help or share information about their mental health. In workplace well-being programs, for example, employees might be less likely to share information if they feel that it could be used by their employers. Trust is in great measure a consequence of the software design of systems and apps used to collect and manage the data.

Figure 1. Development Method.



Preliminaries

ElGamal Cryptography

We take advantage of ElGamal encryption [15], a public-key cryptographic system with an algorithm that is both simple and efficient and can provide simple consumer revocation with a low cost and overhead. ElGamal encryption, invented by Taher ElGamal [15], is a public-key cryptography system. One of the drawbacks of ElGamal encryption is that it is very computationally inefficient and time-consuming to decrypt fairly large data. Thus, the algorithm is best suited to the encryption and decryption of small data. In this project, we mainly use ElGamal encryption to add a further layer of protection, by encrypting/decrypting another encryption key instead of the data.

There are three main steps of the ElGamal encryption algorithm:

- Initialization: Given a prime p, a primitive root c of p, compute $b=c^x \bmod p$, where x is a randomly selected secret key. The public key is thus {p, b, c} and private key is x.
- Encryption: Generate random value r and encrypt data m as follows:

$E(m) = m \times b^r \bmod p = m \times c^{rx} \bmod p$

Also note: $g=c^r \bmod p$

Decryption: This decrypts m with secret key x as follows:

$D_x(E(m)) = g^{-x} \times E(m) \bmod p = (c^r)^{-x} \times m \times c^{rx} \bmod p = c^{-rx} \times m \times c^{rx} \bmod p = m \bmod p$

Symmetric/Asymmetric Cryptography

We use both symmetric and asymmetric encryption and decryption in our work to protect the health data from being accessed by untrusted social networks. We utilize both cryptography methods because they provide stronger security and higher performance while supporting larger data sizes in eHealth.

Architecture

Figure 2 demonstrates our system. The model we used to test our application assumes a patient who monitors and tracks their health and activity data through a mobile phone app. The app may then connect to, and store the data in, a social network such as Facebook, Fitbit, or other cloud-based service provider using an application programming interface. An authorized doctor

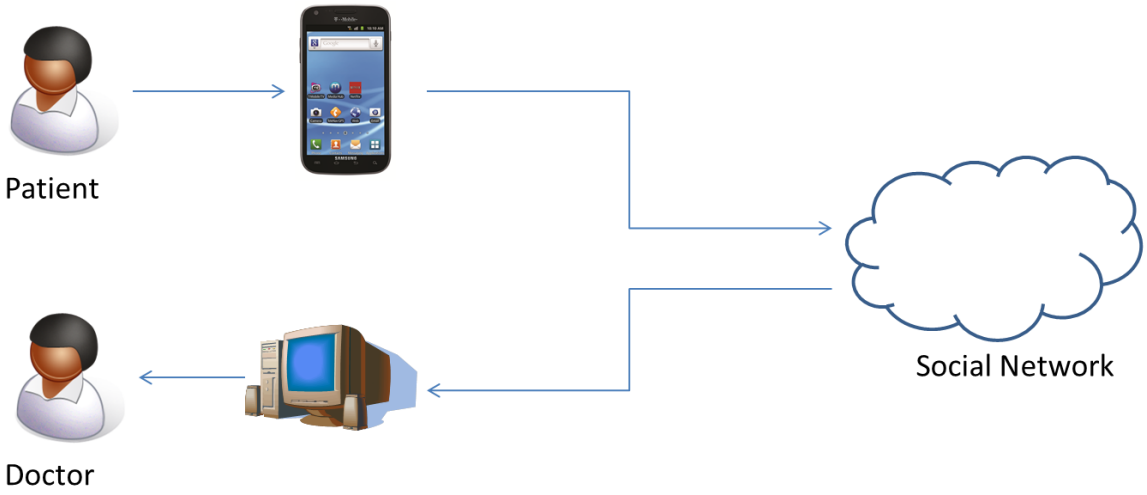
can log in to and retrieve the patient's data and use the data for analysis and diagnosis.

For the sake of our evaluation, we have simplified the application so that it provides the most common features found in commercial products. Our prototype app allows the patient to enter a text value (eg, the description of an activity), a number value (eg, the amount of time spent), and an image. The app also includes a button used to encrypt the text, number, and image and send the data to a cloud server that is used to represent the social network. In our work, we developed a local cloud server that does encryption/decryption operations.

One of the main limitations of our work is that current social networks cannot automatically carry out encryption/decryption. However, we mainly wanted to demonstrate the potential capability of our system should a social network provide this feature in the future. Another limitation of our work is that, once the doctor has fully decrypted the patient's health data, there is no way to revoke access. This is currently beyond the scope of our paper. The doctor however, would not be able to view any further health information posted by the patient.

One of the main goals of our system is to make it simple to use for both patients and doctors. Our system is not designed to replace existing health record systems but provide a convenient way for patients and doctors to communicate with each other remotely while ensuring privacy and security of health data. In terms of privacy, we offer a solution that enables the patient to define who can access their personal health data. We do not focus on the other aspects of privacy such as determining when the data were accessed, how the data were accessed, and to what extent the data are communicated. In terms of security, we provide solutions to availability through the use of the cloud and confidentiality in terms of allowing only authorized doctors to access the data. We do not focus on integrity or accountability in this work.

Figure 2. User Interactions in the System.



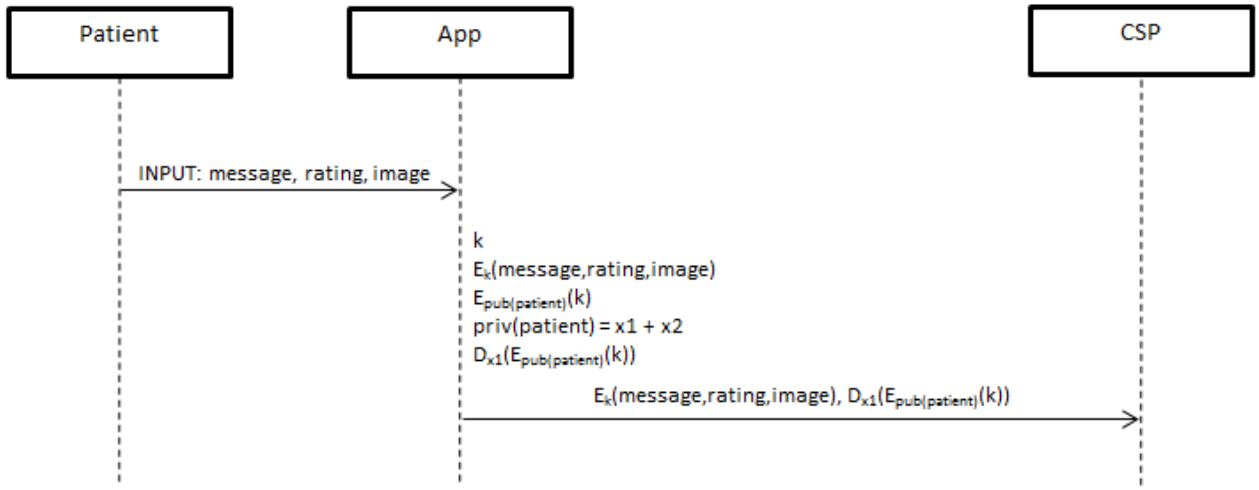
Protocol

To describe the protocol, we assume that the patient's public and private key pair has already been generated and stored in the app. We also assume the social network to be honest-but-curious in the sense that the rules of the protocol will be followed as intended but will still try to find out any sensitive information if possible.

Data Storage

The patient first runs the prototype app and inputs a text string and a number value, and uploads an image onto his mobile phone. When the patient presses the "Send" button, the app will then generate an arbitrary symmetric key and encrypt the text, number, and image. The symmetric key will then be encrypted using the public key. The encrypted data contents and encrypted symmetric key will then be sent to the social network, for storage (see Figure 3).

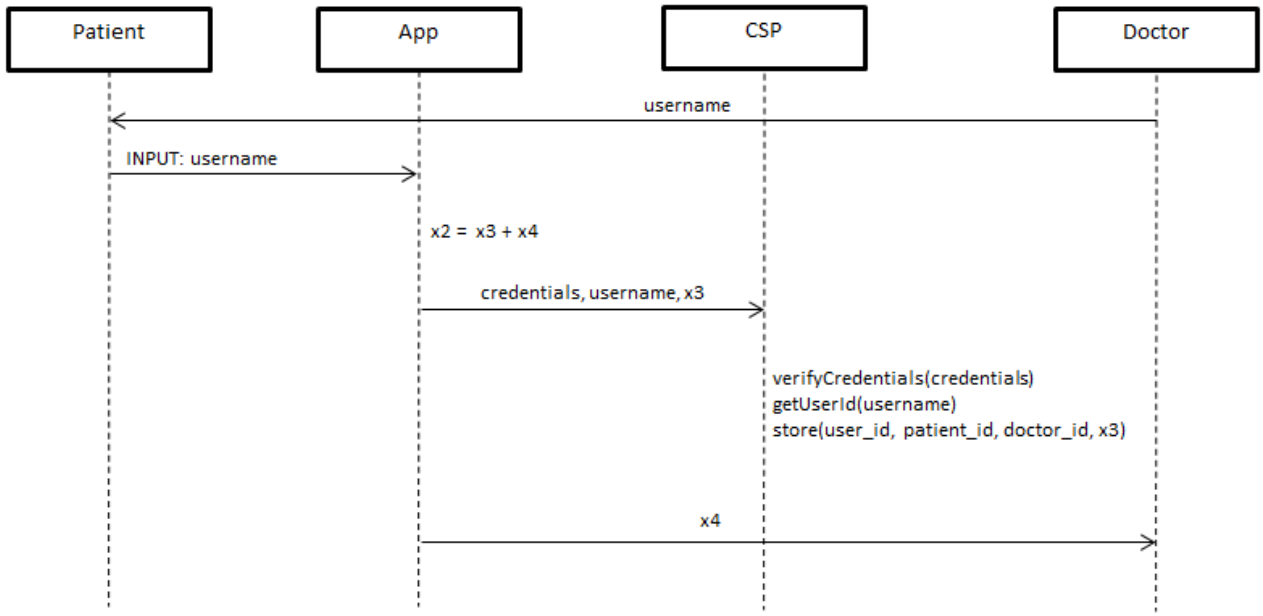
Figure 3. Data Storage Protocol.



Data Sharing

When the patient decides to share the data with a doctor, he presses the "Share" button on the app and enters the doctor's social network username. The app will then partition the patient's private key into 2 random parts. The first partition will be sent to the social network and the other will be sent to the doctor. By doing this, the untrusted social network has no knowledge of the full private key, because the other partition is stored on the doctor's local machine (see Figure 4).

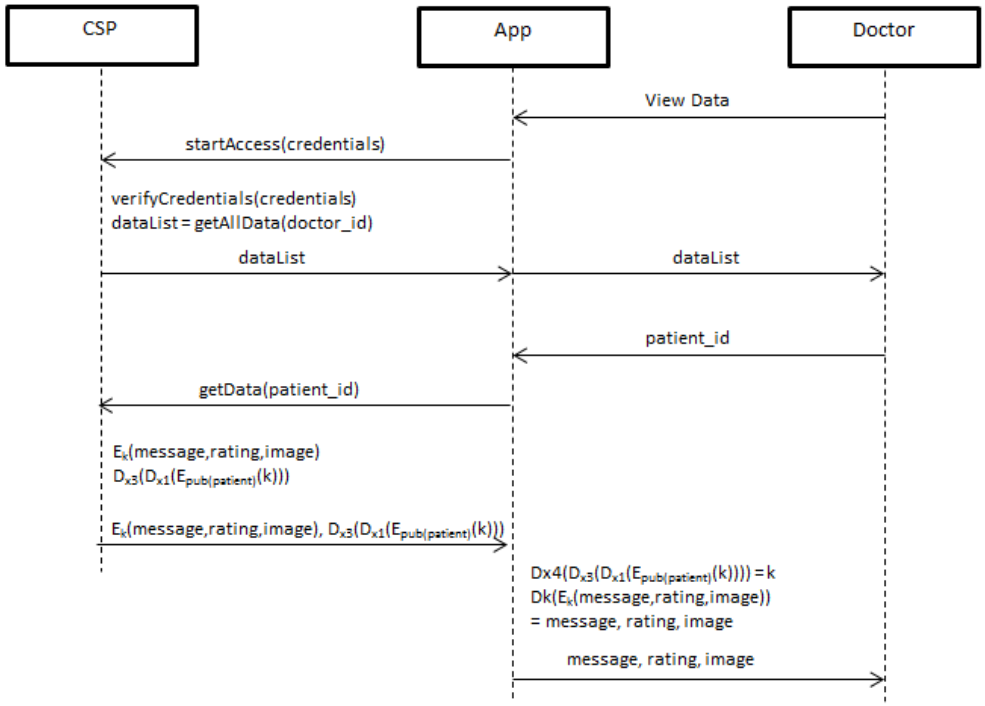
Figure 4. Data Sharing Protocol.



Data Access

When the doctor wishes to access the patient's data, they simply call the social network to retrieve the data. The social network partially decrypts the symmetric key using the partial key supplied by the patient and sends the encrypted data contents and partially decrypted symmetric key to the doctor. The doctor uses the partial key supplied by the patient to fully decrypt the symmetric key and finally decrypt the data contents. The standard method of accessing data involves the data consumer downloading the encrypted data from the cloud and decrypting the data on his own machine, using the encryption key supplied by the data owner. In our protocol, the data consumer does not have access to the other half of the key, which prevents the data consumer from ever knowing the full encryption key (see Figure 5).

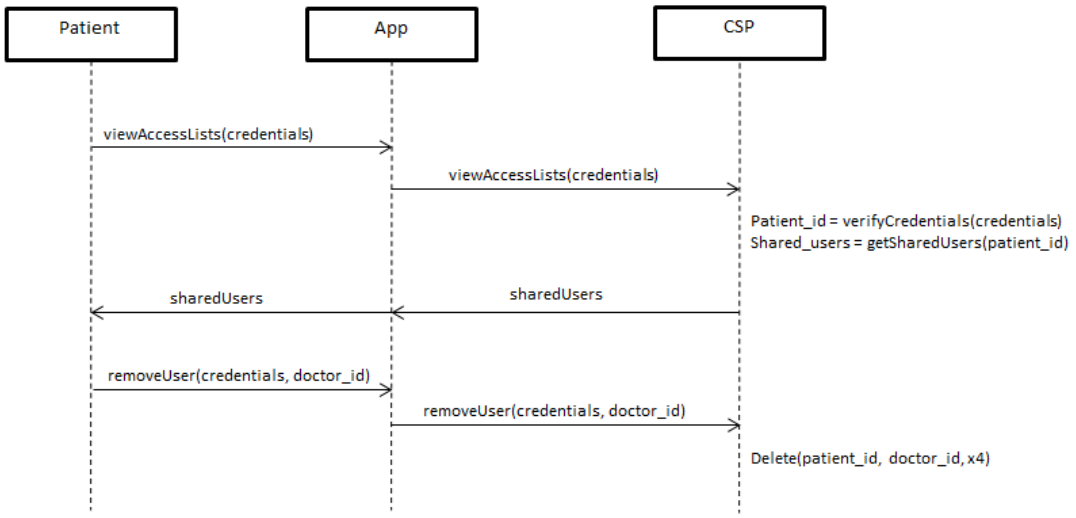
Figure 5. Data Access Protocol.



Access Revocation

When the patient decides to revoke a specific user's access to his eHealth data, the patient sends a request to the social network platform to remove the doctor's partial key entry from storage. If the doctor attempts to download the data from the social network, he will only see the encrypted text ("ciphertext"). The doctor will not be able to fully decrypt or read the data without the partial key. In the trivial solution described earlier, the data owner would have to re-encrypt the data and redistribute the new encryption key to all of the remaining consumers in the group, thus placing a burden upon the data owner. In our solution, because the data consumer has no knowledge of the other half of the key partition stored in the cloud, the data owner would simply have to delete that key partition. Thus, he need not worry about re-encryption and the redistribution of keys (see Figure 6).

Figure 6. Access Revocation Protocol.



Security Analysis

To verify the security of our protocol, we have used an automatic cryptographic verifier tool called ProVerif [33], which has been used extensively in research work [34].

We first modeled the behavior of the symmetric and asymmetric encryption, ElGamal encryption/decryption, and digital signatures.

We then modeled the patient by following the logic of the protocol. In other words, the patient sending their encrypted health data to the cloud server is modeled.

The cloud provider model simply retrieved the encrypted data from the patient via the public communication channel. When requested by the doctor, it would carry out a partial decryption of the symmetric key using the doctor's key partition and send it back to the doctor via the public communication channel.

The doctor was modeled as retrieving the key partition from the patient via the private communication channel. The doctor then retrieves the encrypted data and uses her own key partition to fully decrypt the partially decrypted symmetric key and then fully decrypt the encrypted data to reveal the plaintext health data.

Each of the processes of the data owner, cloud provider, and data consumer were run simultaneously, to simulate realism.

Usability Analysis

Participant Recruitment

In total, we recruited 5 medical professionals and 15 students to carry out the usability testing of our eHealth application. According to Nielsen [35], the minimum number of participants required in a usability study is 5. We chose to recruit medical professionals, because of their experience with patients and health issues. They were also the most likely potential users of our system. The medical professionals included 2 doctors, 2 medical officers, and 1 medical intern. We chose also chose young people (ie, students) because they were the most likely to use mobile phones and would be likely potential end users of the system. We recruited students aged more than 18 years. Of the 20 participants, 17 (85%) were aged more than 25 years and 3 (15%) were from 18 to 25 years of age. We obtained ethics approval to carry out the study. All students reported having a fair amount of experience using mobile apps.

To carry out the usability tests, we provided participants with a 4-inch LG mobile phone with Android operating system (OS) and a 10-inch ASUS Eee Pad tablet [36], which contained our secure eHealth app. We also launched our Web service, which would interact with the mobile phone to store and retrieve eHealth data and enable the sharing with, and revocation of, other users.

All 20 participants were given the same demo. Each participant was first introduced to the main idea of our secure eHealth system. We then asked the participants to carry out simple tasks such as the following:

- Report current mood
- Share information with another user
- Show that the other user can view the user's mood submission
- View mood submissions, etc

Each participant was told that their mood submission was encrypted, and they were shown the back end of their stored mood submission. Participants then answered our trust and usability questionnaire.

We have illustrated the user interface of our MindFeedback app with Figures 7-9.

Figure 7. Screenshot of app login.

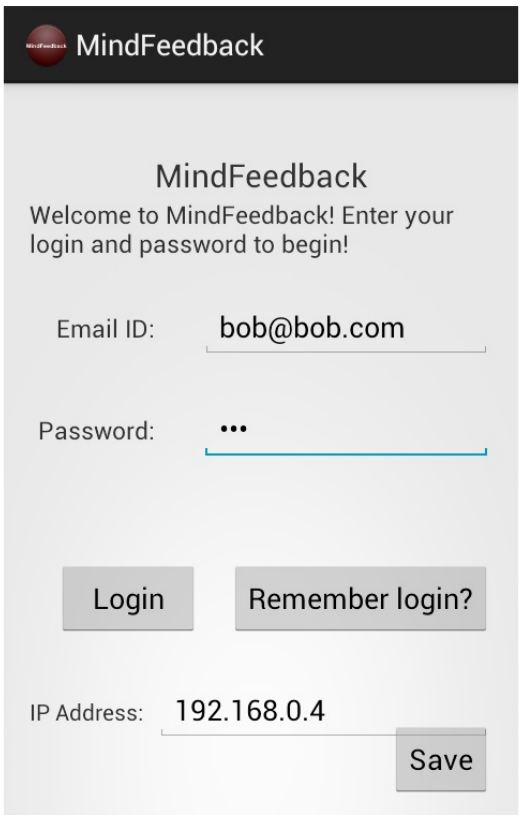


Figure 8. Screenshot of patient mood input.

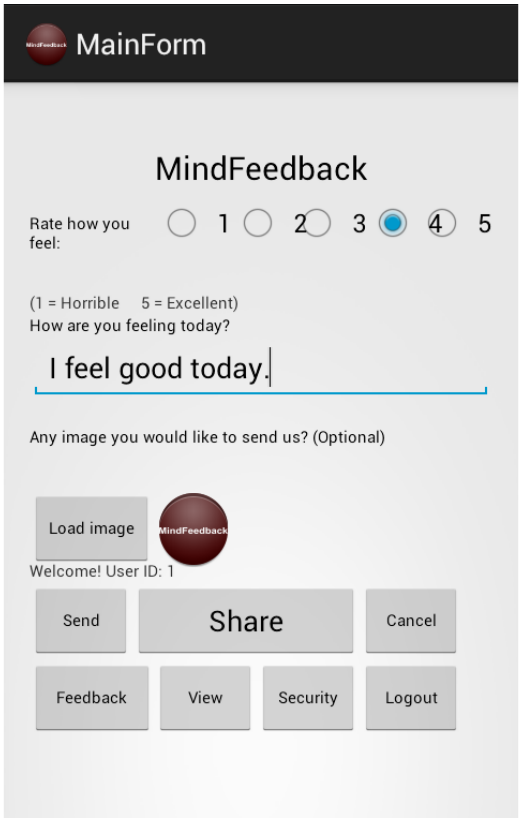
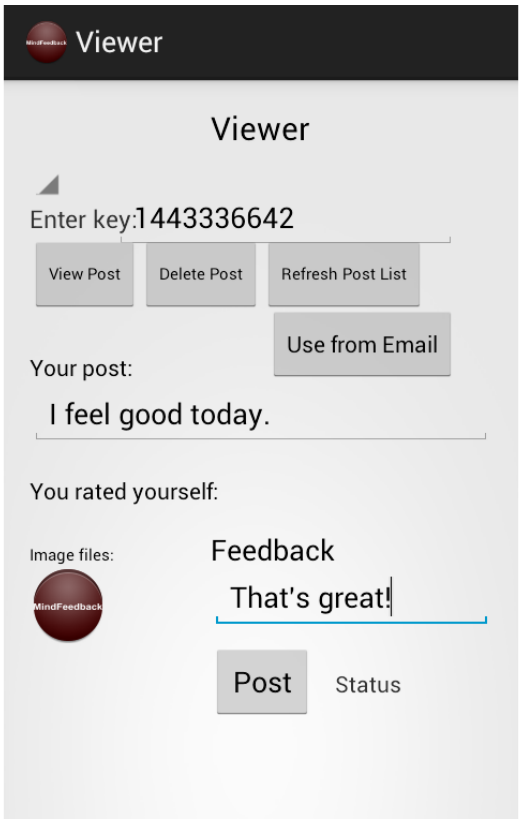


Figure 9. Doctor's view of patient's health data.



Instruments

We asked the participants to think aloud while taking notes. Finally, participants answered a short questionnaire (see Textbox 1), with questions related to trust and security [11,12] and usability (the Usability, Satisfaction and Ease of use questionnaire [37]). The questionnaire asked the participant to

assess our system based on trust and security, ease of use, and satisfaction, based on a 7-point Likert scale.

We investigated the relationship between how trustworthy and secure our system is and how useful our system is to everyday users. SurveyMonkey was used to provide the questionnaires to the participants and to carry out the analysis of the questionnaire responses.

Textbox 1. Questionnaire for all participants

Demographic questions
Are you male or female?
What is your ethnicity?
What is the highest level of school you have completed or the highest degree you have received?
Seven-point Likert scale questions
Trust and security
When I'm connected to the Internet, I am concerned about exposing my health information to the public.
I am not too concerned about what others see when I post my health-related information on the Internet.
This system has made me more aware of what I may be exposing to others on the network.
I feel safer when using the system.
Personal information, which I input, is managed carefully and will not be leaked.
Ease of use
It is easy to use.
It is user-friendly.
It requires the fewest steps possible to accomplish what I want to do with it.
Both occasional and regular users would like it.
I can use it successfully every time.
The app is tedious.
I require written instructions to use it.
It is difficult to recover from mistakes.
Satisfaction
I am satisfied with it.
It works the way I want it to work.
The app could be better.
The app wasn't as satisfactory compared to other health apps.
Feedback
Would you like to provide any other feedback on our system?

Performance Tests

The computational overhead introduced by our encryption system on storage and retrieval of eHealth information was tested with simple Advanced Encryption Standard (AES) encryption/decryption of similar text data. We carried out 20 test cases and measured the time taken for each test case. To carry out the tests, we used the ASUS Eee Pad Transformer Prime TF201 tablet with Android OS [36] to run our MindFeedback app. Testing was done on an HP Notebook running Windows 8 with Intel Core i5 and 4GB RAM to run the AES encryption/decryption operations and also to interface with our app to retrieve performance time information of MindFeedback.

Scalability Analysis

The scalability tests measured the maximum load distribution our system can handle. This was done using a commercial scalability testing tool that made calls to the login() and getdata() methods of our cloud service. The tests showed that the maximum number of threads executed concurrently without the system becoming a bottleneck was 200. Tests were on an HP Notebook running Windows 8 with Intel Core i5 and 4GB RAM.

Results

Security Analysis

Informal Analysis

We now provide a brief security risk analysis of our work.

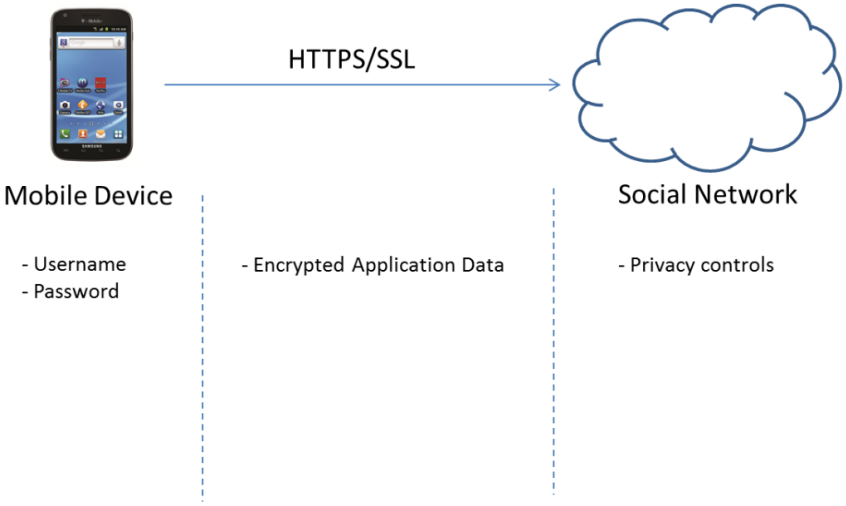
- Insider attacks: Our protocol prevents insider attacks because the data are never fully decrypted in the untrusted cloud under any circumstance. The data remain encrypted at all times on the untrusted cloud servers as well as on untrusted public communication channels.
- User revocation: Revocation of a doctor from data access can be achieved efficiently without having to re-encrypt the data each time. The doctor's key partition is simply removed from the cloud storage. This way, if the revoked doctor now attempts to access the health data, he will not be able to retrieve the full plaintext without the remaining key partition.
- Update secrecy: Because health data are constantly changing, patients may wish to update their health data. This is made possible in our protocol; as long as the updated version is encrypted with the same symmetric key that was used to encrypt the original health data, the patients may update their health data any number of times as they wish. This makes our solution feasible to be deployed in a real-world scenario.
- Mobile stealing: In the event someone steals the patient's mobile phone, they will not be able to access the personal health information as they would need to know the patient's credentials such as email id and password in order to access the mobile phone app. Hence, a patient does not need to be tied down to only one mobile phone device and can keep changing his device as often as he would like without any loss of personal health information.

Formal Analysis

We used an automatic cryptographic verifier tool called ProVerif [33] to formally verify our protocol. The tool tests the protocol against all types of adversary attacks, such as man-in-the-middle attacks. We tested the storage of eHealth data by the patient and the retrieval of health data by an authorized doctor. Specifically, we tested the Data Storage and Data Access phases of our protocol. Our protocol was found to be secure against such attacks.

Figure 10 illustrates the security mechanisms used in our system. The mobile app requires username and password credentials to be able to use our system. All health data that are sent to the social network are encrypted and sent securely via HTTPS/SSL. The social network also has privacy controls that the patient can adjust to suit their needs.

Figure 10. Secure communication paths.



Usability Analysis

Potential Users

We conducted a quantitative-based usability evaluation. Table 1 contains the responses from the 15 participants regarding the questions related to trust and security, ease of use, and satisfaction.

From our trust and security results, 10 out of 15 participants (67%) had at least some concern over what others see when they post health-related information on the Internet. Out of 15 participants, 12 (80%) felt that their data would be kept private and secure when using our system and were also made more aware of the type of information that they may be exposing over the Internet. In regard to whether their personal information will be managed carefully and not leaked to the outside, nearly half of the participants agreed. Participants did mention that some form of training or a video demonstration would have communicated the security of the system a lot more effectively.

From our ease-of-use responses, we found that 11 out of 15 participants (73%) found our system easy to use and learn, user-friendly, and were able to use it successfully, every time. However, 4 out of 15 participants (27%) did find the app a little "tedious" to work with initially, and required some instructions to understand the system a little better. Overall, the satisfaction of the app was mostly positive. Out of 15 participants, 13 (87%) were satisfied with our app and found that it worked in the way they wanted it to. However, most agreed that the app could have been improved. For instance, participants provided feedback that the app could have had a better-looking and much more intuitive interface.

Table 1. Potential users responses to questionnaire

Question	Strongly disagree	Disagree	Partially disagree	Neither disagree nor agree	Partially agree	Agree	Strongly agree
Trust and security							
When I'm connected to the Internet, I am concerned about exposing my health information to the public.		2 (13.33%)	2 (13.33%)	1 (6.67%)	2 (13.33%)	5 (33.33%)	3 (20.00%)
I am not too concerned about what others see when I post my health-related information on the Internet.	4 (26.67%)	5 (33.33%)	1 (6.67%)	2 (13.33%)	2 (13.33%)	1 (6.67%)	
This system has made me more aware of what I may be exposing to others on the network		2 (13.33%)		2 (13.33%)	1 (6.67%)	8 (53.33%)	2 (13.33%)
I feel safer when using the system.		1 (6.67%)	1 (6.67%)	1 (6.67%)	2 (13.33%)	7 (46.67%)	3 (20.00%)
Personal information, which I input, is managed carefully and will not be leaked to the outside.		2 (13.33%)	1 (6.67%)	2 (13.33%)	3 (20.00%)	5 (33.33%)	2 (13.33%)
Ease of use							
It is easy to use.		1 (6.67%)	2 (13.33%)	1 (6.67%)		8 (53.33%)	3 (20.00%)
It is user-friendly.		1 (6.67%)	1 (6.67%)	2 (13.33%)	1 (6.67%)	7 (46.67%)	3 (20.00%)
It requires the fewest steps possible to accomplish what I want to do with it.		2 (13.33%)		2 (13.33%)		9 (60.00%)	2 (13.33%)
Both occasional and regular users would like it.		3 (20.00%)	1 (6.67%)	1 (6.67%)	3 (20.00%)	6 (40.00%)	1 (6.67%)
I can use it successfully every time.		1 (6.67%)		3 (20.00%)	1 (6.67%)	8 (53.33%)	2 (13.33%)
The app is tedious to work with.	3 (21.43%)	1 (7.14%)		5 (35.71%)	2 (14.29%)	3 (21.43%)	
I require written instructions to use it.		5 (35.71%)	1 (7.14%)	3 (21.43%)	1 (7.14%)	2 (14.29%)	2 (14.29%)
It is difficult to recover from mistakes.	1 (6.67%)	4 (26.67%)	1 (6.67%)	9 (60.00%)			
Satisfaction							
I am satisfied with it.		1 (6.67%)		1 (6.67%)	2 (13.33%)	8 (53.33%)	3 (20.00%)
It works the way I want it to work.		1 (7.14%)		1 (7.14%)	2 (14.29%)	7 (50.00%)	3 (21.43%)
The app could be better.		1 (6.67%)		1 (6.67%)	4 (26.67%)	7 (46.67%)	2 (13.33%)
The app wasn't as satisfactory compared to other health apps	1 (6.67%)	4 (26.67%)	1 (6.67%)	8 (53.33%)	1 (6.67%)		

Medical Professionals

We also performed an identical usability evaluation with the 5 medical professionals. Table 2 contains the responses from the 5 medical professionals regarding trust and security, ease of use, and satisfaction.

Table 2. Medical professionals responses to questionnaire

Question	Strongly disagree	Disagree	Partially disagree	Neither disagree nor agree	Partially agree	Agree	Strongly agree
Trust and security							
When I'm connected to the Internet, I am concerned about exposing my health information to the public.					3 (60%)	2 (40%)	
I am not too concerned about what others see when I post my health-related information on the Internet.	1 (20%)	3 (60%)	1 (20%)				
This system has made me more aware of what I may be exposing to others on the network					2 (40%)	3 (60%)	
I feel safer when using the system.				1 (20%)	3 (60%)	1 (20%)	
Personal information, which I input, is managed carefully and will not be leaked to the outside.					4 (80%)	1 (20%)	
Ease of use							
It is easy to use.					2 (40%)	3 (60%)	
It is user-friendly.			1 (20%)		1 (20%)	3 (60%)	
It requires the fewest steps possible to accomplish what I want to do with it.						5 (100%)	
Both occasional and regular users would like it.				1 (20%)	1 (20%)	3 (60%)	
I can use it successfully every time.				2 (40%)		3 (60%)	
The app is tedious to work with.		3 (60%)		1 (20%)	1 (20%)		
I require written instructions to use it.		2 (40%)			2 (40%)	1 (20%)	
It is difficult to recover from mistakes.		2 (40%)	1 (20%)	2 (40%)			
Satisfaction							
I am satisfied with it.					1 (20%)	3 (60%)	1 (20%)
It works the way I want it to work.				1 (20%)		3 (60%)	1 (20%)
The app could be better.			1 (20%)	1 (20%)	2 (40%)	1 (20%)	
The app wasn't as satisfactory compared to other health apps	1 (20%)	1 (20%)		3 (60%)			

From our trust and security results, 2 out of 5 participants (40%) were strongly concerned about exposing health information over the Internet while the rest were partially concerned. After using our app, 4 out of 5 participants (80%) felt that the personal information they entered into the app would not be leaked to the outside. Results were mainly positive about feeling safer when using the system and being more aware of what they might be exposing to others on the network. In terms of feedback, participants reported that users would not understand the key process and that it might need to be accompanied with images, for better understanding. We needed to better showcase the trivial solution of data sharing, as described in the introduction, and how our system solves the issues of the solution. Another participant reported that the 2-part encryption was ideal.

In terms of ease of use, 3 out of 5 participants (60%) agreed that the app required the fewest steps possible, in order for them

to accomplish what they wanted to with the app. Results were also mostly positive, in terms of the app being user-friendly, easy to use, and the ability to use it successfully, every time. However, a few participants agreed that some form of written instructions was needed to make this app usable. Overall, medical professionals found our system satisfactory. Out of 5 participants, 4 (80%) found the app satisfactory and working in the way they wanted it to.

Similar to the potential users, 2 out of 5 medical professionals (40%) also felt that the app could have been better. For instance, most of the feedback involved improving the user interface. Doctors reported that a notification system for the app would have been very handy. The notification system could pop up or beep and alert a patient when a doctor has provided feedback. For more serious medical problems, the notification system could forward the patient's request to an emergency unit or mental health crisis team, in the event that the doctor cannot respond out of hours. Most doctors provided positive feedback about the security of the app. One participant noted that the 2-part encryption might be frustrating for older patients, and that such a system perfectly suits teenage patients.

Performance Tests

As a measure of performance, we tested the overhead introduced in our system, regarding the storage and retrieval of eHealth information, with simple AES encryption/decryption of similar text data. We carried out 20 test cases and measured the time taken for each test case. To carry out the tests, we used the ASUS Eee Pad Transformer Prime TF201 tablet [36] with Android OS to run our MindFeedback app. We used an HP Notebook running Windows 8 with Intel Core i5 and 4GB RAM to run the AES encryption/decryption operations and to also interface with our app, in order to retrieve performance time information from MindFeedback.

In our performance tests, we measured the overhead introduced by our system compared with a simple AES encryption and decryption operation. We first measured the overhead introduced by uploading the patient's health data to the cloud server. Figure 11 illustrates the results of our upload performance tests.

The diagram clearly highlights the overhead of our system compared with a simple AES encryption solution. The mean time for the simple AES symmetric encryption was 0.18 seconds, with a standard deviation of 0.006 seconds. However, the mean time for the MindFeedback tests was 0.485 seconds, with a standard deviation of 0.09 seconds. The overhead is accounted for the additional encryption of the symmetric key, followed by the partial decryption of the symmetric key through the ElGamal encryption algorithm. There was also some network latency overhead.

We also measured the overhead introduced by our protocol for the download or retrieval of the patient's health data. Figure 12 highlights the results of the performance tests.

As seen in the diagram, the system only had a slight overhead compared with a simple AES decryption operation. The mean time of the AES decryption tests was 0.001 seconds, with a standard deviation of 0.0003 seconds. The mean time of the MindFeedback download tests was 0.961 seconds, with a standard deviation of 0.332 seconds. Note that the patient's encrypted key used to protect health data is first partially decrypted in the cloud server and then fully decrypted on the patient's mobile phone. This is then followed by an AES symmetric decryption using the key on the mobile phone, thus accounting for the overhead.

Figure 11. Upload Overhead.

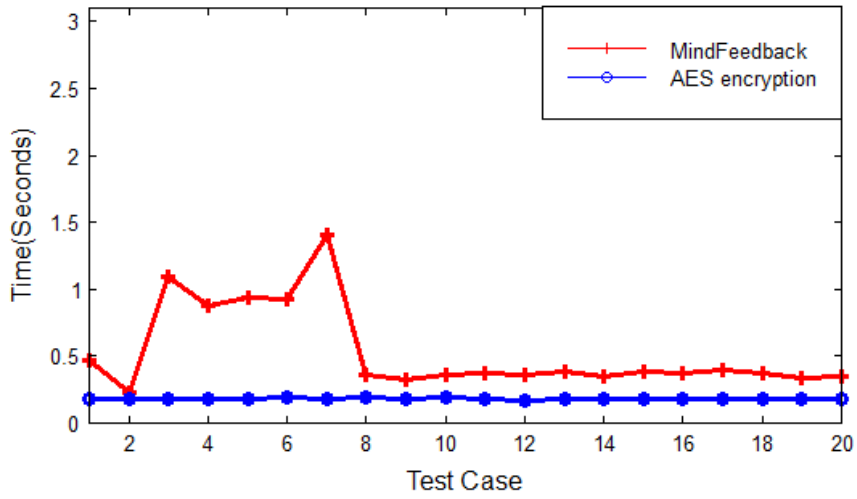
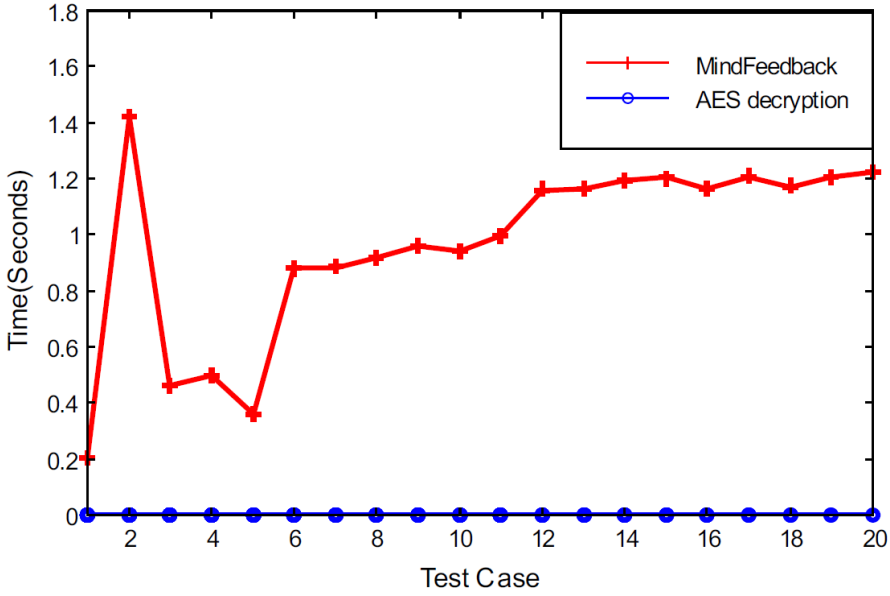


Figure 12. Download overhead.



Scalability Tests

In the scalability tests, we measured the maximum load distribution that our locally deployed SOAP (Simple Object Access Protocol) Web service could handle. We used a scalability tool that made calls to the login and getData methods of our cloud service. The maximum number of threads we were able to run concurrently without the system becoming a bottleneck was 200. We carried out the tests on an HP Notebook running Windows 8 with Intel Core i5 and 4GB RAM.

See Figures 13 and 14 for our scalability distribution over the 200 threads, for both calls to log in and calls to retrieve the data from the cloud service.

The diagrams highlight the near-ideal bell curve distribution. Our system could withstand up to 200 concurrent calls to our Web service, which makes it more feasible for use in a real-world scenario.

Figure 13. Distribution of login performance.

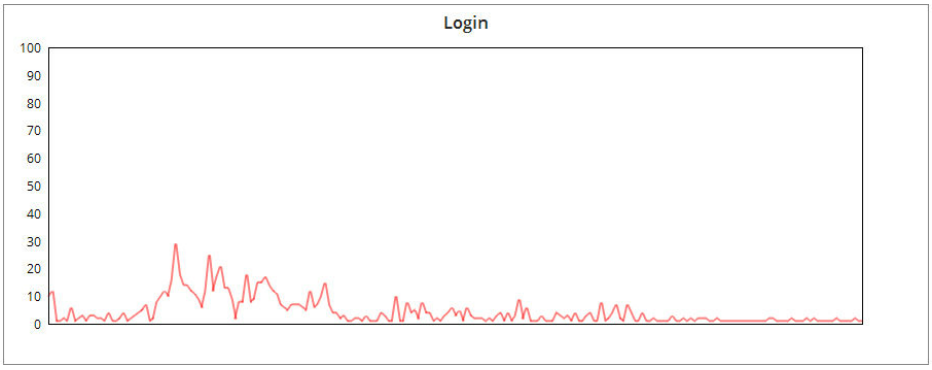
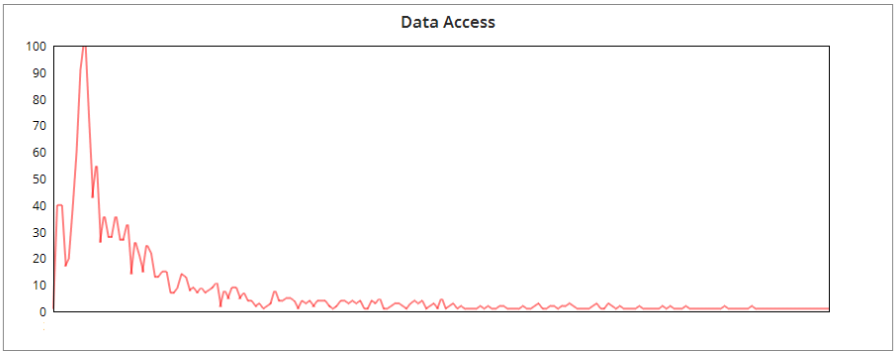


Figure 14. Distribution of data access from cloud performance.



Discussion

eHealth applications are a fast-growing segment in the technology market; however, privacy and security issues hinder the wide-scale adoption that patients can potentially benefit from. In this paper, we presented a solution that will enable patients to share their personal health information with doctors remotely while ensuring privacy and security.

We then presented our system based on the encryption key partitioning algorithm that will enable patients and doctors to communicate with each other privately and securely. We leveraged mobile phones to provide greater convenience for patients. We carried out performance tests, usability tests, and scalability tests to show that our system is feasible to be deployed in a real-world scenario.

Our performance tests were shown to be practical to be deployed in a real-world scenario, even after it introduced a slight overhead due to our security protocol. From the usability tests, we found that many users were concerned when they shared their personal health information online and that they felt safer when using our system. A majority of participants found our app easy to use and efficient but had provided feedback that it could be better. For example, the app could have had a notification system that beeped every time a doctor sent feedback to the patient or alert the emergency unit for more serious medical problems. In terms of scalability, our system was shown to withstand up to 200 concurrent calls to our locally run Web service, thus making it feasible to be deployed in a real-world scenario.

One recommendation for further development is to remove the assumption that the doctor is trusted. That is, once the doctor is able to view the patient's fully decrypted personal health information, she may then accidentally or inadvertently send the data to another doctor without the knowledge and/or permission of the patient. A solution could be developed to prevent unauthorized sharing of personal health information by authorized doctors. One way to do this would be to utilize an additional security token such that the health information can be viewed only if the security token is present in an authorized doctor's device. Another way would be to perhaps encapsulate the personal health information in a secure data object and require that credentials be entered every time an authorized doctor requests access. Another recommendation for future work is to handle the scenario where a revoked doctor colludes with the social network. Currently, this will reveal the full key that will then allow the doctor to decrypt all of the personal health information stored by the patient on the social network.

Acknowledgments

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Conflicts of Interest

None declared.

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Abbreviations

ABE: attribute-based encryption
AES: Advanced Encryption Standard
ECG: electrocardiographic
OS: operating system

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Viewpoint

Putting Meaning into Meaningful Use: A Roadmap to Successful Integration of Evidence at the Point of Care

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Abstract

Pressures to contain health care costs, personalize patient care, use big data, and to enhance health care quality have highlighted the need for integration of evidence at the point of care. The application of evidence-based medicine (EBM) has great promise in the era of electronic health records (EHRs) and health technology. The most successful integration of evidence into EHRs has been complex decision tools that trigger at a critical point of the clinical visit and include patient specific recommendations. The objective of this viewpoint paper is to investigate why the incorporation of complex CDS tools into the EMR is equally complex and continues to challenge health service researchers and implementation scientists. Poor adoption and sustainability of EBM guidelines and CDS tools at the point of care have persisted and continue to document low rates of usage. The barriers cited by physicians include efficiency, perception of usefulness, information content, user interface, and over-triggering. Building on the traditional EHR implementation frameworks, we review keys strategies for successful CDSs: (1) the quality of the evidence, (2) the potential to reduce unnecessary care, (3) ease of integrating evidence at the point of care, (4) the evidence's consistency with clinician perceptions and preferences, (5) incorporating bundled sets or automated documentation, and (6) shared decision making tools. As EHRs become commonplace and insurers demand higher quality and evidence-based care, better methods for integrating evidence into everyday care are warranted. We have outlined basic criteria that should be considered before attempting to integrate evidenced-based decision support tools into the EHR.

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KEYWORDS

clinical decision support tools; framework; implementation

Introduction

Field of Evidence-Based Medicine

Pressures to contain health care costs, personalize patient care, use of big data, and enhance health care quality have highlighted the need for integration of evidence at the point of care [1-5]. In the field of evidence-based medicine (EBM), we talk about the evidence cycle (Figure 1 shows this) [6]. The EBM cycle starts with a question (ask), then accessing the evidence (acquire), appraising the evidence, applying the evidence to care for our patients, and analyzing and adjusting [7]. The application step is where researchers and policy makers have struggled with implementation and often failed. Furthermore, the constant evolving evidence-based guidelines, clinical prediction rules (CPRs), and comparative effectiveness results makes it challenging for providers to apply the latest evidence at the point of care. But the direct application of EBM has great promise in the era of electronic health records (EHRs) and health technology.

With the onset of Health Information Technology for Economic and Clinical Health Act and Meaningful Use initiatives in 2009, researchers have been hopeful that health technology will be the solution to bringing EBM to the point of care. Substantial investments of funding, intellect, and energy have yielded an array of EHRs and electronic clinical decision support (CDS) tools to improve patients' quality of care and reduce inappropriate use of critical resources.

The most successful integration of evidence into EHRs has been complex decision tools that trigger at a critical point of the clinical visit and include patient specific recommendations. In contrast, most of the CDS tools being launched are uni-dimensional and not incorporated into the physicians' workflow. For the purpose of this article, we have designated these forms of evidence integration as "flat reminders": one-dimensional alerts that are typically triggered by one or two EHR components such as an element of patient history [8-11]. Examples include, flu-shot reminders at annual visits or reminders for colon-cancer screening triggered by patients' age (Figure 2 shows this). These flat CDS tools unlike complex CDS rarely include patient-specific medical information, are not integrated into the providers' clinical workflow, do not include tools to support workflow (bundled order sets or documentation corresponding to the tool), or inclusive of patient-centered decision-making tools [12-14].

Complex, multidimensional forms of CDS are patient-specific, provide specific recommendations for rapid frontline decision making, and therefore have had a greater impact on patient outcomes and resource utilization. CPRs are forms of complex CDS. Based on real-time patient data points such as medical history, physical examination, and laboratory data, CPRs are EBM based algorithms that are able to personalize the patient's diagnosis, prognosis, and likely response to treatment [6]. CPRs weigh patient data and generate a composite score to stratify patients' risk of disease onset, disease progression, or outcome events. Physicians find these tools more useful, compared to the flat reminders, when decision making is complex, the clinical stakes are high, or cost savings can be achieved without compromising patient care [6]. Adoption of CPRs have been problematic in that applying complex algorithms at the point of care takes additional time, providers' forget to apply the rule, and they don't document the usage.

Incorporating complex CDS tools, such as CPRs, into an EHR holds great promise for finally realizing their potential by standardizing their application, reinforcing their application, and documentation. The caveat is that incorporation of complex CDS tools into the EMR is equally complex and continues to challenge health service researchers and implementation scientists. Poor adoption and sustainability of CDS tools at the point of care has persisted and continues to have low rates of usage [15-18]. The barriers cited by physicians include efficiency, perception of usefulness, information content, user interface, and over-triggering [19,20].

Over the past five years, our research team has been working to improve the integration and adoption of complex CDS tools. Similar to the EBM cycle, we see CDS integration as a step wise process of: identifying a clinical problem, reviewing the evidence, usability testing of the tool, integration and deployment of the tool into the EHR, incorporation of shared decision making, and continuous monitoring and maintenance for sustained effectiveness (Figure 3 shows this).

Figure 1. Five steps of evidence-based practice. Evidence-based medicine: EBM.

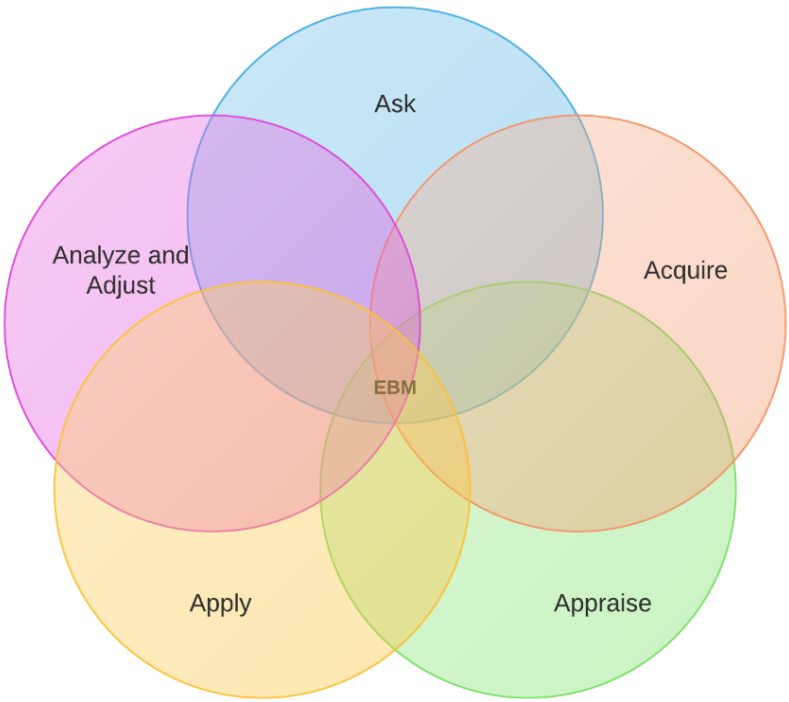


Figure 2. Flat versus dynamic clinical decision support tools. PCP: primary care provider.

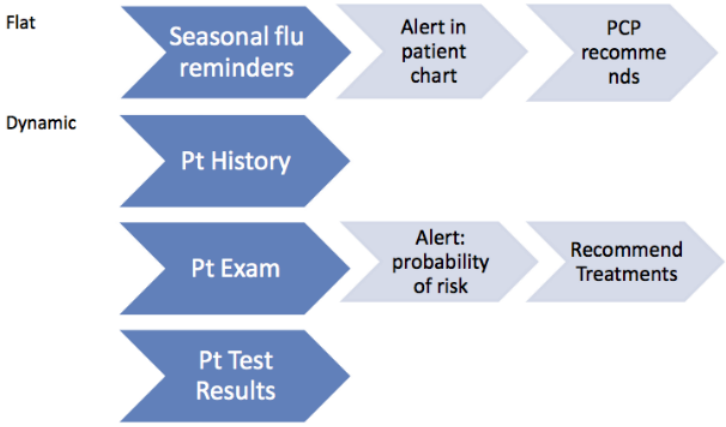
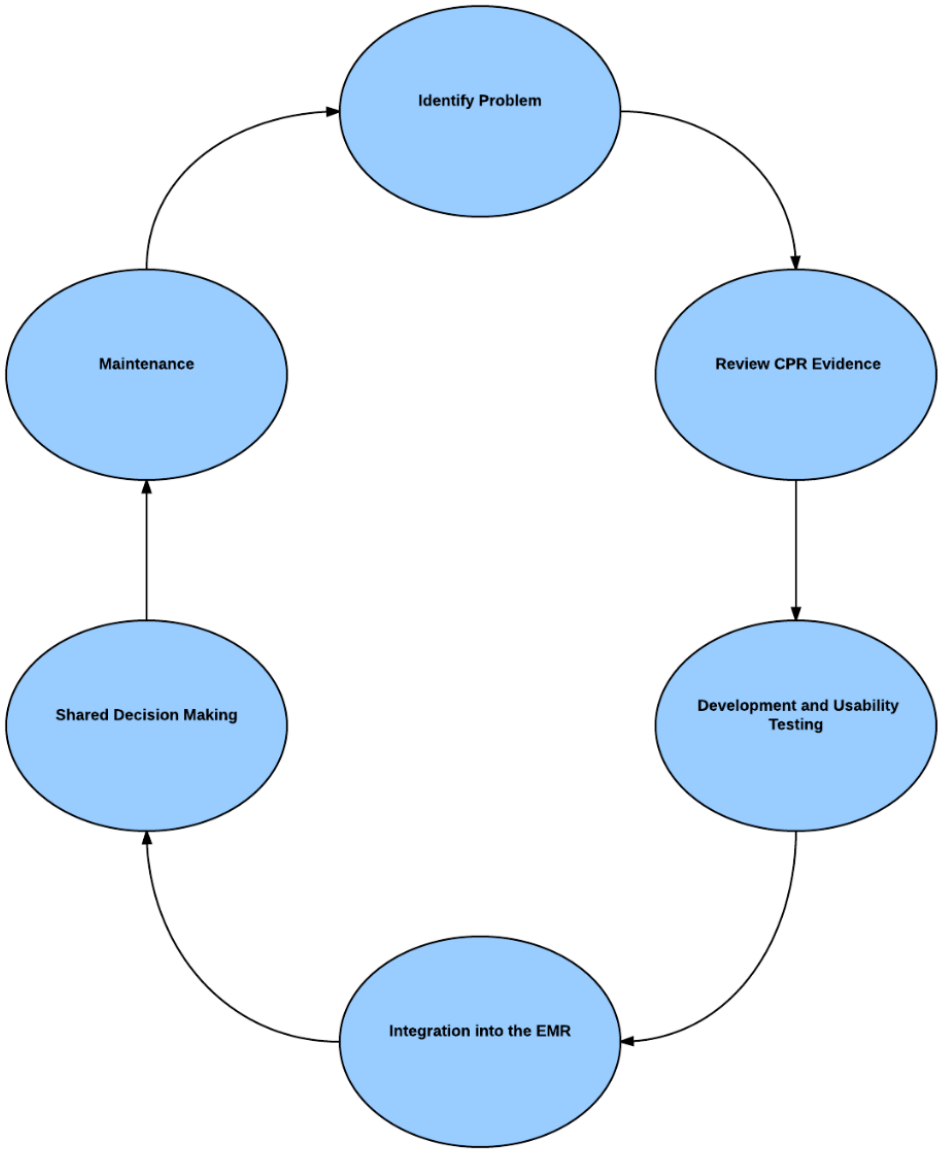


Figure 3. Steps to complex clinical decision support tool integration. CPRs: clinical prediction rules.



Aim of the Study

During our research, we have encountered challenges that have repeatedly emerged. In this paper, we propose strategies to overcome those challenges to the integration of complex CDS in order to improve EHR-embedded CDS tools adoption rates, patient outcomes, and resource utilization [21,22].

Key Considerations for Integrating Evidence-Based Medicine Clinical Decision Support Tools at the Point of Care

Key Strategies for Successful Clinical Decision Support Tools

Building on the traditional EHR implementation frameworks, we review keys strategies for successful CDSs: (1) the quality of the evidence, (2) the potential to reduce unnecessary care, (3) ease of integrating evidence at the point of care, (4) the evidence's consistency with clinician perceptions and preferences, (5) incorporating bundled sets or automated documentation, and (6) shared decision-making tools.

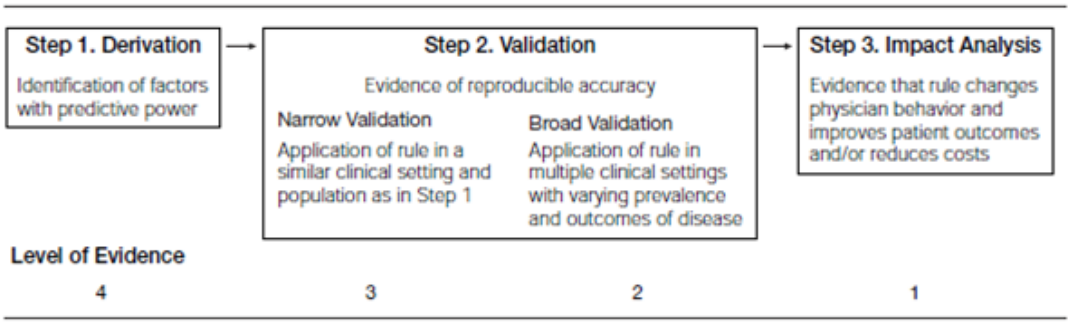
Quality of the Evidence

The first consideration to successful adoption of CDS tools is assessing the quality of the evidence. This may seem an obvious step, but this critical element is often overlooked, with inaccurate assumptions about evidence and impeding the hoped-for results. Therefore, a formal process of evaluating and grading the evidence of the CDS prior to integration is critical. In order for the CDS tool to have a significant impact on health care outcomes, it must be based on high-quality evidence [20].

The quality of CPRs is determined by how well they have been validated and tested. CPRs are typically developed in a three-step process: (1) derivation of the rule and creation of a model, usually with a retrospective database; (2) validation of the rule, in which the model is tested, preferably in a prospective fashion in several different sites to demonstrate that it is transportable and stable; and (3) impact analysis, when the rule's impact on clinical behavior is assessed (Figure 4 shows this) [6]. The further along in the development process, the higher the level or quality of evidence and the more ready it is for integration in the EHR. Only CPRs that have reached a level 1 or 2 of evidence and have shown to have a consistent predictive accuracy should be considered for integration.

Several risk-stratification tools with poor and unclear levels of evidence are currently in wide use, for example, the Modified Early Warning Scoring and the pulmonary embolism rule criteria rule for pulmonary embolism. The rules have been derived, but haven't shown consistency in prospective validations performed in various clinical settings [23-27].

Figure 4. Development and testing of a clinical prediction rule.



Potential to Reduce Unnecessary Care

A second consideration we identified as critical is the potential for the evidence to have a significant effect on health care delivery. Historically, CDS and CPR tools have often been introduced in clinical areas plagued by overuse of diagnostic tests or treatments. CPRs aim to accurately identify patients at very low risk who can possibly forgo further testing and those at high risk who can be prioritized for further diagnostic tests or immediate treatment. If the goal of evidence integration is to reduce unnecessary testing or treatment in low risk populations, then estimating how many patients fall into the low risk category will help give an accurate measure of the potential impact of a prediction rule. Our experience has been that estimating this risk will allow you to weigh the potential impact to the work/resources need to build and implement an EHR based CDS tool.

For example, CPRs that guide clinicians through the complex process of risk stratification usually shift the distribution of patients from higher to lower risk. With a CPR such as the strep or pneumonia rule, shifting patients from medium to low risk could reduce orders for antibiotics, which are recommended for patients with medium or high risk; if this constitutes a large proportion of patients, the CPR will have a substantial impact on public health implications (antibiotic resistance) and reduce unnecessary usage of antibiotics.

Ease of Integrating Evidence at Point of Care

A key to both clinician adoption of CDS tools at the point of care and successful integration is how it easy it is to meld the CPR into workflow and how the patient specific data are entered into the tool. Some CDS tools are extremely complex, requiring multiple data points that may not be automatically integrated into the CDS tool and thus require manual entry. In some practice settings, the EHR may not automatically interface with

required data such as x-ray results in the emergency departments or rapid point-of-care test results in primary care clinics. Busy clinicians are unlikely to adopt tools that require them to manually derive, obtain, or enter data. Examples of overly complex tools are the Pneumonia Severity Index (PSI) used in emergency departments to help providers decide to admit patients. The rule has over 20 data elements [28]. Attempts to integrate PSI in emergency room workflow have failed due to poor adoption of the model.

Automatic, Seamless Triggers

A related issue to ease of integration is "triggering" of the tool. To be truly effective, CDS tools need to be an active (automatic) trigger and seamlessly integrated into the flow of care. Providers should not have to activate the decision support, but rather be automatically offered it in the appropriate setting and related to the appropriate patient. Certain phrases or orders and combinations can act as trigger points in the EMR, such as chief complaint or diagnosis. For a trigger to be successful, it needs to trigger accurately (when truly needed) and not be overly sensitive. In our study on using a CPR for pneumonia, entering cough in the chief complaint section was one method of automatically triggering the complex decision support tool. Ideally, decision support is triggered infrequently and is targeted to the specific condition where it can most assist the provider. If there is no method for accurate triggering, the decision tool may not be effective in changing clinicians' behavior.

Consistency of the Evidence With Provider Perceptions and Preferences

Clinicians are most likely to adopt decision support tools or act on evidence guidelines that align with their predispositions about care. Literature suggests providers' understand the value of CPRs and state they utilize them in decision making, but CPR adoption rates continue to be low and vary across CPRs [15,16,18,29,30]. We have therefore found it helpful to conduct a needs assessment and survey providers on their beliefs and attitudes to better understand their reception and potential for adopting the rules. Furthermore, it allows us to anticipate and approach the cultural barriers to CPR adoption. For example, the success of two accurate CPRs, the Ottawa Ankle Rule (OAR) and the Thrombolysis in Myocardial Infarction (TIMI), varied in clinical impact, not based on the quality of evidence, but upon the attitudes the providers' had on the utility of the CPR in their practice, which hindered the adoption. Dr Ian Stiell derived and validated the OAR CPR to reduce x-ray ordering in emergency rooms among low risk patients presenting with ankle injuries. Implementation of the rule reduced x-ray ordering by over 30% [31]. In contrast, several prediction rules for chest pain risk stratification in emergency rooms have not been widely adopted despite their demonstrated accuracy [32-34]. Physicians in both examples were presented with accurate CPRs, but behaved differently in each situation. In the case of the OAR, most physicians (89.6%) reported using the rule always or most of the time in appropriate circumstances and 42.2% reported basing their decisions to order radiography primarily on the rule [35]. In contrast, physicians using the TIMI rule reported that they looked at the CPR during the triage in 46% of eligible patients, but only one triage decision (1%) was changed by it [33,36]. The OAR CPR in this situation supports their predisposition to confirm their clinical gestalt and empowers them to follow through. In contrast, patients presenting with chest pain may present physicians with a challenging decision that evidence introduction will not help and therefore evidence alone will not change practice patterns. Performing a needs assessment and survey prior to integrating evidence into workflow will potentially uncover these biases and lead to insight on how to overcome those biases.

Incorporating Bundled Sets or Automated Documentation

CPRs that can stratify risk and have a corresponding management plan or diagnostic testing, which can be streamlined and bundled into order sets, will likely have more buy in by physicians, leading to higher usage and therefore larger impact on patient outcomes. The largest incentive we have witnessed through our usability testing is how the CPR and CDS tools can streamline clinical practice instead of impeding and slowing it. By incorporating order sets or automated documentation in progress notes of the EMR and automated documentation in progress notes of the EMR, physicians see the CDS as a facilitator rather than a burden. Therefore, we work to develop CDS tools that offer some incentive to using the tool. In our models, we embedded patient education material in both English and Spanish for patients to take home [21,22,37]. We also developed order sets for recommended antibiotics for patients identified as high risk. Both these aspects were popular with providers.

Shared Decision-Making Tools

The final piece of completing the evidence cycle, which has yet to be sufficiently studied, is the integration of shared decision making when it's appropriate and as long as it's based on the best available evidence. Shared decision making (SDM) is becoming an integral part of patient centered care and is seen as a method to improve patient-clinician communication [38,39]. SDM is a process in which the clinician and patient share information about the disease and treatment options and discuss the patient's preferences to arrive at a decision about a management plan. Decision aids are typically used during the discussions to describe risk of disease and impact of treatment on morbidity and mortality, and have shown to have positive impacts on patient and clinical outcomes [38]. In a systematic review of the literature, it is suggested that patients may benefit from the use of SDM in the emergency department and that SDM is feasible [40]. A randomized controlled trial used SDM tools in patients with chest pain and showed an increase in patients' knowledge and engagement in decision making and patients decided less frequently to be admitted to the observation unit [41,42]. The combination of CPR with SDM allows for tailored messages around their severity of disease and treatment plans, and through the use of the EMR SDM, reminders, tools, and documentation in clinical visits, CDS is becoming easier.

Discussion

As EHRs become commonplace and insurers demand higher quality and evidence-based care, better methods for integrating

evidence into everyday care are warranted. We have outlined basic criteria that should be considered before attempting to integrate evidenced-based decision support tools into the EHR. First and foremost, this process emphasizes a critical appraisal of the quality of the evidence behind the decision support. Second, CDS tools should be evaluated for their ability to perform and impact clinical care through assessments of providers' perception of utility. Finally, usability testing and integration into workflow need to be thoroughly evaluated prior to attempts to integrate evidence. Evaluation of the evidence and usability testing, however, are often lacking in research design, implementation methodology, and training of researchers in this area. If the federal government, EHR vendors, or health care institutions do not support research in these areas, the integration of successful CDS tools will continue to lag in creating change in patient outcomes. At this critical juncture of widespread EHRs and pressure to bend the cost curve, incentives to help industry, government, and academic health centers to support these research areas is urgent.

Conflicts of Interest

None declared.

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Abbreviations

CDS: clinical decision support
CPRs: clinical prediction rules
EBM: evidence-based medicine
EHRs: electronic health records
OAR: Ottawa Ankle Rule
PSI: Pneumonia Severity Index
SDM: shared decision making
TIMI: Thrombolysis in Myocardial Infarction

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Original Paper

Understanding the Impact of Electronic Medical Record Use on Practice-Based Population Health Management: A Mixed-Method Study

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Abstract

Background: Practice-based population health (PBPH) management is the proactive management of patients by their primary care clinical team. The ability of clinics to engage in PBPH and the means by which they incorporate it in a clinical setting remain unknown.

Objective: We conducted the Canadian Population Health Management Challenge to determine the capacity and preparedness of primary care settings to engage in PBPH using their existing medical record systems and to understand the complexities that may exist in PBPH implementation.

Methods: We recruited a sample of electronic medical record (EMR) -enabled and paper-based clinics from across Canada to participate in the challenge. The challenge required clinic staff and physicians to complete time-controlled, evidence-based practice reviews of their patients who may benefit from evidence-informed care, treatment, or interventions across five different areas (immunization, postmyocardial infarction care, cancer screening, diabetes management, and medication recall). We formulated a preparedness index to measure the capacity of clinics to engage in PBPH management. Finally, we conducted follow-up qualitative interviews to provide richer understanding of PBPH implementation and related issues (ie, challenges and facilitators).

Results: A total of 11 primary care clinics participated, representing 21 clinician practices. EMR-enabled clinics completed a full review of charts in an average of 1.37 hours. On the contrary, paper-based clinics reviewed nearly 10% of their charts in an average of 3.9 hours, hinting that they would have required an estimated 40 hours to complete a review of charts in their practice. Furthermore, the index revealed a major gap in preparedness between the EMR and paper-based clinics (0.86–3.78 vs 0.05–0.12), as well as a broad range among the EMR clinics. Finally, building on the results of the qualitative analysis, we identified factors facilitating the integration of PBPH.

Conclusions: Our results suggest that EMR usage is pivotal in setting the foundation to support PBPH. The wide range of performance variation among EMR-enabled clinics suggests that EMR functionality and optimization, its support of clinical practice workflow, and policy issues to ensure adoption of standards are critical issues to facilitate PBPH.

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KEYWORDS

primary health care; electronic medical records; population health management; medical informatics; practice-based care

Introduction

Context

In Canada, the federal government spends 50% of its total budget on the Canada Health Transfer to the provinces and territories [1]. One common goal across jurisdictions in recent years has been to improve and transform primary care [2,3]. Statistics show that four types of chronic diseases (cardiovascular disease, cancers, chronic obstructive pulmonary disease, and diabetes) are the major causes of hospitalization in Canada and are responsible for significant mortality (153,000 patients or 75% of all deaths) and could benefit from improved primary care prevention [4]. Provincially, providing care for patients with complex chronic conditions (largely older adults) and mental health issues accounts for near 50% of health care expenditures in Ontario, Canada's most populous province [5]. All of the above conditions involve a significant role for community-based primary care providers from the aspects both of care and treatment of these conditions and of prevention among at-risk segments of their panel of patients. To prevent the negative impacts of such diseases and decrease their associated costs, it is important that regular care providers be able to proactively identify vulnerable or at-risk patients who may benefit from screening, treatment, or interventions [6-8].

To do this, scholars and practitioners have increasingly recognized the importance of actively managing population health at the primary care level as an essential factor in improving quality of care outcomes [6,9]. It is widely recognized that, to provide a better quality of care for patients with acute and chronic diseases and improve health outcomes, it is important to effectively prevent disease and disability at a population or community level, and potentially at the district or country level [10-12]. This issue is becoming especially important, due to the challenges presented to public health in the international primary care context by the upsurge of new diseases and infections, immigration and change in community demographics, social and economic determinants of health, and enduring environmental disasters [3].

One major effort has been to establish practice-based population health (PBPH) methodologies and procedures for primary care practice [13,14]. PBPH management has been defined as "an approach to care that uses information on a group (population) of patients within a primary care practice or group of practices (practice based) to improve the care and clinical outcomes of patients within that practice" [15]. PBPH focuses on an entire population or its subset (eg, a community) with a common health problem or risk exposure. The goal is to identify and address everyone who is within the target population, and to pinpoint health priorities and actions through a systematic assessment and selection process, with an emphasis on provision of equitable prevention services [16]. To ensure that preventive maneuvers are updated and to fully implement PBPH management, clinical teams need accurate data on the population from their medical records [13,17]. However, medical records kept in paper format make it difficult to optimally retrieve documented information and subsequently integrate PBPH into daily practice workflow [18,19].

One of the key elements that can improve practice engagement with PBPH is the integration of information technology, data quality of electronic patient records, and integrated administrative and clinical workflow [7,20]. This is generally conducted through implementation, adoption, and use of electronic medical record (EMR) or electronic health record (EHR) systems [17,18,21]. Indeed, previous research has shown that the adoption of technological advances such as EMR and EHR systems is key to enabling positive outcomes from implementing PBPH [15,19].

The benefits of electronic systems have been well recognized in the extant literature. For instance, research shows that the use of EMRs in hospital and ambulatory care settings can improve patient safety and reduce adverse events, by using alerts and reminders [22]. In addition, use of EMR functionalities and data quality management with clinicians can assist in improving preventive care maneuvers and chronic disease management [19]. Furthermore, EMR use has been found to lower the cost of care [23] by reducing staff time required for paper-based administrative duties and smoothing the clinic's management workflow for laboratory results [24]. Nevertheless, other existing studies examining the benefits of EMR implementation have provided mixed support for these areas of value [19,22,25,26].

In the context of population health management and PBPH, clinicians' use of and consultation with patient data and the provision of alert and reminder functionalities has been shown to support chronic disease management [27]. Use of EMR data in this regard is independent of electronically enabled chronic disease management software or programs that may function separately from the EMR. Indeed, use of EMR data for PBPH also depends on several factors, such as technical feasibility to access individual-level or aggregated EMR data reports and clinicians' capacity to perform aggregated review and execute follow-up with identified patients. Nevertheless, previous research has highlighted five main approaches in which use of EMR data can support PBPH [15]. First, clinicians can use EMRs to effectively identify the communities of patients who need additional health care services. For instance, lists can be generated of patients who need checkups and follow-up support, or those who require risk-reduction consultation based on specific clinical or demographic indicators. Second, EMRs with functionalities to create reminders or alerts support physicians in conducting follow-up tests, procedures, or education with a patient either within or outside of individual patient encounters. Third, EMR systems may have the ability to send unique notifications based on clinical indicators. Fourth, EMRs can graphically illustrate over time the impact of treatment or preventive maneuvers on longitudinal presentation of clinical laboratory tests or other measured outcomes. EMRs can also generate various quality reports that compare and contrast the practices of caregivers with local (clinicians within the practice),

national, or global standards, provide timely access to guidelines on common diagnosis and treatment care plans, and apply quality measures to PBPH management. Fifth, EMRs can display data in various forms (bar charts, tables), or export and print it in different forms, so that users can use data for further analysis [15,27].

Despite the potential benefits, optimizing use of EMR functionalities in primary care has been particularly complex and challenging [28]. In fact, an international survey of 5000 primary care physicians revealed that the adoption and the extent of optimized EMR usage by clinicians in North America is lower than expected [29]. Specifically in Canada, approximately one-quarter of primary care practices still used paper-only records in 2015, with substantial variation in EMR adoption between provinces [30]. Canadian EMR-enabled primary care practices are also ranked below the international average for preforming specific population health management practices [30]. In 2012, at the time of this study, only 18% of primary care physicians in Canada reported improved management and diagnosis of chronic diseases via EMR use; the rate was even lower (3%) for primary care physicians who reported using multifunctionality of their EMR system to support chronic disease management and preventive care among their panel of patients [24]. Therefore, our study sought to understand how clinics can perform PBPH efficiently in the new context enabled by technology.

Objectives

We report the design and results of the Canadian Population Health Management Challenge, in which we assessed paper-based and EMR-enabled primary care clinics located in Canada on their capacity and preparedness to engage in PBPH management. More specifically, we aimed to answer these questions: How prepared are clinics to adopt PBPH? What are the factors that facilitate PBPH management?

Methods

Sampling

We invited a sample of primary care clinics from across Canada to participate in the Population Health Management Challenge. The challenge required clinic staff or a lead physician to complete time-controlled, evidence-based practice reviews of their patients who may benefit from evidence-informed care, treatment, or interventions across five clinical areas (immunization, postmyocardial infarction care, cancer screening, diabetes management, and medication recall). We sought practices with EMR systems and practices with paper-based patient records. Requests for participation were disseminated broadly via Canada Health Infoway's provincial peer network programs and across provincial EMR funding programs. Programs were encouraged to share the invitation broadly across their networks; therefore, we do not know the total number of invitations disseminated. Community-based primary care clinics or clinician practices were eligible to participate. Clinics interested in participating contacted the study coordinator by email and were later interviewed to determine eligibility and review participation requirements. Clinics that volunteered to participate were required to appoint a lead physician or a staff member for a 6-hour period to complete the challenge at a specified date and time. Real-time monitoring and support was provided while participants completed the time-controlled, evidence-based practice reviews that made up the 6 challenge modules using a Web-based tool. The Web-based tool systematically captured the time to complete each evidence-based review module. All participants completed a Web-based orientation and registration session before the date and time they initiated the challenge. Participants completed 2 rounds of the challenge (round 1 in August 2011 and round 2 in October–November 2011).

Instruments and Measures

Clinic and clinician practice demographic data were collected during the orientation and training session: (1) the descriptive characteristics of the clinic and participating clinician practices (number of active patients, number of clinicians and care staff, year of graduation), (2) the type and use of chart recording systems (EMR, paper), and (3) the challenge participant's function within the clinic. The challenge consisted of 6 evidence-based review modules requiring participants to review active patient charts or records and enter the results of their review—all within a specified time limit (please see Multimedia Appendix 1 for formatted screen examples used to capture clinic characteristics and challenge modules).

The challenge modules were designed by a committee of practicing Canadian family physicians and primary care researchers and consisted of multiple indicators to support the appropriate definition of eligible patients within a participating practice who may benefit from evidence-informed care, treatment, or interventions across five focus areas (noted above), each completed sequentially (Table 1). We chose clinical scenarios to represent typical information retrieval situations commonly found in primary care and specifically grounded in current evidence-based practice [21,31-36]. The first task of each module required initial consultation of all patient charts (of the participating physician's practice) to identify the target patient population that met the selection criterion for the evidence-based review. Beyond a simple registry, all subsequent indicators or tasks within the module were focused on this target population to further define the patients eligible to receive the evidence-based directed care, treatment, or intervention. Finally, each module required participants to specify the source or method of data abstraction (EMR or paper charts), percentage of eligible charts that were actually reviewed within the recorded time, and the degree of confidence (assessed on a 5-point Likert scale) that the abstracted results for each module had captured all eligible patients within the practice.

Table 1. Modules and allotted time to complete each one in the Canadian Population Health Management Challenge.

Module	Description	Time limit (minutes)
1	Identify all active patients over the age of 65 years and indicate those who have not received a vaccination against pneumococcal pneumonia.	45
2	Identify all active patients who have had a myocardial infarct and indicate those for whom a statin medication has not been prescribed.	45
3	Prepare a registry, including phone numbers, of all active patients who are female over the age of 50 years and identify those who have not had a mammogram in the last 3 years.	60
4	Prepare a registry, including contact information, of all active patients who are taking the drug metformin and have a creatinine result greater than 150 μmol/L. With the registry in hand, assess the practice's ability to perform a recall of this medication.	45
5	Identify all active patients diagnosed with type 2 diabetes and indicate those for whom the latest hemoglobin A_{1c}test indicates a value greater than 0.070.	60
6	Prepare a registry, including contact information, of all active patients who are taking the drug Avandia and have been diagnosed with congestive heart failure.	45

Participants were allowed 45 to 60 minutes to complete each module. The time taken by each participant was systematically recorded by the Web-based data entry tool with automated time-out features for each module. In the event of a participant time-out, the module was halted (data entry no longer possible) and the data collected to that point were recorded to the database.

To support and enhance our understanding of user experience with the tool and ensure quality of the data collected, we conducted on-site observations at 2 clinics. Each challenge participant completed a follow-up semistructured phone interview. We developed the interview guide based on a review of the extant literature and the observational site visits that we conducted with the first paper-based and EMR-enabled sites while they completed the challenge. The guide was refined jointly with the research team and validated through 2 pilot interviews. All interviews were recorded and transcribed verbatim. As a quality improvement study, this study was not reviewed by a research ethics board. The research team did not consult patients' records and challenge modules did not require the capture of personal health information.

Development of the PBPH Preparedness Score

We formulated a preparedness score as a relative measure of a clinic's capacity to engage in PBPH management. We based clinic preparedness on two key principles: timeliness and completeness. A clinic that requires less time to specify a defined patient population with complete clinical criteria across its full panel of patients is deemed to be more prepared for PBPH management than a clinic that takes longer to complete a full panel review or has incomplete clinical criteria.

We used 2 sets of values to compute the PBPH preparedness score: (1) the total time required to complete the challenge modules, and (2) the percentage of data fields that were completed within challenge modules (degradation factor). We computed the score for each clinic that undertook the challenge on behalf of one or more clinician practices and that was supported by the time data recorded automatically by the Web-based tool and the self-reported proportion of charts actually reviewed to the overall number of patients in the physician's practice.

For each practice, we computed the mean percentage of modules completed, inclusive of all the data fields in each of the 6 modules. We then defined the mean percentage complete for clinics with multiple participating practices as the average of the mean percentage complete across all the physician practices of the clinic on a module-by-module basis. Then we combined the mean percentage complete for the clinic with the time allocated for the completion of each module and the actual time taken by the clinic to complete the modules for all practices, according to the following formula: score = (mean percentage for clinic × time allocated to complete section) / time taken by all practices to complete section.

The PBPH preparedness score can be interpreted as the percentage of the challenge that the clinic was able to complete in the allotted time. The inverse of the score, multiplied by the overall time allowed to complete the challenge, provides an estimation of the time the clinic would require to complete all tasks across modules that composed the challenge.

More precisely, we defined the percentage complete as the ratio of the number of charts that had all criteria identified (either met the criteria or did not) over the total number of charts in the clinic. This is estimated and self-reported by challenge participants for each module before advancing to the next module whether they reached the time limit or not. For the first participating clinics, we assigned an average percentage complete based on notes taken by the on-site observers. Missing values for the percentage complete of a task were imputed using the following two rules. First, if the practice had complete clinical criteria data fields within the module, we assigned full percentage (100%) complete, as all data elements were present for the required analysis. Second, if such information was not provided, we assigned zero percentage to the associated percentage completed.

We ranked clinics based on their fastest time and completeness of clinical criteria, ordering them from the highest to lowest capacity to conduct PBPH management based on the preparedness score.

We analyzed qualitative data in 2 stages. We first performed a within-case analysis of the resulting transcripts. Within-case

analysis allowed us to focus on the particularities of each case. We used documentation and observational data to corroborate and validate the insight provided by the interviews [37]. We then proceeded to a cross-case analysis in order to contrast and compare data and to allow for common patterns to emerge. For the cross-case analysis, we followed a grounded theory approach [38]. Following a round of open coding, we used an axial coding strategy, and we grouped codes with the same content and meaning into categories. From these we identified the following categories: (1) motivation to participate in the challenge, (2) current patient and clinical data retrieval challenges, (3) key learning points, and (4) future developments. Then, through selective coding, we analyzed the patterns.

Results

A total of 55 clinics responded to the national communications strategy inviting participation in the study. The study coordinator contacted and interviewed interested practices to determine eligibility and review participation requirements. Of these, 11 (8 EMR-enabled; 3 paper-based) clinics volunteered to participate in the challenge. The remaining 44 declined to participate due to lack of time and available staff, or because of personal, business, or operational conflicts with the timing of the data collection periods. Among EMR-enabled clinics, the lack of knowledge about data retrieval and getting queries from an EMR was consistently mentioned as the key reason for nonparticipation. For clinics with paper-based record systems, the task of data retrieval through manual chart reviews was the key barrier to participation. During the orientation session conducted preceding the challenge, 1 paper-based clinic withdrew because the tasks were deemed beyond the capacity of the designated staff member assigned to the challenge.

Among volunteering clinics, the main motivation to participate in the challenge was, first, to assess their performance vis-à-vis other clinics and, second, to evaluate the efficiency of their current practices. Additionally, clinic managers hoped that the challenge could advance adoption and optimized use of EMRs in Canada more generally by highlighting the potential benefits of advanced use to colleagues, regional partners, and government agencies.

Challenge modules were completed either by a primary care physician (4 clinics) or by medical record or information technology staff (7). Table 2 lists the participating clinics and other demographic information such as their location, the practice size and type of medical record keeping system, and the person responsible for executing the challenge.

Table 2. Descriptive information on clinics participating in the Canadian Population Health Management Challenge.

Clinic type and clinic number	No. of practices	Location	Size[a]	Record system type	Role of participant
EMR[b] -enabled clinics					
1	1	Ontario	7500	EMR	Office Manager
2	1	Ontario	7400	EMR	Physician
3	1	New Brunswick	8300	EMR	Physician
4	1	Quebec	22,300	EMR	Physician
5	3	Ontario	65,000	EMR + analytics database	Office Manager and IT[c]specialist
6	4	Nova Scotia	4100	EMR	IT Director
7	4	British Columbia	8500	EMR	Office Manager
8	2	Ontario	150,000	EMR	Office Manager
Paper-based clinics					
1	2	Quebec	27,800	Paper + eBilling + eAppointments	IT Manager
2	1	Quebec	23,000	Paper	Archivist
3	1	Newfoundland	3000	Paper	Physician

[a]Active patient = 1 count.

[b]Electronic medical record.

[c]Information technology.

Figure 1 illustrates each clinic's rankings based on their overall average preparedness score. See Multimedia Appendix 2 for a detailed data summary of the module results for participating clinics.

Overall, EMR-enabled clinics completed a full review (100% of active patient records) in an average of 1.37 hours. Paper-based clinics reviewed approximately 10% of charts in 3.9 hours, thus requiring an estimated 40 hours (or 1 work week) to complete a full practice review (Multimedia Appendix 2). On a scale of 1 to 5, EMR-enabled clinics were more confident than paper-based clinics that they had captured all eligible patients (overall average 3.8 vs 1.9, respectively). Figure 1 illustrates the overall preparedness score and self-reported participant confidence in completion of reviews for paper-based and EMR-enabled clinics. While an expected capacity gap does

exist between EMR-enabled and paper-based clinics (0.86–3.78 vs 0.05–0.12, respectively), results suggest a broad range among the EMR-enabled clinics, which may be due to a variety of factors to support or hinder capacity for PBPH.

To better understand the discrepancies between the clinics' preparedness and performance on conducting the challenge, we relied on our qualitative data. The analysis helped clarify the main challenges and critical issues that facilitate PBPH in primary care settings.

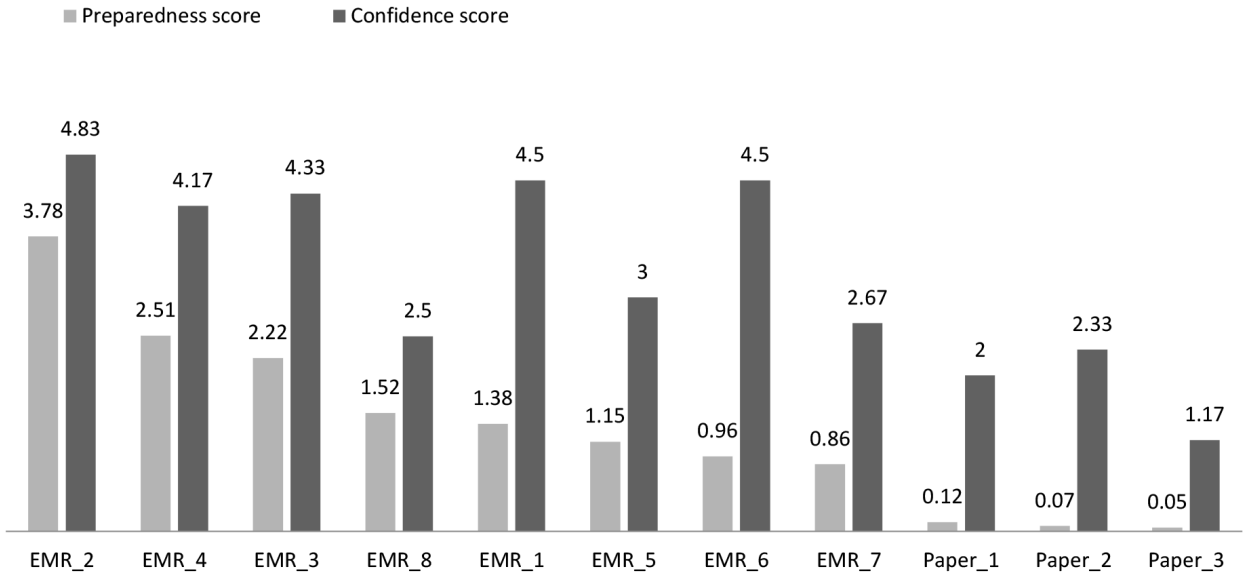
Overall, our analysis showed that participants saw data retrieval as a critical activity in their current practice, but many mentioned that they do not perform it frequently enough or on a regular basis. Yet some indicated that data retrieval may not be equally important for every staff member or clinician depending on their role in patient and population health management.

Clinical teams tend to collect a lot of information in an EMR; all interviewees were concerned that this rich source of data was not always exploited adequately. The most common challenge found to inhibit proper use of data was the logistics of data retrieval. Most participants believed that data retrieval is a difficult, time-consuming task that was not comprehensive enough in their clinic, and has technical problems and limitations that influence database updates and integration. Exploiting the data (eg, writing queries, doing data analysis) was also regarded as a complex process that necessitates both a good understanding of the system's functionalities and good access to the raw data. Almost all participants mentioned that they were not satisfied with their current data retrieval process in their practice, mostly because of the technical limitations of their systems and lack of resources required to keep track of and manage the quality of the data stored in their system.

In the participants' opinion, the most important action to be taken to improve the data retrieval process was to standardize the data items, tools, and data entry forms. Most clinics emphasized the need for an easier-to-use and more consistent data entry method and codification, so that it would reduce the complexity for physicians. They also highlighted the need for making systems more user-friendly and easier to navigate for the average staff member or clinician, particularly for those without advanced computer or statistical programming knowledge or skills.

Overall, participants assessed their participation in the challenge as a positive experience, which helped them validate their views about EMRs. It also reinforced their ideas about the effectiveness and efficiency of their current work practices and systems used in the clinic, and that it highlighted limitations. For paper-based clinics, our results supported the importance of investing in EMRs, and displayed the significant differences in terms of processing efficiencies of PBPH. For EMR-enabled clinics, the study highlighted to management and staff the ways in which they can improve their use of the system (eg, investing in training and education initiatives for current and future clinicians, establishing EMR data standards, and developing data abstraction and presentation tools), as well as where they can enhance existing tools to improve work habits, quality of care, and performance.

Figure 1. Overall ranking based on the average preparedness score across included modules in the Canadian Population Health Management Challenge. EMR: Electronic medical record-enabled clinics; Paper: Paper-based clinics.



Discussion

Our study aimed to assess the capacity and preparedness of primary care settings for PBPH. First, we developed a preparedness score to reflect upon the relative performance of the participating clinics. The sampling approach allowed the performance of paper-based manual record systems to be compared to that of EMR-enabled or automated patient record systems.

While the preparedness score shows that EMR-enabled clinics have a higher capacity and confidence in PBPH reviews, our results also highlight a gap in the ranges of preparedness scores observed. We found a 7-fold (7.2 times) difference between the best-performing paper-based clinic and the worst-performing

EMR clinic. Although a performance gap was to be expected based on existing research [14], the clinic scores showed that the actual gap is very significant. Our results also demonstrated a large gap (4.2 times) between the best-performing EMR clinic and the worst-performing EMR clinic. Based on our qualitative interviews and observation, we further found that this gap is mainly related to the absence of clear, user-friendly functional requirements regarding the use of and access to patient-level data within the current EMR systems being used by participating clinics.

In the cases of the best-performing EMR clinics, the challenge participant was a physician, as opposed to an archivist, medical office assistant, or information technology professional, who was reporting on behalf of a single practice. These clinics achieved a performance level that was, at least, 1.5 times better than the subsequent clinic among the ranked scores. Our qualitative data suggest that familiarity with the record layout and its content could explain the enhanced performance. Therefore, performance across all EMRs could be improved by incorporating data entry standards as well as coding standards. In this regard, data entry standards (eg, HL7 clinical document architecture) and coding standards (eg, SNOMED-CT) would allow medical personnel to "know where to look" and to effectively use the search capabilities of EMRs in support of PBPH. As discussed by participants, searching text fields for misspelled or aliased terms presents added complexity to the review and is also time consuming, which can further negatively affect the implementation of PBPH into practice workflow. Overall, these results are consistent with previous findings that emphasize the important role of EMRs (or information technology, in general) as the necessary factor in transforming the quality of primary care services [39,40].

Regarding paper-based clinics, the best-performing clinic achieved a performance level that was 1.7 times better than the next paper-based clinic and 2.4 times better than the lowest-level paper-based clinic. The observational data suggest that this enhanced performance was due to the mixed search strategy used by the best-performing clinic. In each module of the challenge, the initial population was determined using data held in the clinic's electronic scheduling and electronic billing systems. Once these sources had provided a narrowly defined population list, the paper charts were reviewed. The repurposing of these electronic systems allowed this clinic to effectively cross-reference their patient records and establish initial subpopulations. From this, it can be seen that PBPH could possibly be undertaken by a paper-based clinic using a series of cross-reference tables or registries. This approach could prove effective in small practices where the administrative burden of maintaining the registries could be minimized. However, in a large practice, the strategy would be extremely labor intensive and subject to completeness concerns.

Most clinics chose to report on a single clinician's practice. However, in a few cases, multiple practices were included. In line with the general findings, our data imply that, in these cases, EMR-enabled clinics have a clear advantage over paper-based clinics. In a paper-based clinic, the formulation of the query, which is the actual act of pulling a filed chart and looking at composite clinical notes and information, must be undertaken anew for each practice. In an EMR-enabled clinic, the formulation of the query is done for the first practice but is simply reused for the subsequent practice(s).

Finally, the analysis of follow-up interviews revealed the key challenges clinicians face in PBPH management. The most important issue in pursuing PBPH is the lack of systematic data storage retrieval practices in clinics. Despite advances in using information systems in health care contexts (whether for PBPH or not), many clinicians still perceive EMR use as an encounter-based electronic patient chart, instead of a tool to support prospective care and panel management [41]. Despite this, recent reports also highlight technical barriers in data retrieval and protection of privacy [42]. We also found that standardization of data and integration of databases are important steps in overcoming the challenges related to PBPH. These results are comparable with the results of previous studies that have emphasized the integration of databases and medical records that collect patient data from different sources or users [43].

Limitations

We must acknowledge some limitations to this study. Neither the instrument of measure (the challenge) nor the measure derived from the instrument (the preparedness score) was rigorously validated. Validation of the preparedness score could prove advantageous, as it could be a tool for government agencies and clinic managers to evaluate the degree of preparedness and to assess the required effort and cost in undertaking PBPH. Nevertheless, to date, the preparedness score has exhibited important interpretation properties that would support the evaluation of the cost-benefit of different medical record keeping processes.

Conclusion

The results of this study suggest that the PBPH preparedness score reflects the preparedness of the clinics participating in the challenge. The use of an EMR seems pivotal in setting the foundation to support PBPH management in primary care and subsequently to drive the associated beneficial outcomes for patients and clinicians. The range of capacity in EMR-enabled clinics suggests that for PBPH management to be effectively undertaken, key determinants of EMR optimization need to be addressed.

Despite the limitations, the study provides important contributions. The insights proposed by our findings can be used to show the criticality of EMR adoption for pursuing PBPH management. Although the results of previous studies looking at the advantages of EMR adoption have been mixed [22,25,26], our findings support the positive and significant effects of EMR use for improving the performance of clinics' PBPH practice and the potential to affect quality of care and patient outcomes. The 2015 Commonwealth Fund survey of primary care physicians reports that EMR adoption has advanced substantially among Canadian and US primary care clinics (73% and 82%, respectively) [30]. However, use of multifunctionalities to support population health management remains below the international average [30]. This study adds to our existing knowledge of the potential benefits such systems can provide

to primary health care providers and emphasizes the need for investing in initiatives to support current and future clinicians to overcome the challenges related to using data for proactive preventive and care management purposes. Furthermore, we established a tool (preparedness score) that provides a basis for comparing and contrasting the capacity of clinics to conduct evidence-informed PBPH management practices. Based on the score, stakeholders can understand the capacity of clinics' preparedness to apply PBPH efforts in a clinical setting. Overall, using a similar challenge and preparedness score can shed light on the feasibility of population health management and the issues that should be addressed in order to implement it fully with associated resources in a specific context. Finally, policy makers and EMR vendors can use the qualitative findings to help regulate and improve future EMR systems, databases, and audit-reporting analytical functionalities. Creating easy-to-use EMR systems for clinical and care teams with a straightforward, optimized design, and retrieval and analytical features to support existing clinical practices and workflow, with integrated standards (especially with regard to data entry), is among the key factors to support advanced use of EMR data for quality outcomes of patient care through PBPH.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Sample screenshots of the Challenge.

[PDF File (Adobe PDF File), 352KB - medinform_v4i2e10_app1.pdf]

Multimedia Appendix 2

Time and completeness ratio of modules for each clinic.

[PDF File (Adobe PDF File), 37KB - medinform_v4i2e10_app2.pdf]

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Abbreviations

EMR: electronic medical record
EHR: electronic health record
PBPH: practice-based population health

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Original Paper

Electronic Health Record-Related Safety Concerns: A Cross-Sectional Survey of Electronic Health Record Users

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Abstract

Background: The rapid expansion in the use of electronic health records (EHR) has increased the number of medical errors originating in health information systems (HIS). The sociotechnical approach helps in understanding risks in the development, implementation, and use of EHR and health information technology (HIT) while accounting for complex interactions of technology within the health care system.

Objective: This study addresses two important questions: (1) "which of the common EHR error types are associated with perceived high- and extreme-risk severity ratings among EHR users?", and (2) "which variables are associated with high- and extreme-risk severity ratings?"

Methods: This study was a quantitative, non-experimental, descriptive study of EHR users. We conducted a cross-sectional web-based questionnaire study at the largest hospital district in Finland. Statistical tests included the reliability of the summative scales tested with Cronbach's alpha. Logistic regression served to assess the association of the independent variables to each of the eight risk factors examined.

Results: A total of 2864 eligible respondents provided the final data. Almost half of the respondents reported a high level of risk related to the error type "extended EHR unavailability". The lowest overall risk level was associated with "selecting incorrectly from a list of items". In multivariate analyses, profession and clinical unit proved to be the strongest predictors for high perceived risk. Physicians perceived risk levels to be the highest (P<.001 in six of eight error types), while emergency departments, operating rooms, and procedure units were associated with higher perceived risk levels (P<.001 in four of eight error types). Previous participation in eLearning courses on EHR-use was associated with lower risk for some of the risk factors.

Conclusions: Based on a large number of Finnish EHR users in hospitals, this study indicates that HIT safety hazards should be taken very seriously, particularly in operating rooms, procedure units, emergency departments, and intensive care units/critical care units. Health care organizations should use proactive and systematic assessments of EHR risks before harmful events occur. An EHR training program should be compulsory for all EHR users in order to address EHR safety concerns resulting from the failure to use HIT appropriately.

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KEYWORDS

Electronic Health Records; Health Information Technology; Patient Safety; Risk Assessment; Questionnaire

Introduction

Previous success in the adoption and use of health information technology (HIT) has been darkened by the growing number of reports of its unintended consequences and potential for errors [1]. Risks associated with electronic health records (EHR) have been identified as related to technologies themselves, their applications, and their use [2]. The systematic analysis of EHR-related safety concerns is clearly a prerequisite for recognizing safety threats [3,4]. The sociotechnical approach facilitates understanding of the risks in the development, implementation, and use of EHR and HIT while accounting for complex interactions of technology within the health care system [5-12].

Sittig and Singh have provided extensive work and a foundation for understanding EHR safety. These researchers define the HIT work system as the combination of the hardware and software required to implement HIT, as well as the social environment in which it is implemented [6-8]. According to Sittig and Singh's research, HIT errors may involve failures of either structures or processes. These errors can occur in the design and development, implementation and use, or evaluation and optimization phases of the HIT lifecycle [9]. HIT-related errors occur anytime the HIT system is unavailable for use, malfunctions during use, is used incorrectly, or interacts with another system component which incorrectly results in data loss or incorrect entry, display, or transmission. The dimensions are not independent, sequential, or hierarchical, but rather interdependent and interrelated concepts similar to the compositions of other complex adaptive systems [6-8]. This approach is consistent with the currently recommended approaches to systems and human factors used to identify and minimize error [9]. HIT errors should be defined from the socio-technical viewpoint of end users [6-8].

Risk assessment is the process through which organizations develop an understanding of the risks they face [13]. This process is supported by various tools and techniques. Risk analysis consists of determining the consequences and their probabilities for identified risk events. The consequences and their probabilities are then combined to determine a level of risk [14]. Use of a risk assessment matrix is a growing practice. The simplicity and ease of use of this approach contributes to widespread adoption, including a generic international standard for risk assessment techniques to support risk management [13]. Organizations can reduce the number and severity of EHR-related safety events by anticipating the risk factors [15].

The results of a recent study suggest that EHR safety depends on persistent testing and monitoring, especially in terms of the ongoing appraisal of sociotechnical factors that affect the use and maintenance of EHRs. Because the new EHR adopters lack relevant skills and resources, it is more critical to develop techniques to support awareness of the risks, as well as their monitoring and management [16]. One method to support awareness of risks is to identify risk indicators that are easily detectable. Sittig and Singh present a red-flag-based approach that can serve to identify potential EHR safety concerns. Common EHR-related safety concerns have been identified based on Sittig and Singh's work in EHR-related patient safety, and a survey focusing on the frequency of serious EHR-related safety events, variables affecting serious EHR-related safety events, and the tracking of EHR-related safety measurements [15,16].

The research data in this study has been refined to explore users' perceptions of high- and extreme-risk severity ratings in the use of EHR. We were interested in assessing EHR users' perceptions of EHR safety issues because no previous study has explored this problem area in a specialized hospital context. Consequently, we used a mixed-methods approach in several phases to develop and validate a questionnaire based on Sittig and Singh's research and findings [15,16]. The final Finnish questionnaire consisted of eight error types, each with three to six related questions. Future research will focus on developing a tool to mitigate EHR-related safety concerns.

Methods

Research Questions

Our goal was to study health care professionals' perceptions of common EHR concerns. The specific objective was to concentrate on severe-risk error types and risk factors.

This study aimed to answer the following questions:

1. Which of the common EHR error types are associated with perceived high- and extreme-risk severity ratings among EHR users?
2. Which variables are associated with high- and extreme-risk severity ratings?

Recruitment

This study was a quantitative, non-experimental descriptive study of Finnish EHR users. A cross-sectional web-based questionnaire study took place over a four-week time period in the beginning of 2015. The study was conducted in the Hospital District of Helsinki and Uusimaa, and included 23 hospitals (covering a population of 1.6 million Finns; 34% of the Finnish population) that treat half a million patients annually. The hospital district runs the largest academic teaching hospital (Helsinki University Hospital) in Finland, which covers all medical specialties and emergency services in its different facilities. Furthermore, the district runs four regional hospitals that support local primary care outside the Helsinki metropolitan area. The entire hospital district has approximately 22,300 employees [17].

All nurses, nursing aids, physicians, clinical secretaries, and academic hospital workers (eg psychologists, pharmacists and clinical nutritionists) working, and potentially using the EHR, throughout the hospital district comprised the target population. The qualifications of health care professionals in Finland, as in other member states of the European Union (EU), are in accordance with the EU directive on professional qualifications (2005/36/EC) [18]. This directive applies to doctors, specialist doctors, nurses, specialist nurses, and midwives. There are no set entry requirements for clinical secretaries, but they do require proficient information technology (IT) skills to use and process EHRs.

These hospitals have used the same EHRs for several years. The hospital district has a computerized physician order entry with clinical decision support and major ancillary systems (ie laboratory), a picture archiving and communication system, as well as a clinical data repository for reviewing results. The closed loop medication system is not part of the EHRs. These hospitals have the same risk-assessment approach and systematic education for all clinicians as part of their patient safety programs.

The questionnaire took place in early 2015. At the same time, a new version of the EHR program was implemented in order to incorporate the system into the Finnish national health care archive, known as KanTa. Although the overall availability of EHR in 2014 was as high as 99.9%, the system's total unplanned widespread unavailability for12.4 hours during 2014 threatened the continuity of operations in these hospitals.

A commercial online platform (Webpropol) served to conduct the survey. We sent the questionnaire, with detailed information for answering, as well as an explanation of the risk matrix, to all potential EHR users (N=17,336) at the same time. Identifying exactly which individuals use EHR was impossible, so questionnaires were sent to all professionals in these groups. We also advised the participants to rate all error types and risk factors on the questionnaire in their own working environment during the last 12 months. We sent two reminder e-mails to all individuals who had not completed the questionnaire.

The organization's research review process approved the study protocol. Since patients were not the subject of this study, Finnish national legislation (488/199) did not require the approval of the Institutional Review Process for the study [19]. All respondents will remain anonymous, and the study involved no financial incentives.

Questionnaire Items and Assessment Scale

The questionnaire consisted of eight error types based on Sittig and Singh's previous research [7,15,16]. Each of the error types included three to six EHR-related safety issues or risk factors based on commonly identified EHR safety concerns.

The error type *incorrect patient identification* includes questions related to key patient-identifying information. These errors include information missing from the EHR screens or printouts, the absence of documented processes and procedures for verifying patient identification at crucial stages of patient visits, and incorrect site information or incorrect patient surgery/procedure information originated from an order that was entered for the wrong patient. One commonly recognized safety issue, in which nurses use copies of one or more patient barcode identification bands taped to their clipboard as a workaround when performing barcoded medication administration, was omitted during questionnaire development because this practice does not exist in these hospitals' EHRs.

The error type *extended EHR unavailability* means that some portion or, more likely, all of the patient's medical records are unavailable for review. This error results from total or partial failure of the EHR system, or planned downtime.

Failure to heed a computer-generated warning or alert is an error type in which critical information, even if sent to the correct person at the right time and displayed prominently on the computer screen, can be overlooked due to an overabundance of other false-positive information. This error means that items can potentially indicate the existence of a given condition when this is actually not the case. Overlooked data such as these can lead to erroneous or delayed diagnoses or treatments.

System-to-system interface errors are the result of communication problems between applications. These errors can prevent data from one application (eg a laboratory system) from reaching another application (eg the EHR), or corrupt the data itself.

Failure to find or use the most recent patient data errors can cause clinicians to make erroneous clinical decisions and lead to incorrect, unnecessary or delayed tests, procedures, or therapies. Such failures usually result from difficulties navigating, viewing, understanding, or interacting with user interfaces.

The error type *EHR time measurement translational challenge* occurs when the computer cannot properly translate time measurements as EHR users understand and enter them. Examples of consequences associated with this error type include routine tests, medications, or procedures that can be ordered *daily*, yet continue long after they are clinically needed because the order lacked a stop date.

Incorrect item selected from a list of items is an error type that occurs when an EHR user inadvertently selects a listed item that appears directly over the item the user intended to select. Such errors can occur if the user fails to notice or understand the difference between items, or simply selects the incorrect item. *Open, incomplete or missing orders* can result from failure to complete the order entry process, including signing and submitting the orders.

Health care failure mode and effects analysis (HFMEA) is a technique for preventing process and product problems before they occur. HFMEA focuses on what problems could occur, as well as their severity [20]. The HFMEA approach entails the prioritization of potential risks by determining the severity and probability of a failure mode [21]. The questionnaire scale in this study was based on the qualitative risk matrix after consulting with a professor of risk assessment research. The basic structure of the risk matrix is consistent with a widely adopted concept of risk and consists of one axis representing categories of probability (likelihood or frequency) of possible hazardous events, while the other axis represents categories of severity (impact or consequences) of those events (ie how often do these things happen, and how bad are they when they occur?). Each intersecting cell of the matrix (ie column-row pair) is pre-assigned an overall risk severity as insignificant, low-, medium-, high-, and extreme-risk. The questionnaire scale consisted of these values, with *insignificant* corresponding to a value of 1 and *extreme-risk* to 5 [22,23].

Statistical Analyses

We sent the questionnaire to every potential EHR user, encompassing all staff members in the hospital district's 23

hospitals. Previous data on personnel absenteeism of the 17,336 total staff members indicated that at least 10% of them would be on different kinds of leave (eg sick, study, maternity, parental, or research leave) and thus ineligible to participate in the survey.

Of the 15,602 eligible respondents, 2868 completed the survey, yielding an overall response rate of 18.38%. Of the 2868 respondents, 4 were eliminated due to missing data on all but a few questions, leaving a final dataset of 2864 respondents. To assess the representativeness of the sample, we gathered the sex, age, profession and education distributions of all staff members from the hospital district's centralized human resources (HR) systems' personnel records, and used $\chi 2$ tests to compare the corresponding sample distributions between participating and non-participating employees. Despite the relatively low response rate, comparison of the respondents' background characteristics to personnel department data on all staff members revealed only a few significant demographic differences between participating and non-participating employees. We also collected information on the respondents' sex, age, profession and education distributions from the HR systems and used $\chi 2$ tests to compare the corresponding sample distributions. The sex, age and education distributions did not differ in a statistically significant manner from the staff records. Registered nursing professionals and medical doctors, compared to other professionals, were slightly overrepresented in the sample ($P<.001$). However, this was not considered problematic, since only respondents who did not use the EHR were asked not to answer the questionnaire, and non-users consisted mainly of professionals other than nurses and doctors (eg administrative department staff).

The dependent variables were based on the eight multi-item scales described above, each having between three and six individual question items. We tested the reliability of the summative scales with Cronbach's alpha. All of the dimensions showed good internal reliability, with alpha values ranging from .789 to .888 (see Multimedia Appendix 1). For the statistical analyses, we regrouped each of the multi-item scales into binary variables. After the preliminary analyses, we decided to define the outcome variable as responses of "Poses a high risk" (value 4 on a scale from 1 to 5) or "Poses an extreme risk" (value 5 on a scale from 1 to 5) to any of the items on the subscale. We chose this cut-off point because reporting a severe risk related to patient care was considered an important indicator of patient safety. Logistic regression served to assess the association of the independent variables to each of the eight risk factors.

After initial univariate models and model selection using backward variable selection, including all of the available independent variables, only the following information about a respondent figured in the final multivariate models: profession, type of clinical unit, professional experience (in years), EHR training mode (type of EHR training received , such as classroom training or eLearning) and self-reported EHR skills (assessed on a scale of 4 to 10 and regrouped into three groups labeled *poor*, *fair*, and *good*). In the models, we included variables at $P<.10$ level of significance, and a 95 % confidence level was used to calculate CIs. We used statistical software R version 3.1.2 to carry out all statistical analyses [24].

Results

Respondents' Characteristics and Perceived Risk Level

The final dataset consisted of 2864 eligible respondents, 85.16% (2439/2864) of whom were women and 77.72% (2226/2864) of whom were aged 34 years or older. The participants were primarily nursing professionals (71.37%, 2044/2864) and held a university of applied sciences or equivalent degree (56.81%, 1627/2864); 15.12% (433/2864) were physicians. As expected, the largest proportion of participants (57.19%, 1638/2864) worked in a ward or outpatient clinic.

Of the respondents, 92.18% (2640/2864) used EHRs several times per shift. An additional 3.00% (86/2864) of the respondents said they consulted the EHR system once or twice per shift, while 1.01% (29/2864) of the respondents did not use the EHR themselves, but acted as the superior of other EHR users and consequently were aware of EHR risk factors.

A total of 30.73% (880/2864) of the respondents had participated in EHR eTraining, 28.04% (803/2864) attended a general lecture about EHR, and 21.30% (610/2864) received classroom training; 10.61% (304/2864) received personal guidance or training from an IT support person.

The distribution of background variables and the percentage of respondents reporting a high- or extreme-risk rating per error type (defined as reporting a high or extreme risk level on at least one subscale item) appears in Multimedia Appendix 2.

The highest proportion, nearly half of the respondents in both gender groups (48.99%, 1403/2864), reported a high-risk level related to *extended EHR unavailability*. A high perceived risk was reportedly related to *incorrect patient identification*, *system-to-system interface errors*, *failure to find or use the most recent data*, *EHR time measurement errors*, and *open/incomplete orders*. The lowest overall risk level was associated with *selecting an incorrect item from a list of items* (27.02% [659/2439] of females and 32.94% [140/425] of males). Men reported higher levels of perceived risk scores than did women. Older respondents tended to report higher risk levels, but the association was inconsistent across all error types.

Physicians reported higher risk levels on all of the eight factors, especially those relating to *extended EHR unavailability* and *failures to find the most recent patient data*. Registered nursing professionals reported the second highest overall risk scoring, and the highest values were related to *extended EHR unavailability* and *open/incomplete or missing orders*. Clinical clerks and academic specialists reported lower risk levels than did other professionals. Clinical clerks' highest perceived scoring was related to *extended EHR unavailability*, whereas academic specialists' highest values were related to *failure to find or use the most recent patient data* and *system-to-system interface errors*.

Emergency departments (ED), operating rooms (OR), and procedure units were associated with higher perceived risk levels, whereas clinical laboratory and radiology units were related to lower risk scoring. Professionals working on general wards reported high-risk scoring on *extended EHR*

unavailability, *failure to find or use the most recent patient data*, and *open, incomplete or missing patient data*.

Having received no EHR training was associated with higher perceived risk levels, and classroom and eLearning correlated with lower risk levels. However, we found no differences in the error type relating to *system-to-system interface errors*. Poor self-reported EHR skills were related to high perceived risk.

Factors Associated with Perceived Risk Ratings in Multivariate Logistic Regression Analyses

The initial univariate analyses (results not shown) found profession and clinical unit to be the strongest predictors for perceived high- and extreme-risk ratings. Physicians reported a higher perceived risk on all risk dimensions (odds ratios between 1.21 and 2.55). The associations remained statistically significant in the multivariate analyses, even after adjusting for education, work experience, type of EHR training received, and self-reported EHR skills for all of the risk factors, except the one related to *incorrect patient identification* (odds ratios between 1.30 and 2.51). Academic specialists reported lower levels of perceived risk, and the association remained significant in multivariate models of four of the eight risk levels measured.

Health care professionals working in EDs, ORs, and procedure units reported higher perceived risk ratings on all error types. The association remained robust for most dependent variables, even after adjusting for profession and other background variables. Professionals working at an intensive care unit (ICU)/critical care unit (CCU) reported higher perceived risk ratings on *extended EHR unavailability*, *system-to-system interface errors* and *open, incomplete or missing orders*, but in the multivariate models the association remained significant only for *interface* errors. Lower perceived risk levels were associated with working in a clinical laboratory or in radiology, providing less acute patient care, and working in outpatient units, although to a somewhat lesser degree.

Prior participation in eLearning courses on EHR-use was associated with lower risk ratings on some of the risk factors (*extended EHR unavailability*, *P*=.03; *EHR warning dismissed*, *P*=.015; *failure to find or use the most recent patient data*, *P*=.018). General lecture training was associated with greater risk, although the association did not remain significant in most of the multivariate models. As expected, poor self-reported EHR-use skills were associated with higher risk ratings, and the effect remained significant even after controlling for other factors. However, controlling for the level of EHR-use skills in multivariate models failed to explain the association of the other factors with the risk dimensions. The association of background variables with perceived EHR risk rating appears in Multimedia Appendix 3.

We also tested the interaction between professional qualification and working unit. The interaction terms did not remain significant in the multivariate analyses, in large part due to small sample sizes in some of the subgroups. To analyze the joint association between profession and clinical unit, we combined academic specialists and clinical clerks into one group and assigned labor wards to the *other units* group (see Figure 1 and Multimedia Appendix 4 for margins of error and 95% CIs).

In EDs and ORs we detected a general tendency towards relatively high-risk factors in all professional groups, except for *system interface errors* and *failures to find most recent patient information*, for which physicians reported higher risk levels than did nurses. Physicians generally tended to report higher risk for outpatient wards and general wards. Figures 1-4 show the proportion of high-risk assessments according to respondents' professions and clinical units.

Figure 1. Proportion of high risk according to respondents' professions and clinical unit (+95% CIs) in incorrect patient identification.

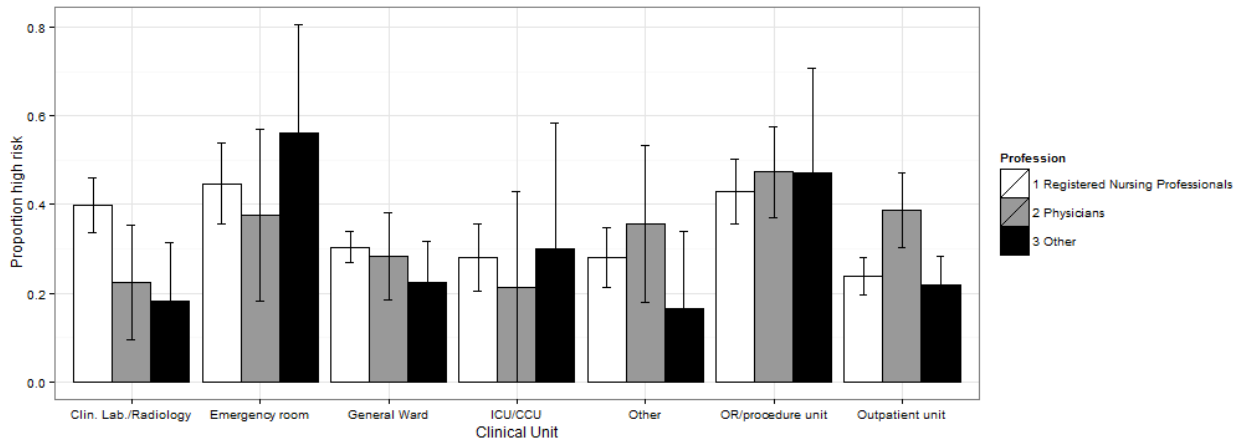


Figure 2. Proportion of high risk according to respondents' professions and clinical unit (+95% CIs) in extended EHR unavailability.

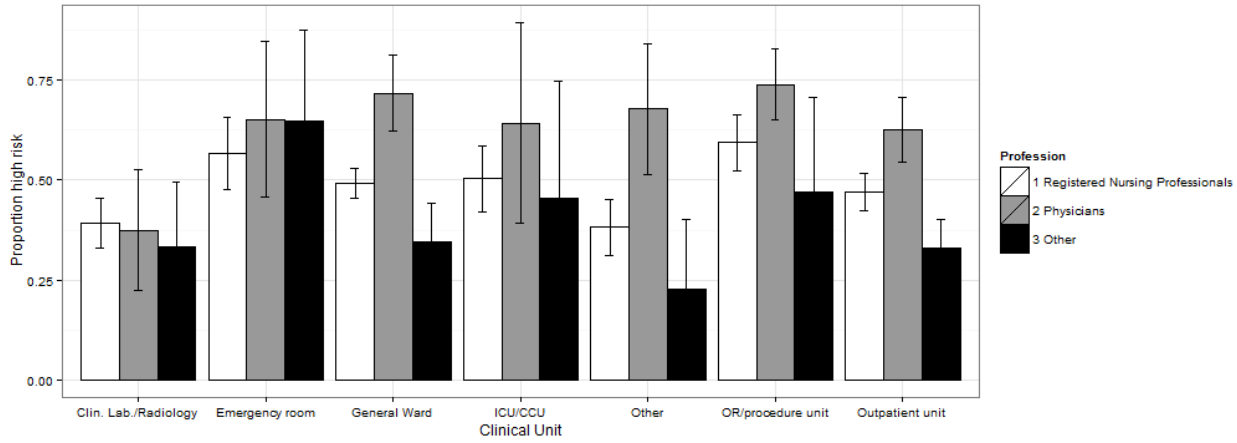


Figure 3. Proportion of high risk according to respondents' professions and clinical unit (+95% CIs) in system-to-system interface errors.

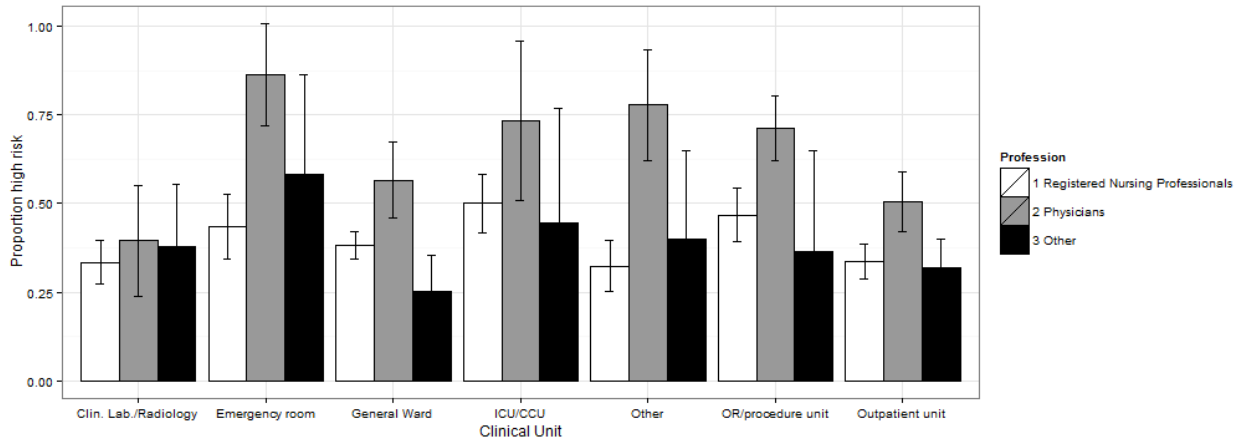
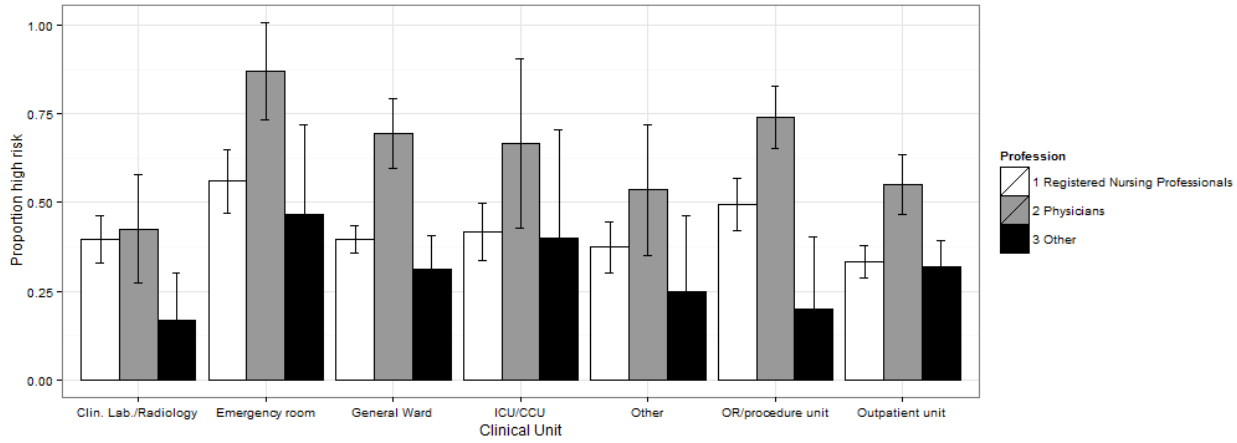


Figure 4. Proportion of high risk according to respondents' professions and clinical unit (+95% CIs) in failure to find or use the most recent patient data.



Discussion

Principal Results and Comparison with Prior Work

Research interest in EHR safety has been growing recently [25,26], but data specifically relating to EHR risk levels and severe-risk problem areas remain scarce, and to date no studies have explored this kind of specialized hospital context. One previous survey of risk managers and health care system lawyers provided valuable data about EHR-related serious events, but lacked EHR users' perceptions. This previous survey also notes that additional data are needed to identify the extent of EHR-related safety concerns. To date, serious EHR-related events appear to be underreported and understudied [27].

Our study findings are based on a large number of EHR users in hospitals with a 100% degree of EHR implementation; approximately 92% of respondents used the EHR system several times per shift. Consequently, respondents were well aware of existing EHR safety concerns in their working environment. Despite the lack of similar studies, our results can be compared with previous study results.

Almost half of the respondents reported a severe perceived risk level related to *extended EHR unavailability*, which was perceived to be an especially high-risk area in EDs and CCUs. Although previous studies have not found this result, it can be explained by the fact that the literature has recognized *error type* as a high priority practice in all areas of EHR safety and, as such, a critical safety issue. Loss of continuous access to patient information risks leading to patient injuries [28]. Our finding of severe perceived risk can also be explained by hospitals with 100% EHR adoption rates, where paper records are no longer in use and comprehensive contingency plans have seen only partial implementation. Our results stress the importance of contingency planning, which includes processes and preparations that should be available when an incident occurs. The organizations' activities, structured processes, and tasks are core requirements to continue operating and to minimize patient risk [29-32]. This area is important, especially because unexpected downtimes related to EHRs are fairly common in US-based health care organizations [33], and also occurred in this study. Moreover, this EHR concern merits greater interest, as the adoption of EHR systems has grown in recent years and continues to grow steadily [34]. A recent study in the United States shows that concerns about future EHR-use are related to the prolonged downtime of EHR systems, even if such incidents have seldom occurred in the past five years [27]. The potential consequences of an EHR downtime failure have become a cause for increasing concern as hospitals and health care organizations adopt large-scale EHR systems to handle many operations within the broader health care system. This also means that downtime can quickly affect not just a single ward or department, but an entire community [2,34,35]. We seek to emphasize how potential risks related to EHR downtimes are known to occur long after implementation [2]. Our study reinforces this previous result.

Previous studies have also shown that most (94%) safety concerns are related to either unmet data-display needs in the EHR, software upgrades or modifications, data transmission between components of the EHR, or hidden dependencies within the EHR [28]. In our study, approximately 40% of severe perceived risk was related to *system-to-system interface errors*, failure to find or use the most recent data, *EHR time measurement errors*, and *open or incomplete orders*. Unlike previously published studies, the lowest overall risk level in this study was associated with *selecting an incorrect item from a list of items*. *Selecting an incorrect item from a list of items* is partly a user interface issue, and previous studies have shown that usability is a key attribute of EHR system quality among users [32,36]. Studies have also reported that clinicians' safety concerns often stem from EHR design and usability which fail to meet user requirements [37]. Our result for this specific error type may result from regulations [38] related to the safety and performance of medical devices in the EU. Products that fall within this scope (eg medical software) must meet all applicable essential safety requirements and must bear an EC conformity mark to indicate that they comply with all relevant EU directives. Manufacturers may only put medical devices into service that do not compromise the safety and health of patients, users and others. Therefore, the most obvious issues in the program (eg overly narrow columns in the drop-down menus) have been corrected.

In this study, profession proved to be a strong predictor for severe perceived risk, alongside clinical unit. Physicians reported a higher perceived risk with all EHR problem areas and factors. Large questionnaire studies in Finland have explored physicians' views about EHR development and confirmed that physicians were critical of their IT systems [39]. High satisfaction among physicians associated strongly with perceived benefits [40]. In Finland, the previous survey results [39] showed that the EHR tools that physicians used daily can lead to a waste of operative resources and hinder physicians' work. This result may also partly explain the physicians' perceptions in this study, but this question requires further research.

In EDs, ORs, and to a somewhat lesser degree ICUs, the risk factors tended to be relatively high for all professional groups, except for *system interface errors* and *failures to locate the most recent patient information*, for which physicians reported higher risk levels than did nurses. A recent study indicates that the use of EHR technology strongly impacts ICU physician work (eg more time spent on clinical review and documentation) and workflow (eg clinical review and documentation becoming the focal point of many other tasks) [41]. Studies in the literature have examined the unintended consequences of information systems in EDs. The unique and particularly challenging characteristics of EDs, including rapid turnover, frequent transitions in care, constant interruptions, variation in patient volumes, and unfamiliar patients, make the ED environment particularly prone to errors. Thus, those implementing and maintaining HIT in such environments must give these factors careful consideration [42].

Participation in eLearning courses on EHR-use was associated with lower risk for some of the risk factors. Conversely, self-reported poor EHR-use skills were associated with higher risk scoring. This result can be viewed in the light of previous research. One of the major factors limiting clinicians' adoption of an EHR system is low computer literacy and inadequate EHR training. A general consensus suggests a need for on-going support and additional systems training to optimize the efficient use of EHRs, but studies in this area are few. One study often identified learning as a necessary and inevitable condition for the efficient use of EHR [43,44]. Training supports EHR adoption and use, and according Ventres, high-quality training improves physicians' proficiency in using an EHR system [45]. Consistent with these results, inadequate and poor-quality training was associated with poor utilization of EHR and participants failed to benefit from the full potential of the EHR system [46] . Additionally, one should take into account the broader educational perspective of informatics when striving to achieve safe care; informatics is an essential component of health care organizations' skills and HIT safety, and should be

integrated into educational programs [47,48]. Consequently, EHR training and skills supporting more efficient use seem to affect how EHR safety issues are controlled. Thus, EHR training is one core solution for meeting EHR safety concerns resulting from the failure to use HIT appropriately, or the misuse of HIT.

Finally, because comprehensive data on IT-related safety events are lacking, alternative approaches are needed to assess and respond appropriately to the HIT-related safety risks. The health information technology safety (HITS) framework described in a recent paper suggests that organizations will change their existing patient safety structures and processes to incorporate the unique set of skills needed for comprehensive HITS measurement. Organizations are encouraged to use clinicians trained in clinical informatics, and utilize a multidisciplinary oversight committee to help identify and prioritize risks [49]. The questionnaire developed for this study is one potential tool for this kind of approach.

Limitations

Readers should take into account certain limitations of our study. Like all questionnaire studies, ours was subject to potential problems associated with response bias [50,51]. Some employees who responded to our survey may have had a greater interest in problems with EHRs than did non-responders. Thus, although our data may overestimate the actual risk level of electronic health records, it still provides valuable new information, especially about the variables associated with the most critical problem areas.

Possible validity and reliability weaknesses of the questionnaire are the most significant issues to be taken into account in this type of research. Considerable resources served to ensure a process of translation and adaptation in this study. The multi-phased questionnaire development process aimed to ensure semantic equivalence of the translated terms, thereby rendering good final face validity.

Some limitations in the study design limit one's capacity to generalize the findings to a wider context. The response rate was relatively low, as is typical of many questionnaire studies [51,52]. Time constraints are reportedly a major barrier to studying health care professionals' perceptions in this hospital setting. Consideration of the length of the questionnaire is thus relevant. Our questionnaire is designed to address the most important EHR problem areas at this time, and shortening it would have proved difficult. In the future, however, these problem areas may be revised as needed.

The use of qualitative assessment scales is subjective, and raters tend to vary. The fact that the personnel at responding hospitals systematically received training in the use of the risk matrix as part of the patient safety program significantly increased the reliability of this study.

Conclusions

In conclusion, HIT safety hazards should be taken very seriously. Health care organizations should systematically assess EHR risks before harmful events occur. On the basis of this questionnaire study of 2864 respondents, our study indicates that the error type *extended EHR unavailability* is perceived as the most serious safety concern. The perceived risk ratings were relatively high for all professional groups in EDs and ORs. Consequently, implementing and maintaining EHRs in these areas will require consideration and follow-up.

Previous participation in eLearning courses on EHR-use was associated with lower risk for some of the risk factors. EHR training programs and preferably well-designed eTraining courses should be compulsory for all EHR users. EHR training is an important solution in meeting EHR safety concerns resulting from the failure to use HIT appropriately.

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Conflicts of Interest

None declared. This work benefited from the support of Finnish governmental research funding (study grant TYH2014224).

Multimedia Appendix 1

Sum variable means and reliability estimates (N=2678).

[PDF File (Adobe PDF File), 31KB - medinform_v4i2e13_app1.pdf]

Multimedia Appendix 2

Distribution of background variables and proportion of respondents reporting a high- or extreme-risk severity rating, including margins of error and 95 % CIs for the proportions (N=2864).

[PDF File (Adobe PDF File), 383KB - medinform_v4i2e13_app2.pdf]

Multimedia Appendix 3

Association of background variables with perceived EHR risk rating (Odds ratios [OR], 95 % CIs, and P-values [P] from logistic regression analyses).

[PDF File (Adobe PDF File), 436KB - medinform_v4i2e13_app3.pdf]

Multimedia Appendix 4

Table A3. Proportion of high risk according to respondents' professions and clinical unit (+95% confidence intervals) by risk type including margin of errors and 95 % confidence intervals for the proportions (N=2,864).

[PDF File (Adobe PDF File), 328KB - medinform_v4i2e13_app4.pdf]

Multimedia Appendix 5

Translation of Questionnaire Items from Finnish to English.

[XLSX File (Microsoft Excel File), 16KB - medinform_v4i2e13_app5.xlsx]

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Abbreviations

CCU: critical care unit
ED: emergency department
EHR: electronic health record
EU: European Union
HFMEA: health care failure mode and effects analysis
HIS: health information system
HIT: health information technology
HITS: health information technology safety
HR: human resources
ICU: intensive care unit
IT: information technology
OR: operating room

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Original Paper

Evaluating Health Information Systems Using Ontologies

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Abstract

Background: There are several frameworks that attempt to address the challenges of evaluation of health information systems by offering models, methods, and guidelines about what to evaluate, how to evaluate, and how to report the evaluation results. Model-based evaluation frameworks usually suggest universally applicable evaluation aspects but do not consider case-specific aspects. On the other hand, evaluation frameworks that are case specific, by eliciting user requirements, limit their output to the evaluation aspects suggested by the users in the early phases of system development. In addition, these case-specific approaches extract different sets of evaluation aspects from each case, making it challenging to collectively compare, unify, or aggregate the evaluation of a set of heterogeneous health information systems.

Objectives: The aim of this paper is to find a method capable of suggesting evaluation aspects for a set of one or more health information systems—whether similar or heterogeneous—by organizing, unifying, and aggregating the quality attributes extracted from those systems and from an external evaluation framework.

Methods: On the basis of the available literature in semantic networks and ontologies, a method (called Unified eValuation using Ontology; UVON) was developed that can organize, unify, and aggregate the quality attributes of several health information systems into a tree-style ontology structure. The method was extended to integrate its generated ontology with the evaluation aspects suggested by model-based evaluation frameworks. An approach was developed to extract evaluation aspects from the ontology that also considers evaluation case practicalities such as the maximum number of evaluation aspects to be measured or their required degree of specificity. The method was applied and tested in Future Internet Social and Technological Alignment Research (FI-STAR), a project of 7 cloud-based eHealth applications that were developed and deployed across European Union countries.

Results: The relevance of the evaluation aspects created by the UVON method for the FI-STAR project was validated by the corresponding stakeholders of each case. These evaluation aspects were extracted from a UVON-generated ontology structure that reflects both the internally declared required quality attributes in the 7 eHealth applications of the FI-STAR project and the evaluation aspects recommended by the Model for ASsessment of Telemedicine applications (MAST) evaluation framework. The extracted evaluation aspects were used to create questionnaires (for the corresponding patients and health professionals) to evaluate each individual case and the whole of the FI-STAR project.

Conclusions: The UVON method can provide a relevant set of evaluation aspects for a heterogeneous set of health information systems by organizing, unifying, and aggregating the quality attributes through ontological structures. Those quality attributes can be either suggested by evaluation models or elicited from the stakeholders of those systems in the form of system requirements. The method continues to be systematic, context sensitive, and relevant across a heterogeneous set of health information systems.

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KEYWORDS

health information systems; ontologies; evaluation; technology assessment; biomedical

Introduction

In one aspect at least, the evaluation of health information systems matches well with their implementation: they both fail very often [1,2,3]. Consequently, in the absence of an evaluation that could deliver insight about the impacts, an implementation cannot gain the necessary accreditation to join the club of successful implementations. Beyond the reports in the literature on the frequent accounts of this kind of failure [3], the reported gaps in the literature [4], and newly emerging papers that introduce new ways of doing health information system evaluation [5], including this paper, can be interpreted as a supporting indicator that the attrition war on the complexity and failure-proneness of health information systems is still ongoing [6]. Doing battle with the complexity and failure-proneness of evaluation are models, methods, and frameworks that try to address what to evaluate, how to evaluate, or how to report the result of an evaluation. In this front, this paper tries to contribute to the answer to *what to evaluate*.

Standing as a cornerstone for evaluation is our interpretation of what things constitute success in health information systems. A body of literature has developed concerning the definition and criteria of a successful health technology, in which the criteria for success go beyond the functionalities of the system [7,8]. Models similar to Technology Acceptance Model (TAM), when applied to health technology context, define this success as the end-users' acceptance of a health technology system [9]. The success of a system, and hence, the acceptance of a health information system, can be considered the use of that system when using it is voluntary or it can be considered the overall user acceptance when using it is mandatory [10,11].

To map the definition of success of health information systems onto real-world cases, certain evaluation frameworks have emerged [12,6]. These frameworks, with their models, methods, taxonomies, and guidelines, are intended to capture parts of our knowledge about health information systems. This knowledge enables us to evaluate those systems, and it allows for the enlisting and highlighting of the elements of evaluation processes that are more effective, more efficient, or less prone to failure. Evaluation frameworks, specifically in their summative approach, might address what to evaluate, when to evaluate, or how to evaluate [6]. These frameworks might also elaborate on evaluation design, the way to measure the evaluation aspects, or how to compile, interpret, and report the results [13].

Evaluation frameworks offer a wide range of components for designing, implementing, and reporting an evaluation, among which are suggestions or guidelines for finding out the answer to *what to evaluate*. The answer to *what to evaluate* can range from the impact on structural or procedural qualities to more direct outcomes such as the overall impact on patient care [14]. For example, in the STARE-HI statement, which provides guidelines for the components of a final evaluation report of health informatics, the "outcome measures or evaluation criteria" parallel the *what to evaluate* question [13].

To identify evaluation aspects, evaluation frameworks can take two approaches: top down or bottom up. Frameworks that take a top-down approach try to specify the evaluation aspects through instantiating a model in the context of an evaluation case. Frameworks that focus on finding, selecting, and aggregating evaluation aspects through interacting with users, that is, so-called user-centered frameworks, take a bottom-up approach.

In the model-based category, TAM and TAM2 have wide application in different disciplines including health care [7]. Beginning from a unique dimension of *behavioral intention to use (acceptance)*, as a determinant of success or failure, the models go on to expand it to *perceived usefulness* and *perceived ease of use* [15,7], where these two latter dimensions can become the basic constructs of the evaluation aspects. The Unified Theory of Acceptance and Use of Technology (UTAUT) framework introduces 4 other determinants: performance expectancy, effort expectancy, social influence, and facilitating conditions [7]. Of these, the first two can become basic elements for evaluation aspects, but the last two might need more adaptation to be considered as aspects of evaluation for a health information system.

Some model-based frameworks extend further by taking into consideration the relations between the elements in the model. The Fit between Individuals, Task and Technology model includes the *task* element beside the *technology* and *individual* elements. It then goes on to create a triangle of "fitting" relations between these 3 elements. In this triangle, each of the elements or the interaction between each pair of elements is a determinant of success or failure [11]; therefore, each of those 6 can construct an aspect for evaluation. The Human, Organization, and Technology Fit (HOT-fit) model builds upon the DeLone and McLean Information Systems Success Model [16] and extends further by including the *organization* element beside the *technology* and *human* elements [5]. This model also creates a triangle of "fitting" relations between those 3 elements.

Outcome-based evaluation models, such as the Health IT Evaluation Toolkit provided by the Agency for Healthcare Research and Quality, consider very specific evaluation measures for evaluation. For example, in the previously mentioned toolkit, measures are grouped in domains, such as *efficiency*, and there are suggestions or examples for possible measures for each domain, such as *percent of practices or patient units that have gone paperless* [17].

In contrast to model-based approaches, bottom-up approaches are less detailed on about the evaluation aspects landscape; instead, they form this landscape by what they elicit from stakeholders. Requirement engineering, as a practice in system engineering and software engineering disciplines, is expected

to capture and document, in a systematic way, user needs for a to-be-produced system [18]. The requirements specified by requirement documents, as a reflection of user needs, determine to a considerable extent what things need to be evaluated at the end of the system deployment and usage phase, in a summative evaluation approach. Some requirement engineering strategies apply generic patterns and models to extract requirements [18], thereby showing some similarity, in this regard, to model-based methods.

The advantages of elicitation-based approaches, such as requirement engineering, result from an ability to directly reflect the case-specific user needs in terms of functionalities and qualities. Elicitation-based approaches enumerate and detail the aspects that need to be evaluated, all from the user perspective. Evaluation aspects that are specified through the requirement engineering process can be dynamically added, removed, or changed due to additional interaction with users or other stakeholders at any time. The adjustments made, such as getting more detailed or more generic, are the result of new findings and insights, new priorities, or the limitations that arise in the implementation of the evaluation.

The advantages in the requirement engineering approach come at a cost of certain limitations compared with model-based methods. Most of the requirement elicitation activities are accomplished in the early stages of system development, when the users do not have a clear image of what they want or do not want in the final system [19]. However, a model-based approach goes beyond the requirements expressed by the users of a specific case by presenting models that are summaries of past experiences in a wide range of similar cases and studies.

Being case-specific by using requirement engineering processes has a side effect: the different sets of evaluation aspects elicited from each case, which can even be mutually heterogeneous. Model-based approaches might perform more uniformly in this regard, as they try to enumerate and unify the possible evaluation aspects through their models imposing a kind of unification from the beginning. However, there still exists a group of studies asking for measures to reduce the heterogeneity of evaluation aspects in these approaches [12].

Heterogeneity makes evaluation of multiple cases or aggregation of individual evaluations a challenge. In a normative evaluation, comparability is the cornerstone of evaluation [20]), in the sense that things are supposed to be better or worse than one another or than a common benchmark, standard, norm, average, or mode, in some specific aspects. Without comparability, the evaluation subjects can, at best, only be compared with themselves in the course of their different stages of life (longitudinal study).

In health technology, the challenge of heterogeneity for comparing and evaluation can be more intense. The health technology assessment literature applies a very inclusive definition of *health technology*, which results in a heterogeneous evaluation landscape. The heterogeneity of evaluation aspects is not limited to the heterogeneity of actors and their responses in a health setting; rather, it also includes the heterogeneity of health information technology itself. For example, the glossary of health technology assessment by the International Network of Agencies for Health Technology Assessment (INAHTA) describes health technology as the “pharmaceuticals, devices, procedures, and organizational systems used in health care” [21]. This description conveys how intervention is packaged in chemicals, supported by devices, organized as procedures running over time, or structured or supported by structures in organizational systems. Similarly, inclusive and comprehensive definitions can be found in other studies [22,23]. This heterogeneous evaluation context can create problems for any evaluation framework that tries to stretch to accommodate a diverse set of health technology implementations. This heterogeneity can present challenges for an evaluation framework in comparing evaluation aspects [24] and, consequently, in summing up reports [25] as well as in the creation of unified evaluation guidelines, and even in the evaluation of the evaluation process.

By extracting the lowest common denominators from among evaluation subjects, thereby creating a uniform context for comparison and evaluation, we can tackle the challenge of heterogeneity via elicitation-based evaluation approaches. Vice versa, the evaluation aspects in an evaluation framework suggest the common denominators between different elements. The lowest common denominator, as its mathematical concept suggests, expands to include elements from all parties, where the expansion has been kept to the lowest possible degree.

Usually, there are tradeoffs and challenges around the universality of an evaluation aspect related to how common it is and its relativeness (ie, how low and close to the original elements it lies). When the scopes differ, their nonoverlapped areas might be considerable, making it a challenge to find the common evaluation aspects. Furthermore, the same concepts might be perceived or presented differently by different stakeholders [26]. In addition, different approaches usually target different aspects to be evaluated, as a matter of focus or preference.

It is possible to merge the results of model-centered and elicitation-centered approaches. The merged output provides the advantages of both approaches while allowing the approaches to mutually cover for some of their challenges and shortcomings.

The aim of this paper is to address the question of *what to evaluate* in a health information system by proposing a method (called Unified eValuation using Ontology; UVON) which constructs evaluation aspects by organizing quality attributes in ontological structures. The method deals with the challenges of model-based evaluation frameworks by eliciting case-specific evaluation aspects, adapting and integrating evaluation aspects from some model-based evaluation frameworks and accommodating new cases that show up over time. The method can address heterogeneity by unifying different quality attributes that are extracted from one or more evaluation cases. This unification is possible with some arbitrary degree of balance between similarities and differences with respect to the needs of evaluation implementation. As a proof of the applicability of the proposed method, it has been instantiated and used in a real-world case for evaluating health information systems.

The structure of the rest of this paper is as follows. The research method that resulted in the UVON method is described in

Methods section. The result, that is, the UVON method, is covered in The UVON Method for Unifying the Evaluation Aspects section, whereas its application in the context project is covered in Result of the UVON Method Application in the FI-STAR Project section. The rationale behind the method is discussed in Discussion section and the possible extensions and limitations are found in Extending the Evaluation Using the Ontology and Limitations of the UVON Method sections. The Conclusions section summarizes the conclusions of the paper.

Methods

The FI-STAR case

The FI-STAR project is a pilot project in eHealth systems funded by the European Union (EU). The evaluation of the FI-STAR project has been the major motive, the empirical basis, and the test bed for our proposed evaluation method, that is, the UVON method (to be described in Results section). FI-STAR is a project within the Future Internet Public-Private Partnership Programme (FI-PPP) and relates to the Future Internet (FI) series of technology platforms. The project consists of 7 different eHealth cloud-based applications being developed and deployed in 7 pilots across Europe. Each of these applications serves a different community of patients and health professionals [27] and has different expected clinical outcomes. FI-STAR and its 7 pilot projects rose to the challenge of finding an evaluation mechanism that can be used both to evaluate each project and to aggregate the result of those evaluations as an evaluation of the whole FI-STAR project.

Research Method

A general review of the existing evaluation frameworks was done. Existing model-based evaluation frameworks, which usually suggest universal quality attributes for evaluation, could not cover all the quality attributes (ie, evaluation aspects) reflected by the requirement documents of the pilot projects in FI-STAR. Even if there was a good coverage of the demanded evaluation aspects, there was still no guarantee that they could maintain the same degree of good coverage for the future expansions of the FI-STAR project. On the other hand, the requirement documents from the FI-STAR project were not expected to be the ultimate sources for identifying those quality attributes. It was speculated that there could exist other relevant quality attributes that were captured in the related literature or embedded in other, mostly model-based, health information system evaluation frameworks. For these reasons, it was decided to combine quality attributes both from the FI-STAR sources and a relevant external evaluation framework. To find other relevant evaluation aspects, a more specific review of the current literature was performed that was more focused on finding an evaluation framework of health information systems that sufficiently matched the specifications of the FI-STAR project. The review considered the MAST framework [28] as a candidate evaluation framework. This evaluation framework was expected to cover the quality attributes that were not indicated in the FI-STAR requirement documents but that were considered necessary to evaluate in similar projects. These extra quality attributes are suggested by expert opinions and background studies [28]. Nevertheless, it was necessary to integrate the quality attributes extracted from this framework with the quality attributes extracted from the FI-STAR requirement documents.

Regarding the heterogeneity of FI-STAR's 7 pilot projects, an evaluation mechanism was needed to extract common qualities from different requirement declarations and unify them. A review of the related literature showed that the literature on ontologies refers to the same functionalities, that is, capturing the concepts (quality attributes in our case) and their relations in a domain [29]. It was considered that subclass and superclass relations and the way they are represented in ontology unify the heterogeneous quality attributes that exist in our evaluation case. For the purposes of the possible future expansions of the FI-STAR project, this utilization of ontological structures needed to be systematic and easily repeatable.

Results

A method was developed to organize and unify the captured quality attributes via requirement engineering into a tree-style ontology structure and to integrate that structure with the recommended evaluation aspects from another evaluation framework. The method was applied for the 7 pilots of the FI-STAR project, which resulted in a tree-style ontology of the quality attributes mentioned in the project requirement documents and the MAST evaluation framework. The top 10 nodes of the tree-style ontology were chosen as the 10 aspects of evaluation relevant to the FI-STAR project and its pilot cases.

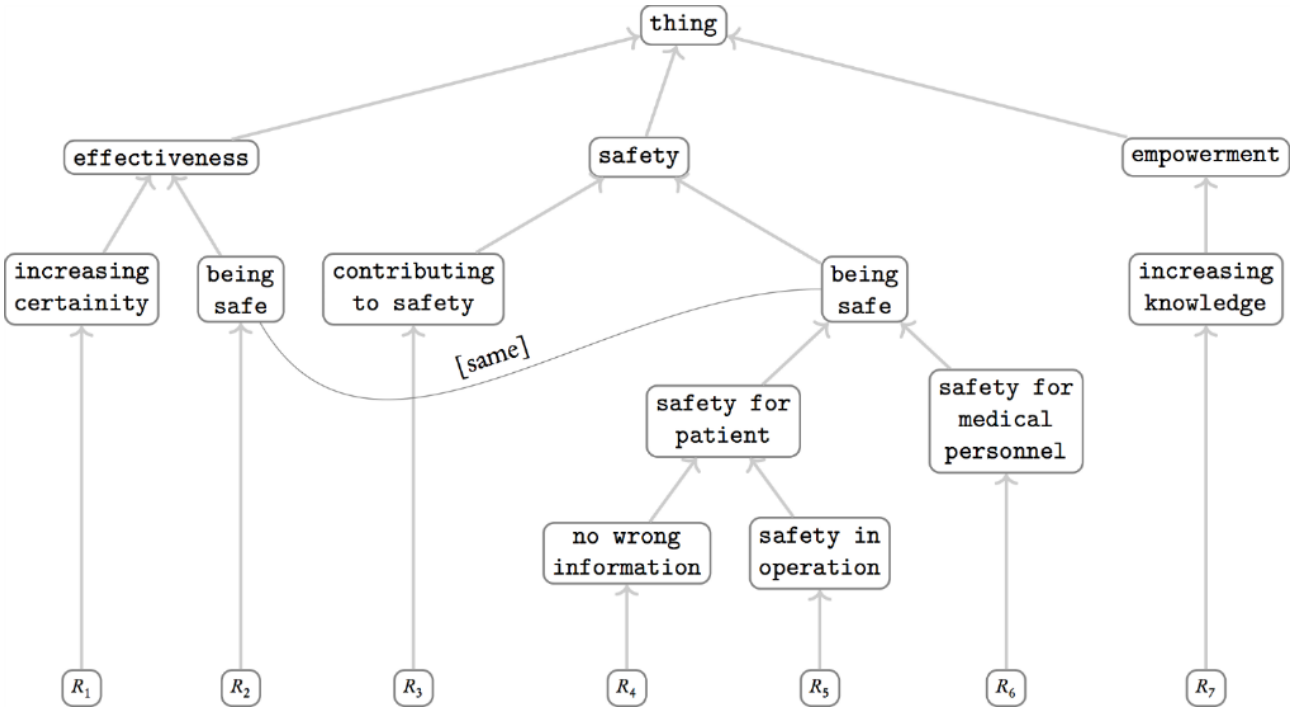
The UVON Method for Unifying the Evaluation Aspects

Methodical capture of a local ontology [30] from the quality attributes, that is, evaluation aspect ontology and reaching unification by the nature of its tree structure is the primary strategy behind our method. Therefore, the UVON method is introduced, so named to underline *Unified eValuation* of aspects as the target and *ONtology* construction or integration as the core algorithm. The ontology construction method presented in this paper is a simple, semiautomated method, configured and tested against FI-STAR project use cases. The UVON method does not try to introduce a new way of ontology construction; rather, it focuses on how to form a local ontology [30,31] out of the quality attributes of a system and use it for the purpose of finding out what to evaluate. In this regard, the ontology construction in the UVON method is a reorganization of common practices, such as those introduced by [29].

The ontology structure, in its tree form, is the backbone of the UVON method. Modern ontology definition languages can show different types of relations, but for the sake of our method here, we only use the *is of type* relation. The *is of type* relation can also describe pairs such as parent and child, superclass and subclass, or general and specific relations. This kind of relation creates a direct acyclic graph structure, which is or can be converted to a tree form. In this tree, the terms and concepts are nodes of the tree. The branches consist of those nodes connected by *is of type* relations. The tree has a root, which is the superclass, parent, or the general form of all other nodes. Traditionally, this node has been called the *thing* [29].

Figure 1 is an example of how this ontology structure can look. All the nodes in this picture are quality attributes, except the leaf nodes at the bottom, which are instances of health information systems. While going up to the top layers in the ontology, the quality attributes become more generic, at the same time aggregating and unifying their child nodes.

Figure 1. An example snapshot of the output ontology while running the UVON method.



The UVON method is composed of 3 phases: α, β, and γ (Figure 2). In the first phase, all quality attributes elicited by the requirement engineering process are collected in an unstructured set that is respectively called α set. In the next phase (β), based on the α set, an ontology is developed by the UVON method, which is called β (beta) ontology. In the next step, if the ontology is extended by an external evaluation framework (as discussed in the method), then it is called γ (gamma) ontology.

The β ontology construction begins with a special initial node (ie, quality attribute) that is called *thing*. All the collected quality attributes are going to begin a journey to find their position in the ontology structure, beginning from the *thing* node and going down the ontology structure to certain points specified by the algorithm. This journey is actually a depth-first tree traversal algorithm [32] with some modifications. To avoid confusion in the course of this algorithm, a quality attribute that seeks to find its position is called a *traveling quality attributes* or Q_t.

The first quality attribute simply needs to add itself as the child of the *thing* root node. For the remaining quality attributes, each checks to see if there exists any child of the *thing* node, where the child is a superclass (superset, super concept, general concept, more abstract form, etc) with regard to the traveling quality attribute (Q_t). If such a child node (quality attribute) exists (let's say Q_n) then the journey continues by taking the route through that child node. The algorithm examines the children of Q_n (if any exist) to see if it is a subclass to any of them (or they are superclass to Q_t).

The journey ends at some point because of the following situations: If there is no child for a new root quality attribute (Q_n), then the traveling quality attribute (Q_t) should be added as a child to this one and its journey ends. That is the same if there exist children to a new root quality attribute (Q_n), but any of them is neither a superclass nor a subclass to our traveling quality attribute. Beside these two situations, it is possible that no child is a superclass, but one or more of them are the subclass of the traveling quality attribute (Q_t). In this situation, the traveling quality attribute (Q_t) itself becomes a child of that new root quality attribute, and those child quality attributes move down to become children of the traveling quality attribute (Q_t).

To keep the ontology as a tree, if a traveling quality attribute (Q_t) finds more than one superclass child of itself in a given situation, then it should replicate (fork) itself into instances, as many as the number of those children, and go through each branch separately. It is important to note that, logically, this replication cannot happen over two disjoint (mutually exclusive) branches. It is also possible to inject new quality attributes in between a parent node and children, but only if it does not break subclass or superclass relations. This injection can help to create ontologies in which the nodes at each level of the tree have a similar degree of generality, and each branch of the tree grows from generic nodes to more specific ones.

This customized depth-first tree traversal algorithm, which actually constructs a tree-style ontology instead of just traversing one, is considered semiautomated, as it relies on human decision in two cases. The first case is when it is needed to consider the superclass to subclass relations between two quality attributes. The gradual development of the ontology through the UVON method spreads the decision about superclass to subclass relations across the course of ontology construction. The unification of heterogeneous quality attributes (nodes) is the

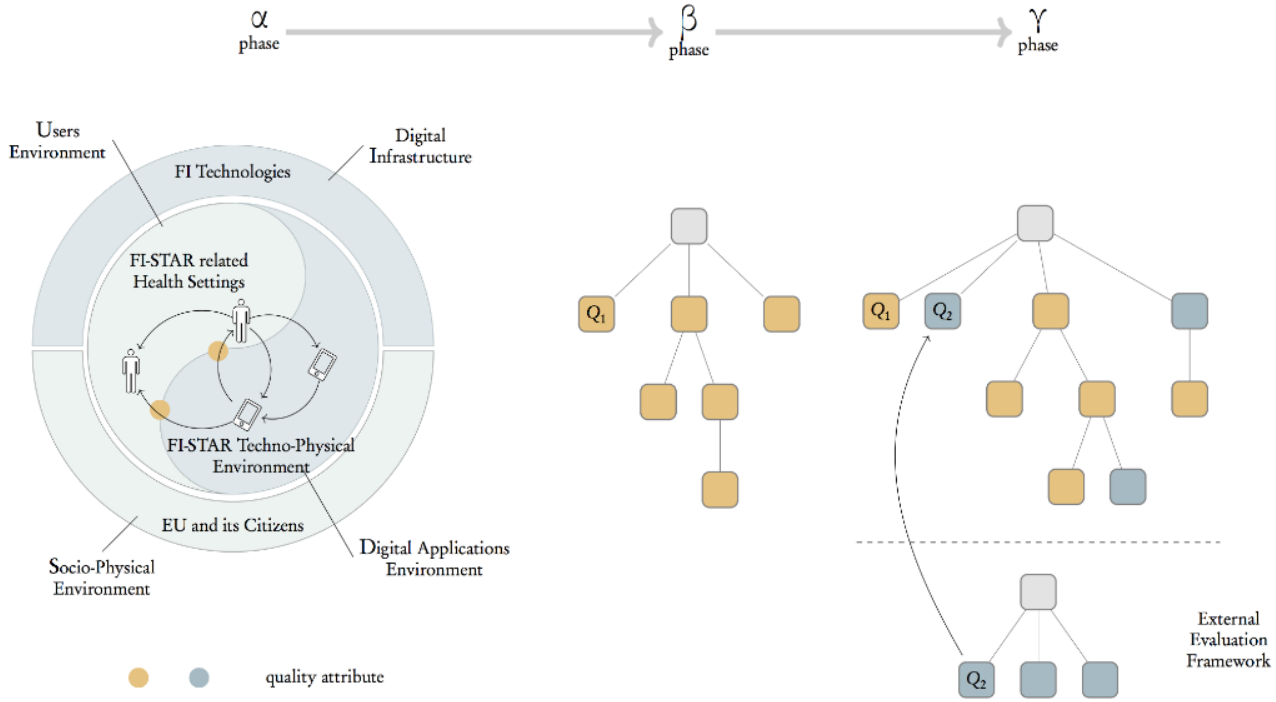
result of accumulating these distributed decisions, which are embodied as superclass to subclass relations. Each of these relations (ie, decisions) makes at least 2 separate quality attributes closer together by representing them through more generic quality attributes.

In addition, one can inject a new quality attribute to the ontology tree, although that quality attribute is not explicitly mentioned in the requirement documents. This injection is only allowed when that quality attribute summarizes or equals a single or a few sibling quality attributes that are already in the ontology. The injection can improve clarity of the ontology. It can also help adjust the branches of the ontology tree to grow to a certain height, which can be helpful when a specific level of the tree is going to be considered as the base for creating a questionnaire. This adjustment of branch height might be needed if a branch is not tall enough to reach a specific level, meaning none of the quality attributes in that branch gets presented in the questionnaire. In addition, if a quality attribute is very specific compared with other quality attributes in that level of the tree, the questions in the questionnaire become inconsistent in their degree of generality. This inconsistency can be handled by injecting more generic quality attributes above the existing leaf node in the branch. All the previously mentioned benefits come with the cost of subjectivity in introducing a new quality attribute.

The γ phase ontology is constructed the same as the β phase, but it adds materials (quality attributes) from external sources. In this sense, the quality attributes specified in an external evaluation framework, probably a model-based one, should be extracted first. Those quality attributes should be fed into the β ontology the same as other quality attributes during the β phase. The UVON method does not discriminate between quality attribute by the origin, but it might be a good practice to mark those quality attributes originally from the external evaluation framework if we need later to make sure they are used by their original names in the summarizing level (to be discussed in the following paragraphs).

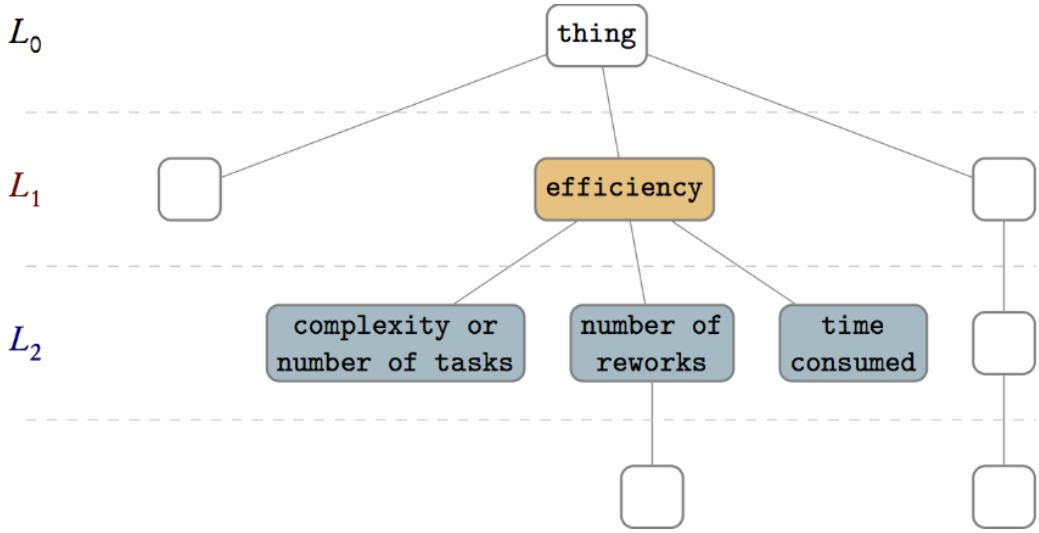
Each level of the resulting ontology tree(s)—except those that are deeper than the length of the shortest branch—represents or summarizes quality attributes of the whole system in some degree of generality or specificity. That of the *root* node is the most general quality attribute, which is too general to be useful for any evaluation; as for the levels below, each gives a view of the quality attributes in the whole system. As each parent node represents a general form of its children, each level summarizes the level below. We refer to one of these levels of the ontology tree that is considered for creating a questionnaire as the *summarizing level*.

Figure 2. Ontology construction for a health information system.



The quality attributes in each of the other levels (such as L_1 in Figure 3) can be evaluation aspects (ie, the answer to *what to evaluate*) that can be measured by a questionnaire or other measurement methods. In addition, depending on the measuring method, the level below the summarizing level can be used to give details for each of the evaluation aspects. The practicalities of measurement in a case determine which summarizing level to choose. Levels closer to the root can be too abstract, whereas deeper levels can be too detailed. In addition, the number of quality attributes in a level can impact which level is appropriate. In the FI-STAR project, the limitation on the number of questions in the questionnaire was a determinant for selecting the summarizing level, where only level 2 fit the project limitations (although level 3 helped to make each question more detailed). It is possible to grow a short branch by adding a chain of children that are the same as their parents to make the branch reach a specific level, thereby making that level selectable as a summarizing level.

Figure 3. More details can be evaluated by looking at deeper nodes in the ontology structure.



Result of the UVON Method Application in the FI-STAR Project

Harvesting the value-cases and requirement documents for all 7 trial-cases in the FI-STAR project provided the initial set of quality attributes, that is, the α set. Several quality attributes were redundant or similar, but it was left to the UVON method to unify them. There were also several quality attributes with the same wording but different conceptual indications in their respective usage contexts. These quality attributes we added to the α set with small modifications to differentiate them from each other. For example, 2 different references to *efficiency* were converted to *efficiency by reducing complexity* and *efficiency by reducing time*.

In the next step, that is, β phase, the UVON method developed β ontology by using the α set. The redundant quality attributes were integrated into single entities, whereas other quality attributes were grouped by their direct or indirect parents in the ontology structure regarding their degree of similarity or dissimilarity.

In addition, it was noticed that quality attributes are preferred—although not necessarily always—to be noun phrases rather than adjective phrases; this is because fulfilling a quality attribute expressed in an adjective phrase could imply that all of its child quality attributes need to be fulfilled. For example, to fulfill the quality of being *safe*, it is required to be both *safe for patient* and *safe for medical personnel*. This is in contrast to the *child is type of parent* relations that exist between the ontology entities. However, if we consider the noun form (noun phrase), that is, *safety* rather than *safe*, then *safety for patient* and *safety for medical personnel* are all subtopics of *safety*; hence, that would be correct and more intuitive. In addition, considering that each node in the ontology is an aspect for evaluation can make deciding parent-child relations more straightforward. For example, the *safety* node should be read as *safety aspect*, and its child should be read as *safety for patient aspect*.

Applying the UVON method in its β and γ phases, respectively, created the β and γ ontology structures (γ in Multimedia Appendix 1). The first ontology structure (β) is based on the α set of collected quality attributes, whereas the second one (γ) extends the β ontology by integrating the MAST framework evaluation aspects (grouped as domains) as specified by MAST [28]. Here, "integration is the process of building an ontology in one subject reusing one or more ontologies in different subjects" [33]. In this sense, γ ontology is constructed by mapping, aligning, or merging [34] the ontological representation of the external framework evaluation aspects (MAST in our case) to the β ontology. The result of the integration is shown in Table 1.

The MAST framework specifies 7 evaluation domains, where each contains several topics (aspects or sub-aspects) [28]. Due to the FI-STAR project requirements, we ignored *clinical effectiveness* and *sociocultural, ethical, and legal* domains (These were the job of other teams). One other domain, *health problem and description of the application* and some aspects in other domains could not be considered as quality attributes and were removed from the process. The remaining 4 domains that were fed into the UVON method are safety, patient perspectives, economic aspects, and organizational aspects. There was an interesting observation, a possible motivation for further investigations: the aspects in those 4 domains overlap considerably with the evaluation aspects that were elicited from FI-STAR users and formed into an ontology by the UVON method.

Both the β and γ ontology structures were described in Web Ontology Language (OWL) using Protégé version 4.x software. OWL, as an ontology language, can describe a domain of knowledge through its lingual elements and their relations [35]. In OWL, there exist individuals, classes, class relations, individual relations, and relation hierarchies [36]. In FI-STAR ontology structures, the individuals were mapped to the use-cases in the FI-STAR project; classes were used to represent quality attributes (i.e., the evaluation aspects); and class relations became the hierarchal relations between quality attributes (ie, *is of type* or the superclass to subclass relations). Individual relations and relation hierarchies were not used.

Table 1. The mapping between MAST evaluation aspects and the final evaluation aspects for the FI-STAR project using UVON.

MAST Domains	Aspects	Final top aspect
Health problem and description of the application		[a]
Safety		
	Clinical safety (patients and staff)	Safety
	Technical safety (technical reliability)	Safety
Clinical effectiveness		[b]
	Effects on mortality	[b]
	Effects on morbidity	[b]
	Effects on health-related quality of life (HRQL)	[b]
	Behavioral outcomes	[b](but can relate to adhereability)
	Usage of health services	[b](but can relate to adhereability)
Patient perspectives		
	Satisfaction and acceptance	[c]
	Understanding of information	Accessibility
	Confidence in the treatment	Trustability and authenticity
	Ability to use the application	Accessibility
	Access and accessibility	Accessibility
	Empowerment, self-efficacy	Empowerment
Economic aspects		
	Amount of resources used when delivering the application and comparators	Efficiency
	Prices for each resource	Efficiency
	Related changes in use of health care	[a]
	Clinical effectiveness	[b]
	Expenditures per year	Affordability
	Revenue per year	[b]
Organizational aspects		
	Process	[a](but can relate to efficiency)
	Structure	[a]
	Culture	[a]
Sociocultural, ethical, and legal aspects		[b]

[a]Not a quality attribute.

[b]Not included because of the FI-STAR project definition and division of tasks.

[c]Had been already covered by some generic questions in the output questionnaire.

Some generic nodes were inserted to group sibling nodes that were conceptually closer together in the ontology structure. If a quality attribute was connected to 2 different branches, it was forked and presented in the both branches (as described before); that keeps the ontology in a tree structure rather than an acyclic directed graph.

Applying the UVON method in the FI-STAR project case, at the end of the γ phase, 10 nodes appeared below the root of the ontology tree (Textbox 1). These 10 quality attributes at the second level of the tree are parents to other child nodes; therefore, each is the unification and aggregation of other quality attributes that were originated either in the FI-STAR requirement documents or the MAST framework and reside below these 10

quality attributes. The number 10 was within the scope of practical considerations for creating an evaluation questionnaire for the FI-STAR project, but we also considered the third level of the tree to provide more details for each question in the questionnaire. Due to separation of responsibilities in the FI-STAR project, these 10 quality attributes do not represent other aspects such as the *clinical effectiveness* or *legal and ethical* ones. The number could have been larger than 10 if we had included those aspects when applying the UVON method in the project.

Textbox 1. The list of quality attributes appearing in the second level of the ontology using the UVON method in the FI-STAR project.

Quality name

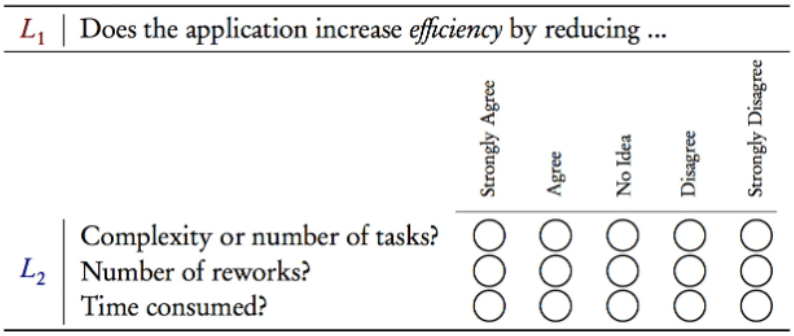
- Accessibility
- Adhereability
- Affordability
- Authenticity
- Availability
- Efficiency
- Effectiveness
- Empowerment
- Safety
- Trustability

In the FI-STAR project, the measurement of evaluation aspects was performed through a questionnaire based on those 10 extracted aspects in the γ ontology. Two versions of the questionnaire had been created: one for the patients and one for the health professionals, where each expressed the same concept in 2 different wordings (Note: one operation theatre case did not have patient questionnaire).

Generally and regarding practicalities of an evaluation case, it is possible to consider deeper levels of the resulting γ ontology in a given case. In the FI-STAR case, this possibility is reflected in a sample question on *efficiency* from the questionnaire (Figure 4), where a general question got more detailed by considering other quality attributes below the second level of the ontology. This possibility of going deeper is also depicted in Figure 3.

In the FI-STAR project, the quality attributes (and later the questionnaires) were delivered to each case's stakeholders, who were asked to validate the relevancy of each quality attribute or the corresponding question regarding their case. All the cases in the FI-STAR project validated and approved their relevancy, whereas some asked for minor changes in the wordings of some of the questions to be clearer for the patient respondents in their case.

Figure 4. Sample questionnaire output from the UVON method.



Discussion

Ontologies are formal and computable ways of capturing knowledge in a domain—whether local or global [30]—by specifying the domain's key concepts (or objects) and interconnecting them by a predefined set of relations [29]. Formality and computability help to communicate knowledge between people or software agents, enable reuse of knowledge, make explicit declaration of the assumptions, and facilitate the analysis and study of the domain knowledge [29]. Inference algorithms can infer and extract new knowledge or predict or deduce new situations by analyzing an ontology. As reflected in the previously mentioned ontology description, an ontology is structured as a network (mathematically a graph). Limiting the kind of relations between the concepts might result in specific structural forms such as trees.

An ontology would be formed as a hierarchy if the relations between the concepts are limited to the *is of type* relation, where each nonleaf concept is a more generic form or superclass to its children. This hierarchy can be an *acyclic direct graph* if we allow one concept to be a subclass of more than one other concept, and it would be a *tree* if one concept is a subclass of

only one other concept. The acyclic directed graph can be converted to a tree if we replicate the same concept-leaf in different branches. The unification that exists in the nature of a tree graph, that is, unification of branches toward the root, is the source of unification that we want to apply for the evaluation of quality attributes in health information systems; that is why the UVON method creates this type of structure.

Ontologies are traditionally the output of manual content curation and its associated consensus-establishment processes [37]. Nevertheless, automated or semiautomated methods of ontology construction might reveal considerable advantages in efficiency, repeatability, and uniformity. The UVON method described in this paper uses a semiautomatic approach toward creating tree-style ontologies for the sake of extracting evaluation aspects.

Extending the Evaluation Using the Ontology

The ontological representation of a health information system gives a computable structure from which several indications, including evaluation aspects, can be extracted. Functions can be defined on this ontology that quantify, combine, compare, or select some of the nodes or branches. The ontology itself can be extended by assigning values to its nodes and edges, giving the possibility of further inferences. For example, if 2 nodes (quality attributes) are disjoint (mutually exclusive), any 2 children from each of them would be disjoint, respectively. If during the application of the UVON method, by mistake, one quality attribute were replicated into 2 disjoint branches, then this mistake can be detected and avoided automatically (replication would be disallowed between those specific nodes).

As discussed in "Result of the UVON Method Application in the FI-STAR Project" section and shown in Table 1, we skipped the *clinical effectiveness* and *sociocultural, ethical, and legal* domains from the MAST framework due to the project definition. Nevertheless, the UVON method can consider those aspects when they are applicable and there are no project restrictions. Therefore, we hope to witness more inclusive applications of the UVON method in the future cases.

In addition, the selection of the MAST framework was due to its common themes with the eHealth applications in the FI-STAR project. We encourage application of the UVON method by considering other relevant evaluation frameworks, not necessarily MAST. The results of those applications can demonstrate the powers, weaknesses, and extension points of the FI-STAR method.

The UVON method is context-insensitive in its approach. Still, more empirical evidence, with a higher degree of diversity, is needed to examine what the challenges or advantages of applying the UVON method are in a more diverse range of fields beyond health information systems.

Limitations of the UVON Method

The UVON method is subject to conceptual and methodological limitations in its capacities. Probably, a prominent conceptual limitation is the fact that the method does not represent or give an account of the dynamics of the health information systems; hence, it cannot facilitate their evaluation. The relations in the UVON-constructed ontologies are restricted to the *is of type* relationship and cannot reflect how qualities or other indicators impact each other. The absence of insight about the dynamics of a health information system prevents predictive evaluations. In consequence, any emergent behavior that is not explicitly captured by requirement documents or the to-be-merged external evaluation framework is going to be ignored. From the other side, it can still be imagined that the output ontologies of the UVON method can be used as scaffolds in models that incorporate dynamics of health information systems.

The UVON method partially relies on subjective decision-making, which can create methodological limitations and challenges. Although the main strategy in the UVON method is to minimize these subjective decisions, the existing ones can still result in creating different ontologies in different applications of the method. As a suggestion, for the sake of reaching more convergence, it is possible to think of enhancing the method with more objective lexical analytical methods. Methods of ontology construction and integration, especially those concerning class inheritance analysis [34], can be valid candidates for these types of methods.

UVON-generated ontologies are not advised for universal application. However, for a new case of evaluation, a UVON-generated ontology that was developed for similar cases can be considered as an alternative to developing a new ontology with consideration to project resource limitations. This reuse should be accomplished with due consideration to the fact that quality attributes of the same wording might indicate slightly different meanings in different cases. This case-sensitivity of meanings might result in different subclass and superclass relations, changing the structure of the ontology and making the reuse of the unadjusted ontology problematic.

The UVON method cannot guarantee that in the output ontology each of the branches that begin from the root will reach the level of the tree (that is, have a node at that level) where we want to base our questionnaire (or any other measurement method). Hence, a short branch might need to be extended to appear at some specific tree level where the questionnaire is based. In addition, the method does not guarantee that the quality attributes in that level are all of the same degree of generality of specificity. It is also not guaranteed that the number of nodes (quality attributes) at any level matches the practicalities of evaluation; there can be too few or too many. For example, in the FI-STAR case, the number of quality attributes in the target level (level 2) had to match with the appropriate maximum number of questions that could be put in a questionnaire; fortunately, it was within the boundaries.

It is also possible, at least in theory, that all quality attributes end up being a direct child of the root *thing* node. The resultant dwarf and horizontally inflated ontology structure does not unify any of the child quality attributes; hence, the method output would be useless. The methodological limitations can result in the need for manual adjustments, such as adding extra nodes between some parent-child nodes. Of course, the manual adjustments can add more subjectivity into the formation of the ontologies.

The UVON method permits integrating evaluation aspects from other evaluation frameworks. Still, it does not guarantee that the result will include all features of the integrated evaluation framework. Still, this integration involves the suggested evaluation aspects of those evaluation frameworks. If a framework dynamically changes its suggested evaluation aspects, for example, based on the evaluation case specifications, the UVON does not follow that dynamic feature. In addition, the straightforward wordings for an evaluation aspect in an evaluation framework might be obscured by going through the integration process in the UVON method, being replaced by more generic terms.

Conclusion

The unifying nature of ontologies, when they are in tree form, can be used to create a common ground of evaluation for heterogeneous health technologies. Ontologies can be originated from requirement and value-case documents, that is, internal; they can be extracted from available external evaluation frameworks, that is, external; or they can be originated from a mix of both internal and external sources. The UVON method introduced in this paper was able to create a common ground for evaluation by creating an ontology from requirement and value-case documents of the 7 trial projects in the FI-STAR project and extend that ontology by mixing elements from the MAST evaluation framework. The UVON method can be used in other, similar cases to create ontologies for evaluation and to mix them with elements from other evaluation frameworks.

The UVON method stands in contrast with other methods that do not consider case-specific internal requirements or cannot be easily extended to include other evaluation frameworks. The ontological structure of evaluation aspects created by the UVON method offers the possibility of further investigations for other indications related to evaluation of the subject systems.

The final result of applying the UVON method in the FI-STAR project resulted in 10 evaluation aspects to be chosen for measurement. This set of evaluation aspects can grow adaptively to project changes, be repeated in similar cases, and be a starting point for future evaluations in similar projects. By applying the UVON method in more cases, a possible stable result can be suggested for the set of generic evaluation aspects that are usable in evaluation cases similar to FI-STAR.

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Authors' Contributions

Regarding the contributions, SE drafted the paper, incorporated contributions from other authors into the paper, contributed to the design of the study, developed the proposed model and method, processed data for β and γ phases of the proposed method, and contributed to the proposed method final result. PA contributed to the design of the study, contributed to the proposed method final result, supervised the research process, and reviewed and commented on the paper. TL contributed to the design of the study, supervised the research process, and reviewed and commented on the paper. SF collected data for the α phase of the proposed method and reviewed and commented on the paper. JB contributed to the design of the study, supervised the research process, and reviewed the paper.

Conflicts of Interest

None declared.

Multimedia Appendix 1

UVON-generated Ontology (in OWL) for the FI-STAR project.

[OWL File, 110KB - medinform_v4i2e20_app1.owl]

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Abbreviations

EU: European Union
FI: Future Internet
FI-STAR: Future Internet Social and Technological Alignment Research
FI-PPP: Future Internet Public-Private Partnership Programme
FITT: Fit between Individuals, Task and Technology
HOT-fit: Human, Organization, and Technology Fit
INAHTA: International Network of Agencies for Health Technology Assessment
MAST: Model for Assessment of Telemedicine applications
OWL: Web Ontology Language
STARE-HI: Statement on the Reporting of Evaluation studies in Health Informatics
TAM: Technology Acceptance Model
TAM2: Technology Acceptance Model 2
UTAUT: Unified Theory of Acceptance and Use of Technology
UVON: Unified eValuation using Ontology

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Original Paper

A Querying Method over RDF-ized Health Level Seven v2.5 Messages Using Life Science Knowledge Resources

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Abstract

Background: Health level seven version 2.5 (HL7 v2.5) is a widespread messaging standard for information exchange between clinical information systems. By applying Semantic Web technologies for handling HL7 v2.5 messages, it is possible to integrate large-scale clinical data with life science knowledge resources.

Objective: Showing feasibility of a querying method over large-scale resource description framework (RDF)-ized HL7 v2.5 messages using publicly available drug databases.

Methods: We developed a method to convert HL7 v2.5 messages into the RDF. We also converted five kinds of drug databases into RDF and provided explicit links between the corresponding items among them. With those linked drug data, we then developed a method for query expansion to search the clinical data using semantic information on drug classes along with four types of temporal patterns. For evaluation purpose, medication orders and laboratory test results for a 3-year period at the University of Tokyo Hospital were used, and the query execution times were measured.

Results: Approximately 650 million RDF triples for medication orders and 790 million RDF triples for laboratory test results were converted. Taking three types of query in use cases for detecting adverse events of drugs as an example, we confirmed these queries were represented in SPARQL Protocol and RDF Query Language (SPARQL) using our methods and comparison with conventional query expressions were performed. The measurement results confirm that the query time is feasible and increases logarithmically or linearly with the amount of data and without diverging.

Conclusions: The proposed methods enabled query expressions that separate knowledge resources and clinical data, thereby suggesting the feasibility for improving the usability of clinical data by enhancing the knowledge resources. We also demonstrate that when HL7 v2.5 messages are automatically converted into RDF, searches are still possible through SPARQL without modifying the structure. As such, the proposed method benefits not only our hospitals, but also numerous hospitals that handle HL7 v2.5 messages. Our approach highlights a potential of large-scale data federation techniques to retrieve clinical information, which could be applied as applications of clinical intelligence to improve clinical practices, such as adverse drug event monitoring and cohort selection for a clinical study as well as discovering new knowledge from clinical information.

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KEYWORDS

electronic health records; health level seven; information storage and retrieval; Semantic Web; linked open data

Introduction

Clinical Data Searches Through Knowledge Level Queries

While secondary use of electronic medical records (EMRs) are widely expected [1,2], medical data in general do not contain adequate amounts of information or knowledge in their original format, making it difficult to retrieve the desired data based on the knowledge in the clinical domain. For example, when we try to screen patients with medication history of "renin angiotensin inhibitors" as possible candidates for a clinical study, it is common for us to prepare a list of drug codes for such drug classes and query a database with the prepared list. If such a query is performed simply using an expression such as "drugs classified as renin angiotensin inhibitors," it will facilitate our use of the database. As a similar example, when we try to screen patients with medication history of "drugs that cause leucopenia," rather than having to list in a query hundreds of codes for drugs showing the adverse events, if drugs that cause leukopenia are identified using external knowledge resources, and if a search is performed over medication data based on the identified drugs, it would facilitate the research use of EMRs.

Clinical Data Searches Using Life Science Knowledge Resources

The Linked Open Data project [3] is an attempt to facilitate data usage via the Internet by making data available in a standard format based on the resource description framework (RDF). In the field of life science, attempts are being made to further increase the value of data sets by linking and integrating them as Linked Data. The Bio2RDF project [4] aims at linking and using over 20 types of data sets including the Kyoto Encyclopedia of Genes and Genomes (KEGG) [5,6], the Open Biological and Biomedical Ontologies [7], the Universal Protein Resource [8], and the Gene Ontology [9]. In addition, the National Bioscience Database Center and the Database Center for Life Science in Japan act as primary driving forces and conduct various activities to promote the use of life science data resources and abroad as Linked Data [10,11].

Applying RDF to build clinical databases for secondary use facilitates integration of external knowledge resources expressed in RDF. Teodoro et al. [12] developed a Web-based antimicrobial resistance monitoring system that uses a Semantic Web-based approach to promote the integration of heterogeneous data sources. Assélé et al. [13] developed a framework to perform SPARQL Protocol and RDF Query Language (SPARQL) queries on clinical databases to obtain results about antibiotic resistance and compared their approach with existing business intelligence approaches in terms of usability and functionality. Riazanov et al. [14] developed an ontology for the clinical domain and reported that SPARQL queries can be expressed and executed in an ad hoc manner by mapping the developed clinical domain ontology and clinical data. Pathak et al. [15,16] used publicly available life science data resources as Linked Data and searched over EMR databases integrated with these resources through SPARQL federation queries. The above studies attempt to improve search usability and functionality by applying Semantic Web technologies to supplement information lacking in the clinical data with knowledge from external resources. However, these studies dealt with only institution-specific EMR databases, and it is not easy to apply their methods at other hospitals because schemas of EMR databases generally differ between hospitals; thus, the RDF data structures constructed from these schemas also differ. To avoid these problems and make these technologies widely available, we use health level seven version 2.5 (HL7 v2.5) [17] messages as clinical data. HL7 v2.5 is a messaging standard for information exchange between clinical information systems and the most widely implemented standard for health care in the world. It specifies a number of standards, guidelines, and methodologies by which various clinical information systems can communicate with each other. HL7 messages, although not comprehensive, contain several important types of data for clinical research, such as patient demographics and diagnostic disease.

RDF for Developing Clinical Databases

Applying RDF in developing clinical databases for secondary use provides the following benefits. First, because the RDF data structure is simple, they can express highly heterogeneous data sets including clinical data, disease concepts, drugs, clinical tests, and genome information using a single data model, making it possible to integrate and handle them in a coherent manner. Second, the inference mechanism supports data sets with hierarchical relationships, such as those containing disease and drug information, through an RDF schema (RDFS) [18] vocabularies. With the relational databases typically used in clinical databases, special measures are required to express the hierarchical structures that exist in data. With RDF, however, this can be accomplished simply by adding the rdfs:subclassOf relationship between the resources. Third, RDF identifies resources through uniform resource identifiers (URIs); therefore, data can be shared via HTTP between different network locations. SPARQL federation query integrates publicly available data sets and allows different network locations to refer to and search over these integrated data sets, maintaining high confidentiality of EMRs. This is expected to be useful when developing clinical databases.

Aim of the Study

Using RDF as the format for HL7 messages, it is possible to integrate large-scale clinical data and life science knowledge resources. In this study, we implement the following measures to verify this approach. We develop a method for converting HL7 messages into RDF data. Noting that publicly available drug databases constitute useful resources for query expansion in clinical data searches, we show how SPARQL describes adverse drug events (ADEs) and perform searches using such SPARQL expressions. We also examine the search performance and discuss the applicability of the proposed approach to the searches over large-scale data.

Methods

RDF and SPARQL

Semantic Web technologies use simple data structures to integrate and use data on a Web-level scale. RDF is the most basic technology for standardizing data expressions, and it consists of a set of URI references (U), a set of blank nodes (B), and a set of literals (L). An RDF triple is a tuple of three elements, that is, a subject (s), a predicate (p), and an object (o), that satisfy $s \in (U \cup B)$, $p \in U$, and $o \in (U \cup B \cup L)$, respectively. The RDF graph is a directed graph of RDF triples. A data schema in RDF is defined by the vocabulary and semantics of the RDFS. The RDFS is a set of vocabulary and inference rules defined for the vocabulary, and the RDF processor executes these inference rules to derive new RDF triples, which are then added to the RDF graph. For example, rdfs:subclassOf is a vocabulary that defines the class–subclass relationship, and this vocabulary is defined by two rules (ie, a transitive rule and a rule to express a lower class instance being also an upper class instance). Through this inference rule, a search over a lower class and its instances becomes possible by using a higher level abstraction as the search terminology.

SPARQL is an RDF query language. It describes, in the query condition, variables of a pattern to match and their values to use for filtering and extracts the subgraphs that match the given pattern from an entire RDF graph so that the corresponding values of the specified variables are obtained. Filtering of values is performed by using FILTER keywords and by computing a boolean value using the values bound to the variables. Examples of typical functions include a function that performs matching of text strings in their regular expressions and functions that perform logic operations. One beneficial feature of SPARQL is that it can handle multiple RDF graphs as a single graph. SPARQL 1.1 further enhances this feature, making it possible for a single federated query [19] to inquire multiple RDF graphs at different network locations. A federated query expression first designates the SPARQL endpoint with a SERVICE keyword and then describes variables of a pattern to match, similar to a regular SPARQL query, in a clause that follows the endpoint. Consequently, using variables, a federation query can describe a query that can search local or remote RDF graphs.

SS-MIX2: HL7 Message-Based Clinical Data Storage in Japan

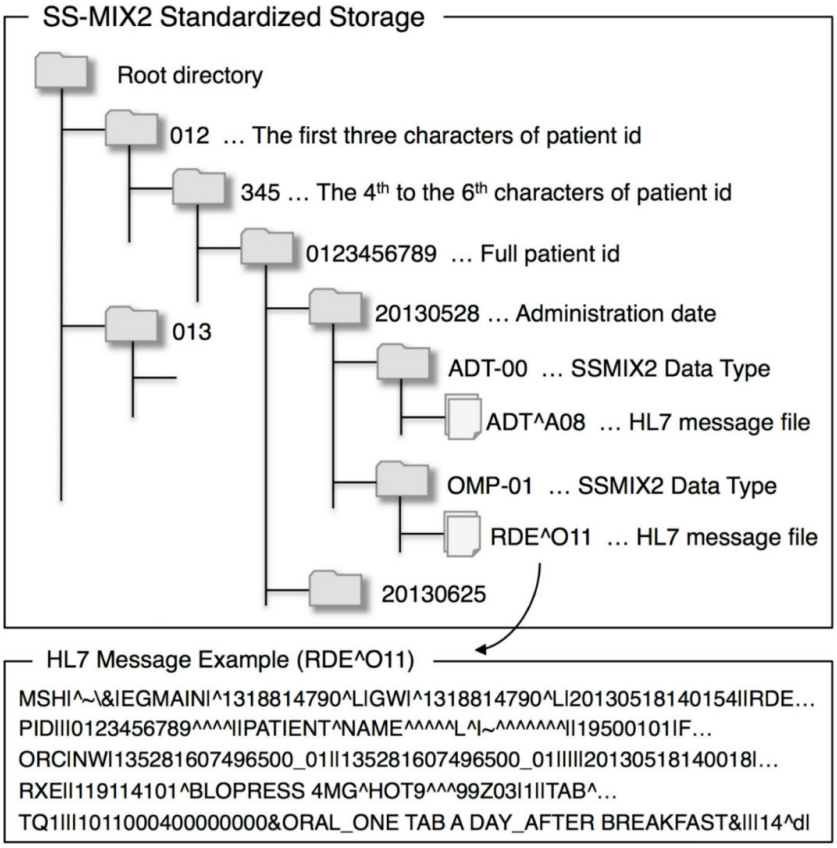
We used HL7 messages stored in the Standardized Structured Medical Record Information Exchange version 2 (SS-MIX2) that has been developed to facilitate secondary use of EMRs as a Ministry project in Japan [20,21]. SS-MIX2 defines the specification of a container for storing EMRs, and the main body of the EMRs is the HL7 v2.5 message. It consists of the standardized storage and the annex storage. The standardized storage contains structured clinical data in the form of an HL7 v2.5 message, such as patient demographics, diagnostic disease, medication orders, laboratory test results, and several kinds of examination orders. The annex storage contains nonstructured clinical data, such as clinical reports, examination reports, and imaging data in arbitrary format. Earlier than the development of the SS-MIX2, standardized terminology for drugs, laboratory tests, procedures, and diagnostic disease has also been developed by the Medical Information System Development Center (MEDIS-DC) [22], and exchange rules for clinical information to be conformed with HL7 have also been developed by the Japanese Association of Healthcare Information System Industry [23]. In 2011, the Ministry of Health, Labor, and Welfare adopted these terminologies and exchange rules as the standard specifications for the health and medical care information field, thereby facilitating the development of standardized medical information systems. Against this background, as of July, 2015, the SS-MIX2 storage has been deployed at 518 hospitals in various regions of Japan [24]. Examples of SS-MIX2 storage applications include (1) an intermediate storage linking multivendor systems and electronic medical record/order entry systems, (2) an intermediate storage for linking regional health care systems, (3) a backup data storage for use in the event of a disaster, and (4) a data source for postmarketing survey of drugs and clinical research.

Structure of SS-MIX2 Storage and HL7 Message

The SS-MIX2 stores HL7 messages below the ordinary directory trees. Under the root directory, patient identifier, administration date, and SS-MIX2 data type are hierarchically located, and corresponding HL7 messages are placed under the bottom directory. The SS-MIX2 data types identify types of clinical information, such as patient demographics, medication orders, and laboratory test results, and these data types are semantically mapped on HL7 message types. For example, HL7 message types to update or delete patient demographics are ADT^A08 and ADT^A23, respectively. SS-MIX2 uses a single data type (ie, ADT-00, for these two HL7 message types). In an HL7 message, each line is called a segment and contains a specific category of information, such as patient identification (PID), order-related information (ORC), and pharmacy (RXE). Each segment consists of a field delimited by a pipe symbol, and the field consists of a field's element delimited by a hat symbol. For example, a patient identifier is located in the third field of the PID segment and a drug code is located in the first field's element in the second field of the RXE segment. Two or more segments may be organized as a logical unit called a segment group, which might or might not repeat. The boundary of the segment group is not identical in a standard form of the HL7 message itself, but it appears in an extensible markup language (XML)-encoded HL7 message described in the next section. Some fields or a field's element may contain a code defined by a certain terminology. In the SS-MIX2, terminologies are used, such as MEDIS DRUG [22] for drugs, JLAC10 [25] for laboratory tests and International Classification of Diseases, and 10th Revision (ICD10) for diagnostic diseases, which are all provided by MEDIS-DC as a nationwide standard. Although these terminologies are unique to Japan except for ICD10, the terminology for drugs can be mapped on the Anatomical Therapeutic Chemical Classification System (ATC) and United States Pharmacopeia (USP) [26] using intermediate resources such as KEGG. This mapping information becomes the key-point to supply an HL7 message with external knowledge recourses by matching a code in the message to a class represented in the recourses. Figure 1 shows examples of an SS-MIX2 storage structure and an HL7 message.

This example HL7 message (RDE^O11) contains information on a medication order for a patient identified by 0123456789 administered on May 28, 2013. The message contains the following segments: message header (MSH), patient identification (PID), order-related information (ORC), pharmacy encoded (RXE), and timing and quantity (TQ1).

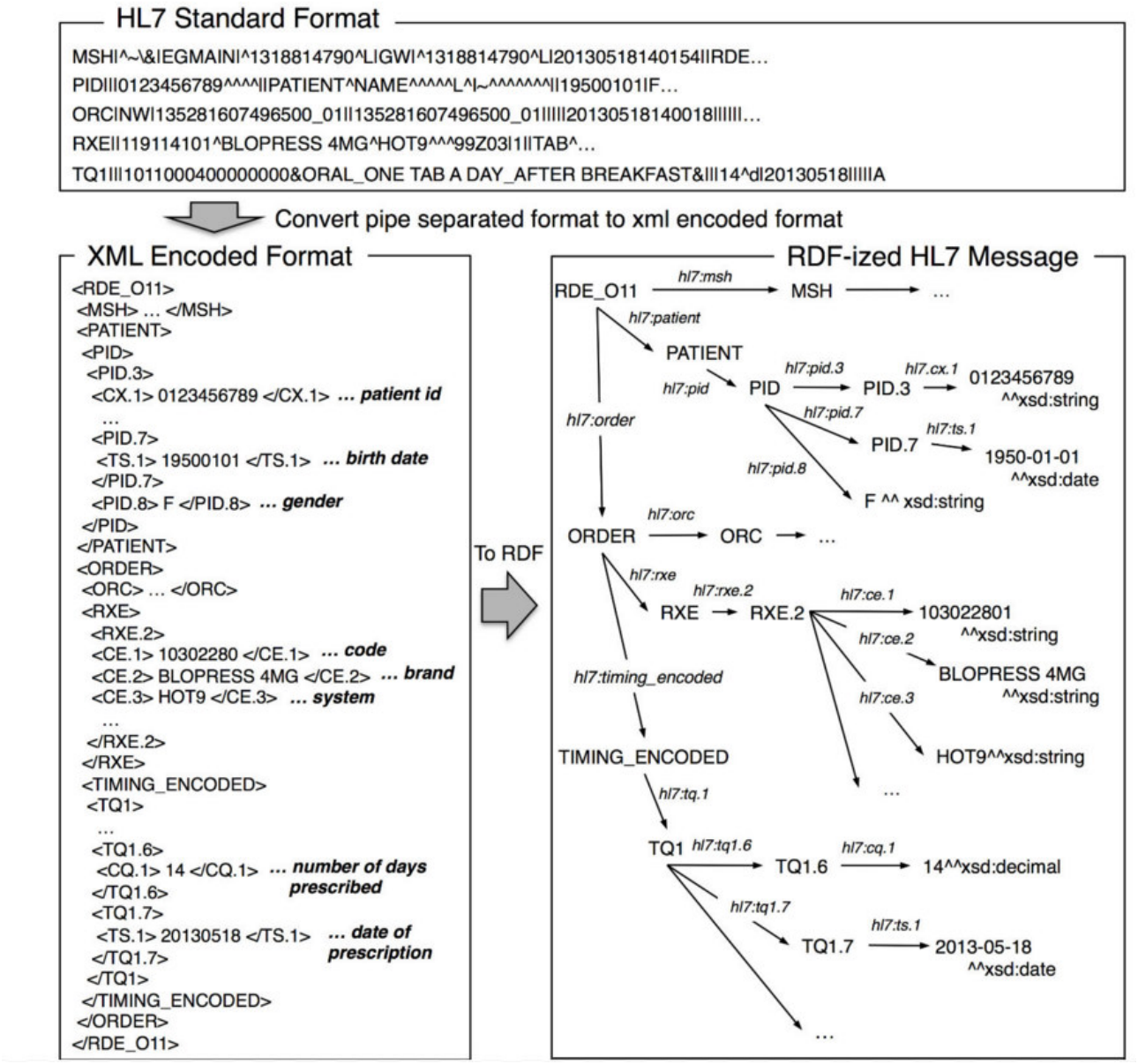
Figure 1. Examples of an SS-MIX2 storage structure and an HL7 message. This example HL7 message (RDE^O11) contains information on a medication order for a patient identified by 0123456789 administered on May 28, 2013. The message contains the following segments: message header (MSH), patient identification (PID), order-related information (ORC), pharmacy encoded (RXE), and timing and quantity (TQ1).



Converting HL7 Messages Into RDF Data

In the standard form of an HL7 message, metadata for fields or a field's elements are not included. For example, the patient's date of birth is located in the seventh field of the PID segment, although, the message itself does not contain the information. If the name of an RDF resource is determined based on its metadata, HL7 messages are efficiently converted to RDF data. Prasser et al. [27] proposed a method that uses a generic Java-based parser provided by the HL7 Application Programming Interface (HAPI), and that uses the Java class and method names as metadata, traversing Java objects, to convert an HL7 message to RDF data [28]. We also use the HAPI to parse a standard form of the HL7 message, although, we first encode the HL7 message to a form of XML that is also defined in the HL7 specifications. In an XML-encoded HL7 message, segments and segment groups are given in hierarchical XML elements. For example, an XML form of an HL7 message for a medication order starts with an <RDE_O11> tag that describes the type of HL7 message, followed by a tag that describes the segment of a message header <MSH> and segment groups of patient information <PATIENT> and order information <ORDER>. In the segment groups, the corresponding segments are included, such as the PID segment in the PATIENT segment group or the ORC and RXE segments in the ORDER segment group. Similarly, each segment contains a tag for each of its fields to describe either the field or the field's element, such as a time stamp <TS> or a coded character string <CWR>, and text data is marked up with these tags. We then applied a generic method of transformation from XML to RDF [29], in which an RDF resource is generated using the element name of the XML as the name of the resource, creating a subject-predicate-object triple by traversing the hierarchical structure, and mapping the text content to an RDF literal. Note that the mapping needs to be determined in advance because the XML-encoded HL7 message does not contain the data type of the text content. Thus, we sought to map the numerical type of the text content to *xsd:decimal*, the date type to *xsd:date*, the timestamp type to *xsd:dateTime*, and all other types to *xsd:string*. In comparison with the previously mentioned method, there is an advantage to be able to use the names of the segment or field defined by the HL7 specifications, which is not modified depending on the implementation of the Java class and method names. Figure 2 shows a medication order in the standard form of an HL7 message, an XML-encoded HL7 message, and an RDF representation after conversion.

Figure 2. A medication order in the HL7 standard format, XML-encoded format, and after conversion to RDF.



URI Naming

To determine a URI of an RDF resource, we considered two requirements: (1) the name of the URI should preferably contain a structured path to facilitate the application's access to RDF resources [30], (2) the name of the URI should be generated uniquely from the available information for an HL7 message to avoid redundancy of referring to an RDF repository each time when determining it. To satisfy these requirements, we constructed the name of the URI by connecting a directory path to an HL7 message file, which is already unique in SS-MIX2 storage, with a path to an element in XML that is encoded from the HL7 message. Note that as several HL7 segment groups, such as ORDER and RESULT may appear multiple times in the same hierarchy layer in the XML, duplication of the path names should be avoided by counting how many times they appear in the path. As the HL7 message specifications define which segment groups may appear multiple times, the name of the URI can uniquely identify the deepest elements by considering the duplication. This naming method depends on SS-MIX2 in terms of using the directory path to an HL7 message, although, if only the path to an HL7 massage is uniquely determined, any other way can be applied. Figure 3 shows a portion of a serialized RDF representation of a medication order.

Depending on the purpose of use of the HL7 message, it may contain numerous redundant segments, fields and field's elements, and it may not be necessary to convert all content to RDF data. For example, a MSH segment that provides header information for communication between systems, as well as fields other than the patient identifier, date of birth, and gender in a PID segment, is not required in clinical research. Therefore, when converting to RDF, the amount of RDF data to generate is reduced by only using the segments and fields that are needed for the purpose.

Figure 3. Serialized RDF representation of a medication order in turtle format.

```
@prefix hl7v25: <http://hl7.org/v25#> .
@prefix ssmix2: <http://ssmix.org/v2#> .
@prefix xsd: <http://www.w3.org/2001/XMLSchema#> .

<http://m.u-tokyo.ac.jp/0123456789/20130518/OMP-01/.../RDE_O11/1>
  hl7v25:PATIENT  <http://m.u-tokyo.ac.jp/0123456789/20130518/OMP-01/.../RDE_O11/1/PATIENT> ;
  hl7v25:ORDER    <http://m.u-tokyo.ac.jp/0123456789/20130518/OMP-01/.../RDE_O11/1/ORDER/1> .

<http://m.u-tokyo.ac.jp/0123456789/20130518/OMP-01/.../RDE_O11/1/ORDER/1>
  hl7v25:ORC  <http://m.u-tokyo.ac.jp/0123456789/20130518/OMP-01/.../RDE_O11/1/ORDER/1/ORC> ;
  hl7v25:RXE  <http://m.u-tokyo.ac.jp/0123456789/20130518/OMP-01/.../RDE_O11/1/ORDER/1/RXE> .

<http://m.u-tokyo.ac.jp/0123456789/20130518/OMP-01/.../RDE_O11/1/ORDER/1/RXE>
  hl7v25:RXE.2   <http://m.u-tokyo.ac.jp/0123456789/20130518/OMP-01/.../RDE_O11/1/ORDER/1/RXE/RXE.2> .

<http://m.u-tokyo.ac.jp/0123456789/20130518/OMP-01/.../RDE_O11/1/ORDER/1/RXE/RXE.2>
  hl7v25:CE.1  "103022801"^^xsd:string ;
  hl7v25:CE.2  "BLOPRESS 4MG"^^xsd:string ;
  hl7v25:CE.3  "HOT9"^^xsd:string .
```

Query Expansion Using Linked Drug Data

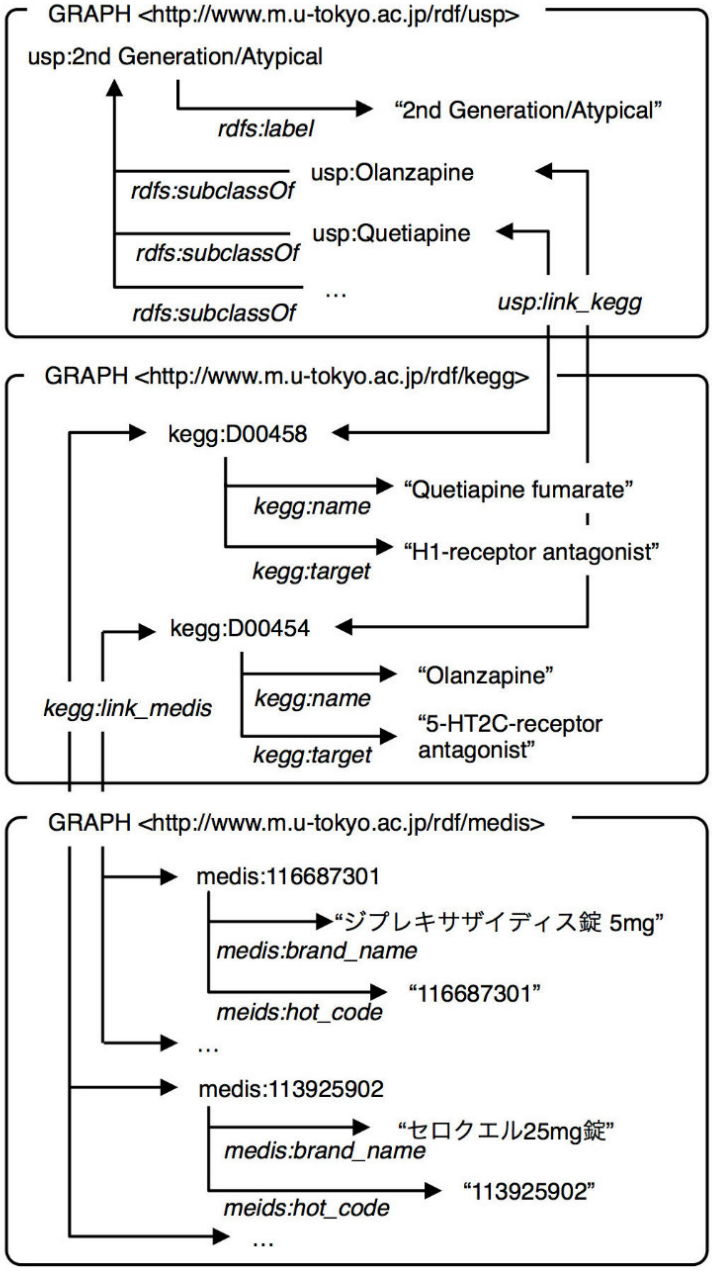
If a type of drug is identified by its detailed information, it is useful for a query to search for ADEs of a drug. By converting drug databases to Linked Data, it is possible to identify drugs through expressions that use their detailed information and to resolve the identified drugs to their codes used in the HL7 message. For example, a medication order search for atypical antipsychotic drugs that have an inhibitory effect on the serotonin 2C (5HT2C) receptor or the histamine H1 (H1) receptor consists of the following steps: (1) use the USP to identify drugs classified as atypical antipsychotic drugs, (2) use a link between the USP and KEGG to identify corresponding KEGG drugs. Then, narrow down the list to those drugs that have an inhibitory effect on the 5HT2C receptor or the H1 receptor, (3) use a link between the KEGG and MEDIS DRUG to identify corresponding drugs on the MEDIS DRUG and to identify the codes of the drugs to use in the HL7 message, and (4) Use the identified drug codes to search for a medication order over HL7 messages. Figure 4 illustrates relationships between USP, KEGG, and MEDIS DRUG used in this search.

To enable this method, we converted publicly available drug databases into RDF and provided explicit links among the corresponding items to obtain linked data. Because there were no data sources publicly available in RDF format, we converted each source individually to RDF. We got the sources of ATC, USP, and KEGG from a website of the KEGG and made the explicit links based on the information obtained from the KEGG. We used rdfs:subclassOf to describe the higher and lower level relationship in the ATC and USP, and inference was executed and materialized in advance. We also got the sources of SIDER 2 (SIDe Effect Resource) [31] and MEDIS DRUG from each website. In the SIDER 2 dataset, drug classes are coded in STITCH [32] identifiers and names of ADEs are coded in MedDRA along with upper and lower bound of the frequency. The information to link between the SIDER 2 and ATC were obtained from website of STITCH. We used the MEDIS DRUG to match the drug concept in the KEGG to the drug code used in the HL7 message, and the information to link between them were obtained from the the KEGG source. This linked drug data set is hereafter referred to as Linked Drug Data. A summary of the Linked Drug Data is shown in Table 1. The Linked Drug Data is available from our project repository [33].

Table 1. A summary of the linked drug data.

Original drug databases	Descriptions	Link to the other databases	Number of drug classes (triples)
Anatomical Therapeutic Chemical Classification System (ATC)	A drug classification system developed by World Health Organization. It divides drugs into different classes according to the organ or system on which they act or their therapeutic and chemical characteristics, such as antihypertensives and the cardiovascular system. In converting to RDF, we used rdfs:subclassOf to represent the hierarchical relationships and added links to the drug classes of KEGG and SIDER 2 at the chemical substance subgroup level.	KEGG, SIDER 2	5770 (48,504)
United States Pharmacopeia Classification (USP)	A drug classification system developed by the US Pharmacopeial Convention. It contains approximately 50 categories, which are typically based on diseases or symptoms that drugs are used to treat, such as pain and psychosis. In the same way as ATC, the hierarchical relationships were represented by rdfs:subclassOf.	KEGG	1459 (7567)
SIDER 2	A resource that contains ADEs and their frequency, which are extracted from package inserts and publicly available documents. The drugs are coded by STITCH compound identifiers, and the ADEs are described in the preferred terms of MedDra.	ATC	997 (7,848,862)
KEGG	A resource that consolidates drug data from Japan, the Unites States, and Europe. It organizes drug data based on their chemical structures and ingredients and adds information on their molecular interactions including chemical drug targets and metabolic enzymes. Many entries also include their mapping to other drug databases, and we use the mapping information to establish links to ATC, USP, and MEDIS DRUG.	ATC, USP, MEDIS DRUG	5780 (109,976)
MEDIS DRUG	A standard drug terminology that maps various drug terminologies used in Japan. We used MEDIS DRUG to match the drug code in KEGG to the drug code used in the HL7 message.	KEGG	26,126 (387,319)

Figure 4. Relationships between USP, KEGG, and MEDIS DRUG used in search for atypical antipsychotic drugs that have an inhibitory effect on the 5HT2C receptor or the H1 receptor.



Temporal Patterns to Determine Adverse Drug Events

To identify adverse events, a query condition needs to describe the temporal relationship between the administration of a drug and the adverse events that were assumed to be caused. We classify the temporal relationships into the following four types of basic temporal patterns and explain query expressions using these patterns to identify adverse events.

Temporal Pattern 1: Searching for all Medication Orders

This pattern is used to retrieve all medication orders of a specific drug without considering their temporal relationships with other events. This is the most basic pattern of clinical data searches.

Temporal Pattern 2: Searching for Adverse Events During Each Medication Period

This pattern estimates the medication period as beginning on the day that a drug medication order was issued and continuing for the number of days prescribed, and it searches for the adverse events during the estimated medication period. Although the medication period estimated in this pattern is likely to be close to the actual drug administration period, irregular medication orders, when issued, could make a period when a drug has been administered appear as it had not been, and the estimated medication period could erroneously exclude such periods. Consequently, it is possible to overlook adverse events during such excluded periods.

Temporal Pattern 3: Identifying Adverse Events During a Period Between the Initial and Final Medications

This pattern assumes that the impact of a certain drug extends from its initial medication date to its final medication date, and it is to identify the adverse events during this period. The drug administration period estimated in this pattern could include extended time periods during which the drug had not been administered, and thus, it is possible that the defined drug administration period significantly deviates from the actual drug administration period. However, because the effects of some drugs could continue for an extended time period after drug administration has ended, this pattern identifies adverse events of these types of drugs whose effects extend beyond the end of the medication period.

Temporal Pattern 4: Excluding Adverse Events Immediately Before an Initial Medication

This pattern is to increase the degree of certainty of a causal relationship between a drug and an adverse event by excluding the adverse events immediately before initial medication of the drug.

Experiment Settings

In the next section, we first show a summary of created RDF data to use in this experiment. To ensure the impartiality of the benchmark results, all segments of the HL7 messages were converted to RDF data, rather than arbitrarily deleting unnecessary segments. We then explain three types of query in use cases for detecting ADEs, which are available in our proposed method and show the execution results of searches using these queries. The goal of our experiments was not to investigate specific adverse events, but rather show that it is possible to search over the RDF-ized HL7 messages using SPARQL queries that combine external knowledge and temporal patterns. So, we finally present results of a benchmark that measures the execution time to show that the searches over RDF-ized HL7 messages through SPARQL provide a feasible response speed.

To show the relationships between the execution time of the query and the amount of data, we divided whole HL7 messages equally into 10 subdatasets in which the HL7 messages were arranged in ascending order of the date of administration. Then, we measured the execution time of the queries issued five times at each point by increasing every subdatasets. We tested two types of query expressions for each three query in order to compare our proposed query expression with a conventional one. The proposed query uses the Linked Drug Data dynamically by SPARQL federation function in the manner as shown in Figures 5 to 7 below. The conventional query enumerates the individual drug codes in SPARQL filter keyword in advance, which were obtained from the Linked Drug Data separately. Thus, the execution time of the proposed query included, (1) a time to search for individual drug codes from an expression like "renin angiotensin inhibitors" by accessing to Linked Drug Data and (2) a time to search for medication records of RDF-ized HL7 data based on the searched drug codes. On the other hand, the execution time of the conventional query did not include a time to search for the individual drug codes because they are enumerated in advance.

We measured the execution time after relaunching the RDF store and clearing the cache each time a query was executed. Therefore, the execution time included the time it takes to load the data to memory, execute the query, and display the execution results. As we observed that the execution speed dropped drastically when SPARQL queries were not completely optimized through automatic optimization, we manually optimized the execution sequences and then locked them using functionality available in Virtuoso. With regard to the environment for executing queries, the RDF-ized HL7 messages and the Linked Drug Data were stored in two different SPARQL endpoints on a secure network. For the RDF-ized HL7 messages, we used hardware with Intel Xeon 2.60 GHz processors and 256 GB random access memory (RAM). For the Linked Drug Data, we used hardware with Intel Xeon 2.20 GHz processors and 128 GB RAM. Both pieces of hardware ran the CentOS6.5 operating system, and Virtuoso Open-Source Edition 7.1.0 was used as the RDF store.

Results

Converted RDF Data

The University of Tokyo Hospital is an educational hospital with more than 1100 beds and 760,000 visits annually. Since 2011, the hospital has been collecting data in the form of HL7 messages in a SS-MIX2 storage. From these collected data, we used the medication orders and laboratory test results during the 3-year period from January 1, 2011 to December 31, 2013. There were approximately 148,000 unique patients, and the number of HL7 messages included was 1.9 million for RDE^O11 (medication orders) and 2.1 million for OUL^R22 (laboratory test results). We then converted them into RDF using the method explained earlier. Approximately 650 million RDF triples for RDE^O11 and 790 million RDF triples for OUL^R22 were converted, and the average number of triples in one message was 360. It was also that the approximate time to convert HL7 messages into RDF were 17 hours and 30 minutes for RDE^O11 and 25 hours 10 minutes for OUL^R22 when we used single CPU (Table 2).

Table 2. Summary of the RDF-ized HL7 messages.

Type of HL7 message	Information content	Number of HL7 messages (million)	Number of RDF triples (million)	Triples in a message	Time to convert HL7 messages into RDF
RDE^O11	Medication order	1.9	650	342	17 hours 30 minutes
OUL^R22	Laboratory test result	2.1	790	376	25 hours 10 minutes
Total	-	4.0	1440	360	42 hours 40 minutes

SPARQL Expressions for Searching Adverse Events

Query 1: Identifying Drugs Based on Pharmaceutical Classification and Searching For All Relevant Medication Orders

This is the most basic query searching medication orders that are classified in a certain pharmaceutical category. The query (Figure 5) searches for all medication orders for drugs classified as renin angiotensin inhibitors. The SERVICE clause that follows the WHERE clause queries the Linked Drug Data stored at a SPARQL endpoint, identifies all ATC subclasses of renin angiotensin inhibitors, and resolves their individual drug codes through the KEGG and MEDIS DRUG. When this finishes, triple pattern matching identifies the patients who were prescribed drugs with the code that the SERVICE clause resolved, and binds the dosage amount, medication date, and number of medication days to their corresponding variables of the patients. Query results are returned in a table with the column names described in variables of the SELECT statement. This query does not consider the temporal relationship with other events; thus, it is for Temporal Pattern 1.

Figure 5. SPARQL expression of Query 1. This query searches all medication orders for drugs classified as renin angiotensin inhibitors.

```
SELECT DISTINCT ?patient ?drug_code ?dose_per_day
                ?prescription_date  ?duration
WHERE {
 SERVICE <http://location-1:8890/sparql>{
  GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/atc>{
   ?atc        rdfs:label          ?atc_name.
   FILTER regex(?atc_name, 'AGENTS ACTING ON
                THE RENIN-ANGIOTENSIN SYSTEM', 'i').
   ?atc_sub    rdfs:subClassOf     ?atc.
   ?atc_sub    atc:link_kegg       ?kegg.
  }
  GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/kegg>{
   ?kegg     kegg:link_medis     ?medis.
  }
  GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/medis/drug>{
   ?medis    medisd:hot9_code    ?drug_code.
  }
 }
  ?patient  ssmix2:OMP-01  [hl7:RDE_O11  ?rdeo11].
  ?rdeo11   hl7:ORDER      [hl7:RXE      ?rxe;
                            hl7:TIMING   ?timing].
  ?rxe      hl7:RXE.2   [hl7:CE.1    ?drug_code];
            hl7:RXE.19  [hl7:CQ.1    ?dose_per_day].
  ?timing   hl7:TQ1   [hl7:TQ1.7 [hl7:TS.1   ?prescription_date]];
            hl7:TQ1   [hl7:TQ1.6 [hl7:CQ.1   ?duration]].
}
```

Query 2: Identifying Drugs Based on Known Adverse Events and Searching for Adverse Events During the Relevant Medication Periods

This query identifies drugs from known adverse events registered in SIDER 2 and searches for clinical cases that may include adverse events resulting from the identified drugs. Specifically, we consider a query (Figure 6) to identify drugs that cause leukopenia or neutropenia as adverse events in SIDER 2 and to search for the clinical cases where the identified drugs were prescribed and a drop in the leukocyte counts was observed during each medication period. Similar to Query 1, the SERVICE clause identifies the drugs that cause leukopenia or neutropenia at a frequency of 30% or higher in SIDER 2 and resolves their individual drug codes through the ATC, KEGG, and MEDIS DRUG. When this finishes, triple pattern matching binds the drug codes of the prescribed drugs, dosage amounts, medication dates, duration of each medication, leukocyte counts, and its examination date to their corresponding variables, and then searches for clinical cases where the leukocyte counts was 3000 or less during the medication period (defined as the period starting on the day of the medication order and continues for the number of prescribed days). Because this query searches for adverse events during each medication period, it is for Temporal Pattern 2.

Figure 6. SPARQL expression of Query 2. This query searches all cases for which a leukocyte count of 3000 or less was observed during the medication period of drug types having leukopenia or neutropenia as adverse events.

```
SELECT DISTINCT ?patient ?drug_code ?dose_per_day
                ?prescription_date ?duration
WHERE {
 SERVICE <http://location-1:8890/sparql>{
  GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/sider>{
   ?sider  sider:link_atc        ?atc;
           sider:a               ?ae.
   ?ae     rdfs:label            ?label;
           sider:lower_bound     ?lb.
   FILTER (regex(?label, 'leukopenia', 'i') || regex(?label, 'neutropenia', 'i')).
   FILTER (?lb > 0.3).
  }
  GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/atc>{
   ?atc    atc:link_kegg         ?kegg.
  }
  GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/kegg>{
   ?kegg   kegg:link_medis       ?medis.
  }
  GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/medis/drug>{
   ?medis  medisd:hot9_code      ?drug_code.
  }}
  ?patient   ssmix2:OMP-01  [hl7:RDE_O11?rdeo11].
  ?rdeo11    hl7:ORDER      [hl7:RXE    ?rxe;  hl7:TIMING  ?timing].
  ?rxe       hl7:RXE.2      [hl7:CE.1   ?drug_code];
             hl7:RXE.19     [hl7:CQ.1   ?dose_per_day]
  ?timing    hl7:TQ1    [hl7:TQ1.7  [hl7:TS.1 ?prescription_date]];
             hl7:TQ1    [hl7:TQ1.6  [hl7:CQ.1 ?duration]].

  ?patient   ssmix2:OML-11  [hl7:OUL_R22 ?oulr22].
  ?oulr22    hl7:SPECIMEN   [hl7:ORDER [hl7:RESULT [hl7:OBX  ?obx]]].
  ?obx       hl7:OBX.3      [hl7:CE.1  '2A990000001992052'^^xsd:string];
             hl7:OBX.5      ?lab_value;
             hl7:OBX.14     [hl7:TS.1   ?lab_date].
  FILTER ( ?prescription_date < ?lab_date && ?lab_date <
                  bif:dateadd('day', ?duration, ?prescription_date)).
  FILTER ( ?lab_value < 3.0 ).
}
```

Query 3: Identifying Drugs Based on Pharmaceutical Classification and Their Targets, and Searching for Adverse Events During the Relevant Drug Medication Periods

This query illustrates that when multiple drug data resources are used, drugs can be identified with more detailed characteristics. In clinical backgrounds, atypical antipsychotic drugs are known to have a tendency to trigger diabetes. It is hypothesized that these drugs cause chronic bulimia by blocking 5HT2C and H1 receptors and bring about obesity and hyperinsulinemia, thereby inducing diabetes [34]. This query may help examine this hypothesis through identifying the drugs that demonstrate these characteristics and extracting clinical cases that satisfy the criteria for diabetes during the medication period. As mentioned above, this query (Figure 7) first narrows down drugs classified as atypical antipsychotic drugs in the USP classification to those in KEGG having an inhibitory effect on 5HT2C or H1 receptors, and then resolves individual drug codes through MEDIS DRUG. It then uses a filter operation to derive the initial and final medication dates for each patient from the medication orders of the drugs with the resolved drug codes, and extracts clinical cases where the HbA1c value or the serum glucose satisfies the criteria for impaired glucose tolerance during the medication period. Note that as the HbA1c value changes gradually, we used the period between the initial and final medications, rather than using each medication period. We also added a condition to exclude clinical cases satisfying the same criteria within 60 days of the initial medication. Therefore, this query is for a combined temporal pattern of Temporal Patterns 3 and 4.

Figure 7. SPARQL expression of Query 3. This query searches all cases satisfying the criteria for impaired glucose tolerance during a period between the initial and final medications of atypical antipsychotic drugs that have a 5HT2C or H1 receptor inhibitory effect. The clinical cases that satisfy the above criteria within 60 days of the initial medication are excluded. In this query, two subqueries are used. In subquery 1, the cases having the period of initial and final medications of the atypical antipsychotic are identified. In subquery 2, the cases satisfying the criteria for impaired glucose tolerance during the period are identified.

```
SELECT DISTINCT ?patient ?hot_code ?first ?last ?lab_date ?lab_value
WHERE {
 FILTER NOT EXISTS {
  ?patient   ssmix2:OML-11   [hl7:OUL_R22 ?oulr22].
  ?oulr22    hl7:SPECIMEN    [hl7:ORDER   [hl7:RESULT [hl7:OBX ?obx]]].
  ?obx       hl7:OBX.3       [hl7:CE.1      ?lab_code];
             hl7:OBX.5       ?lab_value;
             hl7:OBX.14      [hl7:TS.1 ?lab_date].
   FILTER ( (?lab_code   = '0170700_84' &&  ?lab_value > 6.5) ||
            (?lab_code  = '3D045000001920402' && ?lab_value > 6.2)).
   FILTER (bif:dateadd('day', -60, ?first ) <   ?lab_date && ?lab_date < ?first)
 }.
 { # SUBQUERY 2
  SELECT  ?patient ?drug_code   ?first ?last ?lab_date ?lab_value
   WHERE {
   ?patient    ssmix2:OML-11 [hl7:OUL_R22  ?oulr22].
   ?oulr22     hl7:SPECIMEN  [hl7:ORDER   [hl7:RESULT [hl7:OBX ?obx]]].
   ?obx        hl7:OBX.3       [hl7:CE.1    ?lab_code];
               hl7:OBX.5       ?lab_value;
               hl7:OBX.14      [hl7:TS.1    ?lab_date].
   FILTER ( (?lab_code =  '0170700_84'            &&  ?lab_value > 6.5) ||
           (?lab_code  = '3D045000001920402'   && ?lab_value > 6.2)).
   FILTER (?first < ?lab_date && ?lab_date < ?last) .

   { # SUBQUERY 1
    SELECT  ?patient  ?drug_code  (MIN(?p_date) AS ?first)
                                  (MAX(?p_date) AS ?last)
     WHERE {
      SERVICE<http://location-1:8890/sparql>{
       GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/medis/drug>{
        ?medis    medisd:hot9_code          ?drug_code;
                  medisd:kokuji_maisho      ?brand_name;
       }
       GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/kegg>{
        ?kegg     kegg:link_medis   ?medis;
                  kegg:target       ?target.
        FILTER (regex(?target, 'H1-receptor antagonist', 'i') ||
                regex(?target, '5-HT2C-receptor antagonist', 'i')).
       }
       GRAPH <http://www.m.u-tokyo.ac.jp/medinfo/rdf/usp>{
        ?usp          rdfs:label            ?label.
        FILTER (regex(?label, '2nd Generation/Atypical', "i")).
        ?usp_sub      rdfs:subClassOf     ?usp;
                      usp:link_kegg       ?kegg.
       }}
        ?patient      ssmix2:OMP-01 [hl7:RDE_O11  ?rdeo11].
        ?rdeo11       hl7:ORDER       [hl7:RXE   ?rxe;  hl7:TIMING   ?timing].
        ?rxe          hl7:RXE.2       [hl7:CE.1   ?drug_code].
        ?timing       hl7:TQ1         [hl7:TQ1.7 [hl7:TS.1   ?p_date]].
}}}}}
```

Execution Results of Each Query

Table 3 shows the results of executing each query over the RDF-ized HL7 messages for a 3-year period. The Query 1 expression of "drugs classified as renin angiotensin inhibitors" yielded 476 different types of drug codes by the Linked Drug Data, and there were a total of 197,366 medication orders found for these drugs. Similarly, the Query 2 expression of "drug types having leukopenia as adverse events" yielded 131 types of drug codes using SIDER 2, and the Query 3 expression of "of the atypical antipsychotic drugs, those having a 5HT2C or H1 inhibitory effect" yielded 78 drug types, with Queries 2 and 3 obtaining 1171 and 58 results, respectively.

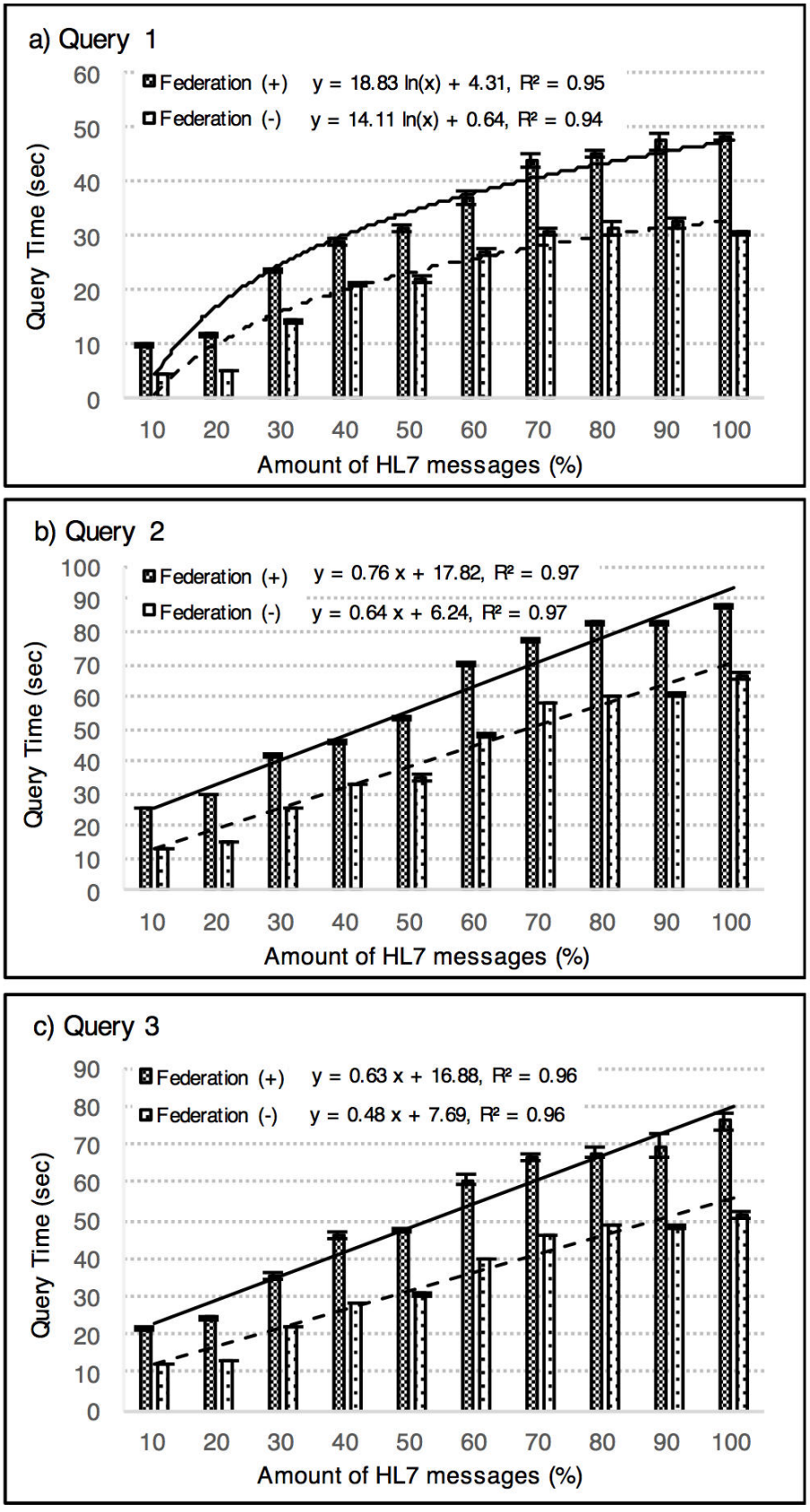
Query Execution Performance

Figure 8 shows, for each three query, the average measured execution times of the two types of query expression (ie, our proposed query that use Linked Drug Data dynamically with SPARQL federation function and a conventional query in which the individual drug codes are enumerated in SPARQL filter keyword). The average execution time of the proposed queries were significantly longer than the conventional one, and these were 49% longer in Query 1, 43% in Query 2, and 51% in Query 3, in total. It was also that the execution time of the Query 1 showed logarithmic growth, and the Query 2 and the Query 3 showed linear growth. The coefficient of determination in these regressions ranged from 0.94 to 0.97.

Table 3. Summary of each query and the respective execution results.

No.	Summary of query condition	Drug data sources to resolve the expression	No. of resolved drug codes	Results
1	Cases for which drug types classified as renin angiotensin inhibitors were prescribed, and all medications of such drugs.	ATC	476	197,366
		KEGG		
		MEDIS DRUG		
2	Cases for which a leukocyte counts of 3000 or less was observed during the medication period of drug types having leukopenia or neutropenia as adverse events, and all corresponding medications.	SIDER 2	131	1171
		ATC		
		KEGG		
		MEDIS DRUG		
3	Cases satisfying the criteria for impaired glucose tolerance during a period between the initial and final medications of atypical antipsychotic drugs that have a 5HT2C or H1 receptor inhibitory effect. Clinical cases that satisfy the above criteria within 60 days of the initial medication are excluded.	USP	78	58
		KEGG		
		MEDIS DRUG		

Figure 8. The average measured execution times of Queries 1, 2, and 3 obtained through the experiments are shown in a), b), c), respectively. In each subfigure, bar graphs represent the average measured execution times of the two types of query expression with standard errors, and solid or dashed line represent the approximate average execution times.



Discussion

Primary Findings

To further improve the usability of EMRs, EMRs need to be integrated with external data sources that serve as knowledge resources. Currently, clinical specialists provide and interpret the knowledge used in making clinical data inquiries and, in many cases, manually translate the knowledge into codes of terminology and describe them in queries. This not only requires time and increases the number of errors [13,15] but also leads to the possibility of differing interpretations of coding, resulting in incompatibility among query results. Semantic Web technology provides a framework for integrating heterogeneous data sets using RDF and enables the extraction of data from multiple endpoints on a network using queries in a uniform format and standard Web protocols. This makes it possibly not only to integrate heterogeneous knowledge resources but also to share publicly available resources as knowledge sources and to handle highly confidential clinical data without compromising their confidentiality.

We converted drug databases to the Linked Drug Data, used them as the knowledge for query expansions, and searched over the RDF-ized HL7 messages. We showed three queries illustrated by the queries for drugs including renin angiotensin inhibitors, as well as more advanced expressions for drugs that cause leukopenia and also for atypical antipsychotic drugs. We only show three queries, although, we believe that wider ranges of queries are possible by combining four temporal patterns and various search expressions to identify drugs. These query expressions require clinical knowledge, and such knowledge must be supplied from external knowledge sources, as clinical data do not contain such knowledge. Our query expression used knowledge of drugs separate from clinical data that exist at a different endpoint on a network through SPARQL's federation query. This suggests that enhancing knowledge resources would improve the search usability of clinical data and the possibility to search over clinical data on a shared knowledge basis.

The Query 1 example resulted in 476 drug code types for renin angiotensin inhibitors. However, in reality, it is unlikely that one hospital adopts all types of renin angiotensin inhibitors, and only a few types are actually adopted by any one hospital. Because different hospitals may adopt different drug types, the drug codes listed for one hospital may not apply to another. The proposed method dynamically resolves the expression like "renin angiotensin inhibitors" using external knowledge resources, enabling clinical data searches using expressions at a level close to the knowledge without considering specific types of drugs that different hospitals may adopt. This not only improves the usability of query expressions for specialists but also suggests the possibility of reusing queries (ie, using the same query at multiple hospitals) [34,35].

The Query 2 example showed a use case for ADEs, which used SIDER 2 to search drugs that potentially cause leukopenia. As for the database of ADEs itself, there is another publicly available database named ADEpedia 2.0 that use RxNorm codes for medications and SNOMED CT or MedDRA codes for phenotypes related to ADEs [36]. In this database, the relationships between the drugs and ADEs are represented by predicates such as 'contraindicated_drug' for information of contraindications and 'causative_agent_of' for adverse drug effects. Although SIDER 2 and ADEpedia 2.0 is useful to search known relationships between the drugs and ADEs, they are not necessarily enough for a use case to investigate unknown ADEs that may be discovered from EMR. To enable this, we needed to complement them by using the different type of drug database. We showed Query 3 example that make use of the information of drug class and type of receptor, which are enabled by linking USP and KEGG. Although this query shows a limited example, increasing variation of the search expression by using multiple drug database is assumed to be useful for investigating ADEs, and in order to do so, it is primarily important that these databases can be linked each other.

We showed a method for converting RDF data not by selecting arbitrary elements contained in the HL7 message but by using all the elements as they are. The reason why is because it was difficult to specify which elements are necessary for a clinical study in advance. As a trade-off, the SPARQL query we showed may be difficult to describe unless we are familiar with the specifications of the HL7 message. The difficulty of describing this SPARQL query will be summarized in the following three points. First, when describing the pattern matching of SPARQL, nesting up to reaching the necessary elements would be considerably deep. For example, until reaching the drug code, it is necessary to pass through five nodes: RDE_O11, ORDER, RXE, RXE.2, and CE.1. For this reason, the user must be familiar with the structure of the HL7 message. In order to solve this problem, it is conceivable to select the elements that are required for a clinical study from the HL7 message, reconstructing a simpler model of RDF data composed of only its elements. To do this, a guideline for which elements should be converted might be useful, and to make such a guideline, it is desirable that Health Level Seven and some associations related to clinical research discuss and select the required elements necessary for clinical researches in general. Second, the vocabulary that is reusable to represent the RDF resource is not used. Some properties such as "patient ID," "birthdate," and "gender" shown in Figure 2 might be good to associate them with the existing vocabulary that is defined in the ontology such as foaf and vCard. However, the vocabulary corresponding to almost all other HL7 elements, including the drug code, medication dose, unit of the dose, and so on did not exist as far as we know. Therefore, in this study, we gave greater importance to keeping the consistency of the method of converting the HL7 to RDF by using the names of the tags obtained when converting the HL7 to XML as the vocabulary rather than reusing only those few vocabulary. Finally, temporal reasoning is important for investigation for ADEs, although, it might be difficult to write it against our RDF-ized HL7 data with SPARQL. We used filter-based solution in Queries 2 and 3 to compare the date of laboratory test results and the date of the medications in order to be able to consider the causal relationships between them. We also used subquery solution in Query 3 to identify the first and the last time of medications of atypical antipsychotic drugs in order to identify diabetes that occurred or not occurred during time frames based on the two time points. Although we showed these queries as possible as simple, they might be typically

verbose and difficult to write. It is conceivable that using Allen's temporal predicates such as "before," "after," and "during" in the pattern matching of the query [14] is useful to avoid the SPARQL filter-based comparison of the time. In order to do that, an interval-based temporal information should be given to the comparable events and they should be connected according to their relationships when the RDF data are created. It might be also that giving a mark to specific time events such as the first and the last time of medications is useful to identify them without the subquery solution. These methods make the description of the query more concise at the expense of computational complexity at the time of creating RDF data. In this study, we did not apply these methods because we focused on using all elements in HL7 message as they are, it would be worth to consider to make the expression of temporal reasoning concise.

Regarding the query execution time, we tested two types of query expression for each three query to show the difference of the execution time between our proposed query expression and a conventional one. As for the conventional expression, the number of the drug codes enumerated in each query were 476, 131, and 78, respectively, as shown in Table 3. The advantage of the proposed query is that the expression is concise and human readable in comparison to the conventional one, and that allows identification of drugs based on the detailed information rather than the drug codes can be listed. On the other hand, the disadvantages are that it is inferior in execution time, it takes approximately 40% to 50% more time than conventional one. It was also that what kind of drug code will be searched is unknown until the query is run. These comparative aspects indicate a trade-off between simplicity of the query expression and the execution time of the query as well as search reliability. In particular, as it is necessary to separately consider the reliability of the drug code obtained by the Linked Drug Data, this can be noted as one of the limitations of this study.

The result of the experiment also showed that the average execution time of the Query 1 showed logarithmic growth, and the time of the Queries 2 and 3 showed linear growth with the coefficient of determination ranged from 0.94 to 0.97. This indicates that these regressions approximated the query execution time well. These results might be counterintuitive especially in the logarithmic growth in Query 1, although, it was assumed to be possible that the logarithmic growth is consistent with computational complexity of B-Tree indices is O(log n), which are used in the RDF database we used. Although the result will not be generalized because an execution time of a query depends on various settings, such as amount of data, the content of the query, and the kind of the database system, the execution time of these queries increased with the amount of data without diverging in our experiments.

Limitations

We converted HL7 messages to RDF data automatically without changing the HL7 message structures. This suggests that the proposed method can be applied not only at the University of Tokyo Hospital that has adopted SS-MIX2 storage but also at numerous other hospitals that use HL7 messages. To demonstrate this, future research is required to verify the applicability of the proposed method at multiple hospitals. In addition, we considered adverse events cases in our research, and thus, it was medication orders and laboratory test results that were converted to RDF data. However, HL7 messages contain other types of clinical data such as patient demographics, diagnostic disease, and some kind of order information. When these types of clinical data are converted to RDF data, a wider variety of query expressions are required to search over the converted RDF data, and future research should examine such query expressions. We have not verified the drugs identified through our query expansions, nor verified extracted clinical data against the gold standard, and these are the limitations of the research.

Conclusions

This study applied Semantic Web technology to use publicly available drug databases as the knowledge for query expansions and demonstrated clinical data searches through SPARQL. The proposed method executed queries with knowledge resources separate from clinical data, suggesting that enhancing knowledge resources would improve the usability of clinical data. This study also converted HL7 messages to RDF data using an automatic way without modifying the HL7 message structures and demonstrated searches over the converted RDF data using SPARQL. This suggests that the proposed method can be applied not only at the University of Tokyo Hospital that has adopted SS-MIX2 storage but also at numerous other hospitals that use HL7 messages. We have not verified the drugs identified through query expansions, nor verified extracted clinical data; such verifications will be performed in future research. Future research also includes applying the proposed method at other hospitals and supporting a wider variety of HL7 messages.

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Conflicts of Interest

None declared.

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Abbreviations

5HT2C: serotonin 2C
ADE: adverse drug event
ATC: Anatomical Therapeutic Chemical Classification System
EMR: electronic medical record
H1: histamine antagonist of the H1 receptor
HAPI: Health Level Seven application programming interface
HL7: Health Level Seven
ICD10: International Classification of Diseases, and 10th Revision
KEGG: Kyoto Encyclopedia of Genes and Genomes
MEDIS-DC: Medical Information System Development Center
MSH: message header
ORC: order-related information
PID: patient identification
RAM: random access memory
RDF: Resource Description Framework
RDFS: Resource Description Framework Schema
RXE: pharmacy
SIDER 2: SIDe Effect Resource
SPARQL: SPARQL Protocol and RDF Query Language
SS-MIX2: Standardized Structured Medical Record Information Exchange version 2
TQ1: timing and quantity
URI: uniform resource identifier
USP: United States Pharmacopeial Convention Classification System
XML: Extensible Markup Language.

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Original Paper

Users' Perspectives on a Picture Archiving and Communication System (PACS): An In-Depth Study in a Teaching Hospital in Kuwait

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Abstract

Background: Picture archiving and communication system (PACS) is a well-known imaging informatics application in health care organizations, specifically designed for the radiology department. Health care providers have exhibited willingness toward evaluating PACS in hospitals to ascertain the critical success and failure of the technology, considering that evaluation is a basic requirement.

Objective: This study aimed at evaluating the success of a PACS in a regional teaching hospital of Kuwait, from users' perspectives, using information systems success criteria.

Methods: An in-depth study was conducted by using quantitative and qualitative methods. This mixed-method study was based on: (1) questionnaires, distributed to all radiologists and technologists and (2) interviews, conducted with PACS administrators.

Results: In all, 60 questionnaires were received from the respondents. These included 39 radiologists (75% response rate) and 21 technologists (62% response rate), with the results showing almost three-quarters (74%, 44 of 59) of the respondents rating PACS positively and as user friendly. This study's findings revealed that the demographic data, including computer experience, was an insignificant factor, having no influence on the users' responses. The findings were further substantiated by the administrators' interview responses, which supported the benefits of PACS, indicating the need for developing a unified policy aimed at streamlining and improving the departmental workflow.

Conclusions: The PACS had a positive and productive impact on the radiologists' and technologists' work performance. They were endeavoring to resolve current problems while keeping abreast of advances in PACS technology, including teleradiology and mobile image viewer, which is steadily increasing in usage in the Kuwaiti health system.

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KEYWORDS

PACS evaluation; user perspective; IS success; imaging informatics; radiology

Introduction

Picture archiving and communication system (PACS) is a well-known imaging informatics application in health care organizations, specifically designed for the radiology department. A PACS could be defined as "an electronic information system (IS) used to acquire, store, transmit, and display medical images" [1]. Using PACS in hospitals has innumerable benefits at various levels [2]. At the management level, this technology has direct implications for cost reduction, rendering the film production process redundant. At the departmental level, the technology enhances productivity, as all tasks are performed digitally and swiftly; at the clinical level, image interpretation and diagnosis become more precise and accurate [3]. For these reasons, health care organizations are increasingly adopting PACS in their clinical radiology departments, despite the high costs, to benefit from the full advantages of using the technology. PACSs are currently being applied in many medical imaging projects around the world, such as in the United States, the United Kingdom, and Asia. However, the available literature reveals gaps with regard to the systems' effectiveness and efficiency concerning their intended use.

The existing literature is abounding with studies evaluating PACS [4]. However, these evaluations invariably had different focus and objectives; for instance, there are studies on PACS before and after the system's implementation [5], users' satisfaction [6], PACS acceptance [7], cost-effectiveness [8,9], and the system's efficiency concerning its use and in saving time [10]. The most widely used form of PACS evaluation concerns its impact on users [4,11,12].

In PACS research and practice, once the system has been adopted and implemented, it becomes imperative to evaluate the technology's effectiveness within an organization [13]. For all practical purposes, evaluation could be defined as "the process of describing the implementation of an information resource and judging its merits and worth" [14]. IS deployment may invariably lead to unintended consequences, affecting the chances of the technology's success [14]. Several researchers have, therefore, recommended evaluation studies specially focused on PACSs to assess its impact in clinical practice [4,15].

It is of paramount significance to investigate the success of PACS, exploring the factors responsible for the success or failure to determine its worth clinically, based on the direct users of this system.

The conceptual basis of this study is focused on this: the impact of PACS was assessed in a regional hospital in Kuwait based on specific criteria. The study is the first of its kind in Kuwait, there being a scarcity of literature in this field.

Research Questions

The research questions were specifically as the following: (1) What impact does the PACS have on the clinical practice of radiologists and technologists in the radiology department of Mubarak Al-Kabeer Hospital? (2) Has the use of the PACS proven successful in improving the radiology department's work performance?

This study aimed at evaluating the success of the PACS in clinical practice, in a bid to determine the technology's merits for radiologists and technologists, including its drawbacks.

Methods

Research Setting

The universe of this study was Mubarak Al-Kabeer Teaching Hospital, which is 1 of the 5 regional hospitals in the State of Kuwait. Table 1 presents the site's profile. This general hospital is a University-teaching hospital in Kuwait and was chosen because it is always at the forefront of development and advanced medicine. Therefore, to ensure the full advantage of the health information system (HIS), the PACS's success needed to be verified. The PACS was first introduced in the radiology department of Mubarak Al-Kabeer Hospital in 2004, marking the transition of clinical services from a film-based system, to an electronic-based system. The PACS used is an off-the-shelf, Oracle-based HIS (GE Centrisity RIS i 4.2 plus, GE PACS IW 3.7.3.9 SP 3). The PACS currently has 35 workstations, with a server capacity of 64 terabytes. Radiologists use the PACS to view images through the radiology information system (RIS), which they use to report their cases. The reports generated by the RIS are then sent to the PACS, through which final reports can be sent to HIS. The treating physician needs to submit an access request to see patients' images on the PACS. In June 2013, the PACS software was upgraded, and currently the system is fully integrated technically with the RIS and the HIS, providing the users with a secured system.

Table 1. Mubarak Al-Kabeer teaching hospital's profile.

Categories	No.
Hospital beds	734
Hospitalized patients	21,124
Physicians	559
Radiologists	52
Radiology technologists	34
PACS administrators	5
Average no. of images examined monthly	32,787

Study Design

An in-depth study was conducted by using quantitative and qualitative methods. This mixed-method study was based on: (1) survey questionnaires, which were distributed to gather information from radiologists and technologists in the radiology department of Mubarak Al-Kabeer Hospital and (2) semi structured interviews, which were conducted to gather empirical information from the PACS administrators. Ethical approval for the study was obtained from the research department of the Ministry of Health, Kuwait.

To gather the responses of radiologists and technologists concerning the use of the PACS in their clinical practice, a validated questionnaire from a previous study was used [16]. The questionnaire was translated from French into English through an official translation office in Kuwait. The English version of the questionnaire was pretested with 5 radiologists and 3 technologists to ensure the suitability and usability of the questions. Accordingly, a number of amendments were made to the questionnaire. These included excluding questions that were found to be irrelevant to the technologists' use of the PACS, which comprised items that focused on retrieving, displaying, comparing, and manipulating of images, including confidence level. In addition, a 7-point Likert scale was changed to 5 points to make it easier and more familiar for the respondents.

In this study, evaluating the PACS's success was based on an integrated multidimensional model, which was constructed from the model primarily developed by Delone and Mclean [17,18], and later it was developed in which 2 constructs were added to the model, namely: system continuance intention and confirmation of expectations [16] (Figure 1).

The questionnaire comprised 7 sections (Textbox 1) for assessing the users' perspectives on 8 interrelated dimensions of the PACS success model. These included: (1) perceived system quality; (2) perceived information quality; (3) perceived service quality; (4) system usage; (5) user satisfaction; (6) perceived net benefits; (7) system continuance intention; and (8) confirmed expectations. The questionnaire was distributed to all radiologists and radiology technologists who had used the PACS in their clinical practice for the last 2 years.

Textbox 1. Sections of the questionnaire.

Section 1: Quality of PACS

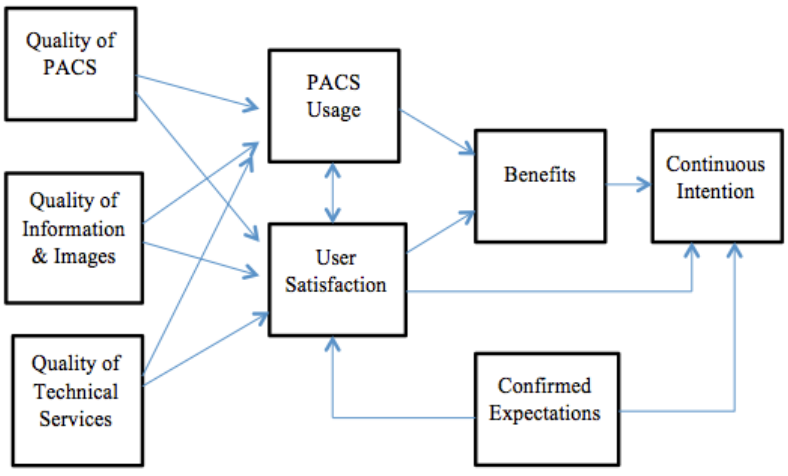
Ease of access and use

- Diversity of functionalities offered by the PACS
- Reliability of the hardware and software
- PACS integration and compatibility with the RIS and the HIS
- Security of the PACS

The data gathered through the questionnaire were complemented by conducting semi structured interviews with PACS administrators to gain an understanding of the prevailing clinical environment, which entails them communicating with radiologists, doctors, and technologists, including providing information technology services and support [19]. Their experience further enriched the information gathered and the study's purpose.

The interviews' focus was primarily similar to that of the questionnaire: to gain a deeper insight into the response patterns of the respondents. The interviews were conducted with the radiology technologists, who are responsible for administering the PACS and overseeing the RIS operations in the radiology department.

Figure 1. An integrated model of picture archiving and communication system (PACS) success.



Statistical Analysis

Data management, analysis, and graphical presentation were carried out using the software Statistical Package for the Social Sciences (SPSS), version 22.0. The questionnaire was evaluated for internal consistency and reliability, and Cronbach alpha values were estimated for major perspectives by combining the Likert scale items for specific aspects, including quality, information, images, technical support and usage, user satisfaction, and overall opinion on the PACS. The descriptive statistics analysis generated frequencies and percentages for all the 5-point Likert scale items (1 as lowest or strongly disagree and 5 as highest or strongly agree) in the questionnaire. The Likert scale data were also analyzed to find average values for overall responses and to compare the mean (±standard deviation, SD) between radiologists and technologists using *t* tests or nonparametric Mann-Whitney tests. The quantitative or continuous variables, age, duration of use (h), and minutes saved every day were first ascertained for normal distribution, applying the Kolmogorov-Smirnov test and were presented as mean ± SD and range for normally distributed variables and as median, range and interquartile (IQ) for skewed data. The chi-square or Fisher exact test was applied to find any association or significant difference between categorical variables. The Spearman correlation coefficient (rho) was used to find any correlations among the number of hours worked, the use of the PACS, and the minutes saved in daily practice. The 2-tailed probability value $P<.05$ was considered statistically significant.

Results

Questionnaires

Respondent Demographics

The study's overall response rate was 70%: 75% of the radiologists and 62% of the technologists of the radiology department. The study had 60 respondents: 39 radiologists (mean age = 36±7.5 SD) and 21 technologists (mean age = 28±10 SD). The respondents' ages varied between 20 and 60 years, with the majority (85%; 51 of 60) aged younger than 40 years. The respondents' average self-rated level of familiarity with computers was 4.8 ± 1.34 (mean ± SD) on a scale of 1-7, and 41% (24 of 59) of the respondents had earlier experience with PACSs before working at this radiology department.

Evaluation of Different Perspectives on the PACS

The overall responses on different perspectives were analyzed, and composite reliability and coefficients (Cronbach alpha) were computed and presented in Table 2, along with mean and range for each perspective. The Cronbach alpha values ranged between.73 and.96, except for one as shown in in Table 2. System quality, images produced, and services, all had high (>.9) Cronbach alpha values.

The overall perspectives of users have been presented on the following aspects:

System Quality

Almost three-quarters (75%; 44 of 59) of the respondents rated the PACS positively and as user friendly, with a mean of 3.28 (Table 2). Comparatively fewer (64%; 38 of 59) respondents mentioned some drawbacks of the system, such as it being temporarily out of service or not working, numerous bugs, waiting time at the workstations, and the screen quality slowing PACS use. The majority (81%; 48 of 59) agreed that the PACS had improved the quality of services at the radiology department (mean=4.01). However, some suggestions were provided by respondents (mean=3.57) with regard to the system's improvement included the provision of more options and investment in upgrading the visualization equipment (PC monitors).

Information Quality

In all, 90% (53 of 59) agreed that the PACS produced better and higher-quality information (mean=3.75) that was accurate, updated, relevant, and timely. The system also provided complete patient information, including adequate access to patients' historical data (mean=3.56).

Image Quality

The PACS users were extremely satisfied with regard to the quality of the images produced, ease of understanding, and relevance (mean=4.27). They found that the PACS produced much better images compared with traditional films (mean=4.33).

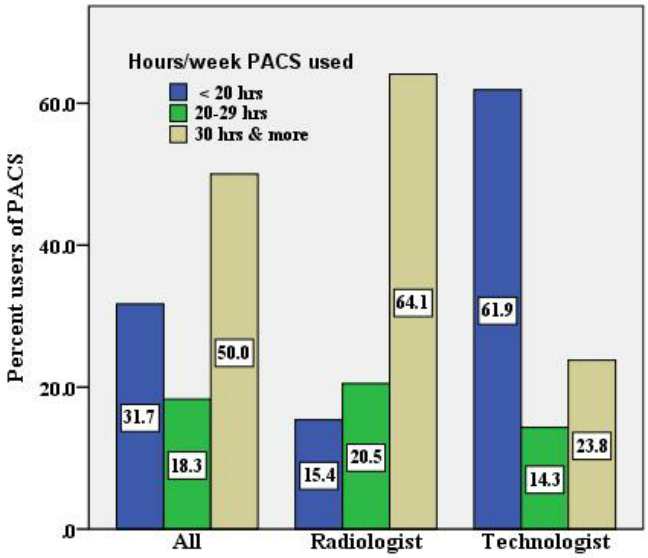
Technical Support and Services

The PACS users were quite satisfied with technical support (mean=3.60) and the reliability, promptness, and dependability of services.

Use of PACS and Satisfaction

In all, 50% (30 of 60) of the respondents mentioned using the PACS for more than 30 hours per week (Figure 2), although a significant difference was found regarding the duration of PACS use (hours/week) between radiologists and technologists ($P<.001$). A high level of user satisfaction was shown with regard to their experience in using the PACS (mean=3.65). The usage of various tools, including making changes to the display format, retrieving and "split screen" to compare images was found to be quite satisfactory (mean=3.57), especially among radiologists.

Figure 2. Respondents' picture archiving and communication system (PACS) use per week.



Future Use and Expectations on PACS

In all, 83.9% (mean=3.39) of PACS users mentioned their expectations better than what they expected originally and showed intention to continue using PACS.

Overall Opinions and Impact of PACS

Based on 21 different statements, 93% (56 of 60) of the PACS users showed consensus on various aspects of the system's benefits and effectiveness (mean=4.01), and the mean was significantly higher for technologists as compared with radiologists (4.22 vs 3.89). Furthermore, the results showed that 80% (48 of 60) of the PACS users reported saving more than 30 minutes of their practice time each day, whereas 38% (23 of 60) mentioned saving more than an hour each day.

Table 2. PACS users and their responses.

User perspectives of the PACS		No. of items	Alpha[a]	Mean[b]	Range
Quality					
	Encouraging features	15	.906	3.284	1.567-4.033
	Non encouraging features	5	.767	3.000	2.50-3.400
Information					
	Produce better information	4	.888	3.754	3.650-4.000
Images					
	Quality of images produced	4	.910	4.272	4.183-4.333
	Compared to traditional films	4	.855	4.333	4.100-4.483
	Confidence in image quality	2	.875	4.205	4.154-4.256
	Data adequacy—access to patient data	2	.808	3.558	3.500-3.617
Technical support					
	Reliable, prompt services	7	.961	3.598	3.483-3.683
Use of the PACS and satisfaction					
	Frequency of PACS use	5	.638	3.573	2.583-4.000
	User satisfaction	3	.887	3.650	3.533-3.717
Future use of the PACS					
	Expectations, and continuance of use	3	.734	3.394	3.233-3.483
Overall opinion and impact of the PACS					
	Improved quality and services (benefits)	21	.919	4.008	3.169-4.390

[a]Cronbach Alpha: Measure of Internal Consistency Reliability.

[b]Mean values are based on a 5-point Likert scale, with 1 being the lowest and 5 being the highest.

Radiologists versus Technologists

Table 3 summarizes the comparison between radiologists' and technologists' responses with regard to their perspectives concerning the PACS. The mean values were significantly higher for the technologists as compared with the radiologists, especially concerning quality, information, patient data, technical support, and overall opinion on impact of the PACS (P<.05). Both professionals showed the highest level of satisfaction (mean >4) with regard to image produced, also their overall opinions on PACS demonstrated improved quality and services (radiologist 3.9 and technologists 4.2).

Table 3. Radiologists' and technologists' responses.

User perspectives on the PACS		Radiologists (n=39)		Technologists (n=21)		*P* value
		Mean[a]	SD	Mean[a]	SD	
Quality						
	Encouraging features	3.109	0.559	3.733	0.528	.006
	None encouraging features	3.070	0.693	3.333	0.563	.244
Information						
	Produce better information	3.539	0.830	4.155	0.886	.007
Images						
	Quality of images produced	4.188	0.692	4.429	0.598	.186
	Compared to traditional films	4.436	0.622	4.143	0.705	.083
	Confidence in image quality[b]	4.205	0.704	—	—	—
	Data adequacy—access to patient data	3.295	1.074	4.048	0.879	.005
Technical support						
	Reliable, prompt services	3.396	1.080	3.973	0.600	.029
Use of the PACS and satisfaction						
	Frequency of PACS use	3.585	0.760	3.552	0.819	.963
	User satisfaction	3.556	0.863	3.825	0.611	.144
Future use of the PACS						
	Expectations and continuance use	3.282	0.867	3.603	0.629	.140
Overall opinion and impact of the PACS						
	Improved quality and services (benefits)	3.892	0.623	4.218	0.427	.050

[a]Mean values are based on a 5-point Likert scale, with 1 being the lowest and 5 being the highest.

[b]Technologists were not asked this question, as the decision on image quality lies on radiologists.

In total, 49% (19 of 39) of the radiologists mentioned saving more than 60 minutes every day, as compared to 19% (4 of 21) of the technologists (*P*=.048) (Figure 3).

During using the PACS, both the professionals reported a good saving in the working time for different modalities, though with much variation (the Kolmogorov–Smirnov tests showed a skewed distribution), the median and interquartile have been presented in Figure 4 as box-plot. The maximum number of minutes saved was 52 minutes (median time) by radiologists in magnetic resonance imaging and 50 minutes by technologists in radiography.

A significant positive correlation was observed between the number of hours using the PACS and the minutes saved in daily practice since the introduction of the PACS (*r*=0.27, *P*=.037).

The level of prior familiarity with computers was found to be similar between the radiologists (4.84±1.34 SD) and the technologists (4.71±1.35 SD) and did not make any significant difference either in the average duration (hours/week) of working with the PACS or the time saved (minutes/day) during practice.

The results of the open-ended questions showed that 24% (9 of 38) of the radiologists and 33% (7 of 21) of the technologists stated that storing, retrieving, and comparing images were the most positive elements associated with the use of the PACS. By contrast, 33% (13 of 39) of the radiologists and 43% (9 of 21) of the technologists stated that frequent glitches were the most negative element associated with the PACS.

Overall, the study's findings revealed that both the radiologists and the technologists perceived the adoption of the PACS positively. The mean scores were mostly above 3 or 4 on a scale of 1-5. The mean scores for image quality and information produced were 4.3 and 3.8, respectively. The users seemed quite satisfied with the services and technical support, with a mean score of 3.6 and showed satisfaction in working with the PACS (mean=3.65). The PACS users clearly mentioned improved services and quality since the system came into practice, with a mean score of 4.

Figure 3. Respondents' Minutes Saved per Day.

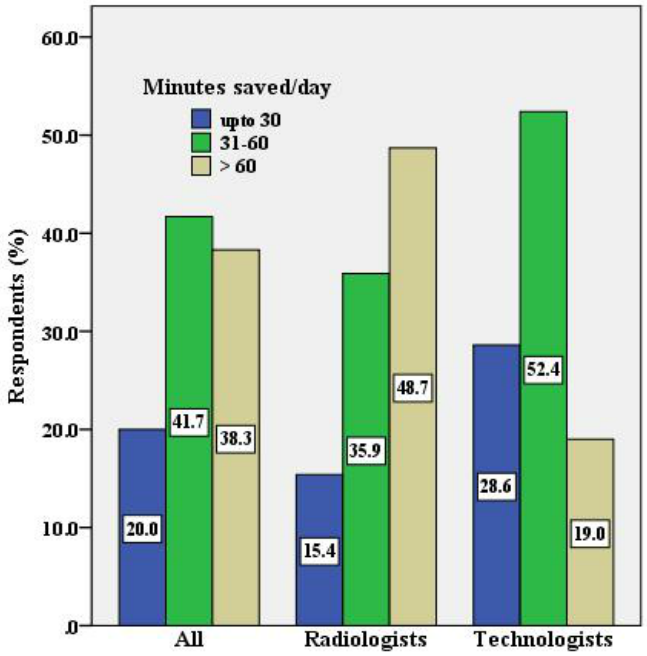
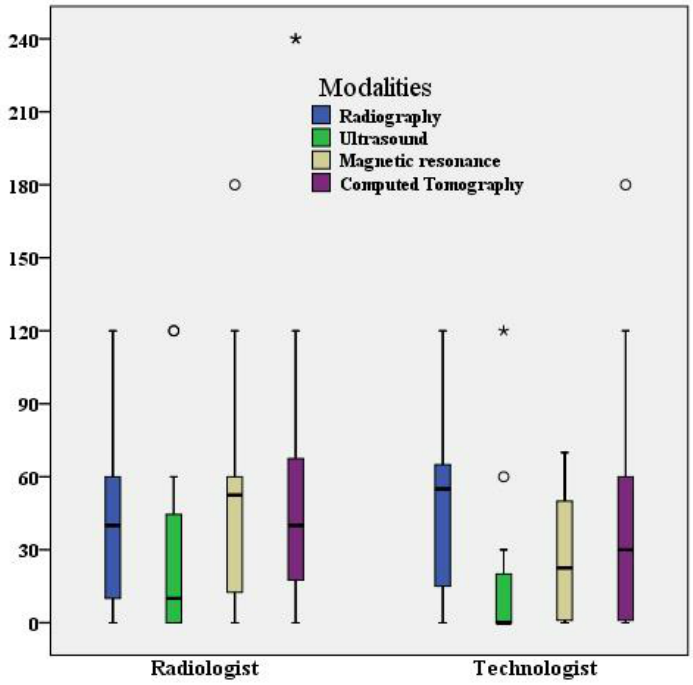


Figure 4. Average minutes (median with interquartile range) saved per day by picture archiving and communication system (PACS) users in different modalities.



Interviews

The opinions of the PACS administrators were obtained by using the interview method, for which a series of semi structured questions on specific themes (Textbox 1) provided the basis for soliciting information.

At the time of the interviews, Mubarak Al-Kabeer Hospital had 5 PACS administrators: For scheduling the interviews, requisite permission was taken from the head of the radiology department, and interview sessions were arranged with the staff during their respective work breaks, over a 5-day period. Each interview session lasted approximately 50 minutes. The interviews were transcribed, and the responses were coded and analyzed using thematic analysis.

The interview results showed that all the interviewees had a BSc degree in radiological sciences, with their ages ranging between 25 and 35 years, and each having work experience of 2-5 years in PACS administration. Of the interviewees, only 3

had undertaken an introductory training program abroad on PACS use and management.

Perceived System Quality

The interview responses confirmed that the PACS provided easy access to authorized users, each with a user identification (ID) number and password, thereby providing a secured workspace depending on the user's position. For instance, a radiology technologist's access is limited to only viewing the reporting screen, with no authorization to change or manipulate it, thus preserving the data, with no hacking or security problems ever encountered or reported.

The interviewees unanimously agreed that the PACS was user friendly and hassle free in its functionality. In one of the interviewee's words, "*We haven't experienced any complaints from radiologists regarding the clarity of the PACS's features, or any difficulties in moving between its functions*," further adding that training in the PACS should be a prerequisite before its use.

The participants also endorsed the reliability and consistency of the existing hardware, including computer systems, networks, and printers, with the software used. The interviews further revealed that the PACS was fully integrated and compatible with the RIS and the HIS, although the workflow did not follow the planned process, as Figure 5 demonstrates. According to one interviewee, "*The real mistakes are not coming from the PACS but from humans, so they're human errors.*" The interview responses also highlighted that the problems associated with PACS integration and compatibility with the RIS and the HIS were the result of disorganized workflow, as shown in Figure 5.

Figure 5 (above) illustrates the workstations where electronic registration of patients through the HIS, and the RIS failed due to receptionist errors such as: (1) no data entry into HIS, manual registration in the RIS; (2) failure of communication between the HIS and the RIS, manual registration in the RIS; (3) and incorrect registration at reception, manual registration in the RIS (Figure 6).

The manual registration at these 3 workstations resulted in: (1) a lack of direct access to patients' imaging results through the HIS; (2) the creation of multiple PACS numbers for the same patient, making it difficult to retrieve previous reports for comparison, as well as the loss of patient data; and (3) delayed patient case management due to a failure in the rapid delivery of results.

Figure 5. Workstations where electronic registrations of patients failed through the health information system (HIS) and radiology information system (RIS).

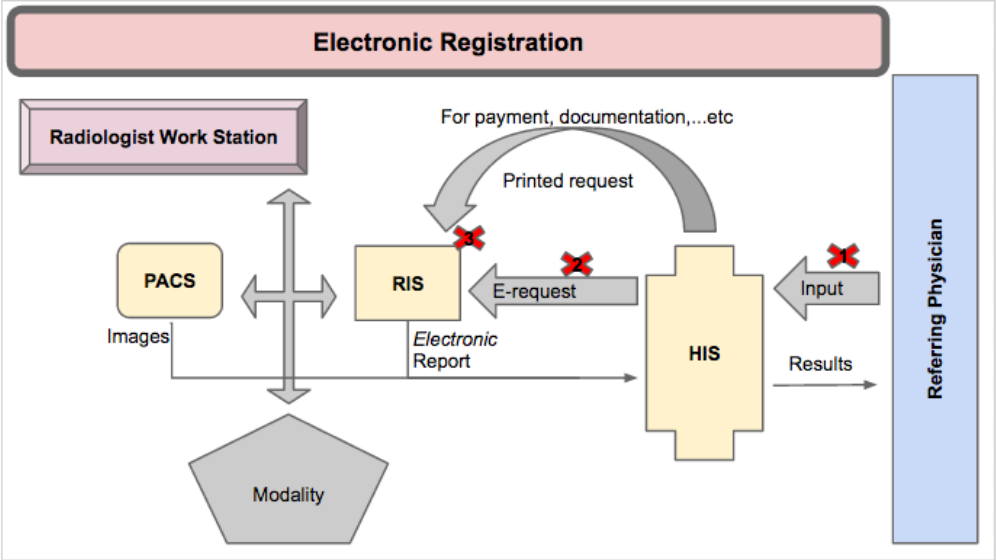
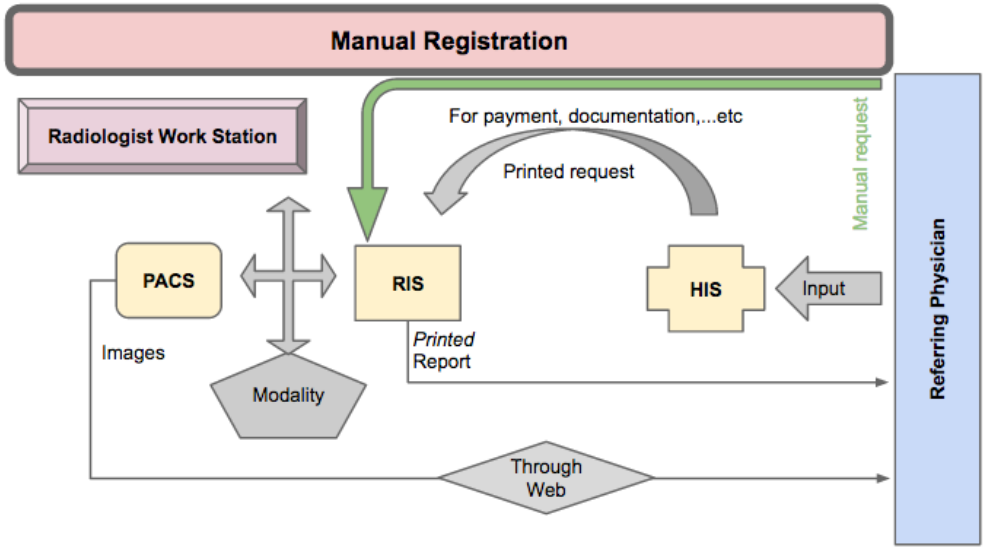


Figure 6. Manual registration of patients through the health information system (HIS) and radiology information system (RIS).



Perceived Information Quality

The interviewees agreed that the PACS provided a standard format for the acquisition of accurate and complete information, together with images, concerning the patients' medical cases, including their name, age, gender, national identification number, medical record number, and medical history. The lapses that occurred in the recorded information were attributed to the registration staff of the diagnostic radiology department because of their noncompliance to instructions, which resulted in incomplete data records of patients at the time of registration.

Perceived Image Quality

The interview responses indicated that one of the main roles of PACS administrators was to ensure that the images were transferred and displayed with clarity to facilitate studying and reporting. The participants further confirmed that "*We experience hangs in the images in PACS, but at an acceptable rate*" and no complaints were mentioned concerning image manipulation and management.

Perceived Technical Support Services

As the interviewees mentioned, the main IT support is delivered through the company that sold the PACS. This usually happens when the PACS administrators face a technical problem that can only be solved through the main IT support at the company. Thus, the PACS administrators asked to have some power to authorize them to solve the technical issues within the radiology department. One of the interviewees stated: "*…even when we want to connect a new printer to the PACS, we have to call the main IT support to perform this function for us.*" However, all of the interviewees complimented the IT support services at the company for their prompt responses to any technical issues.

Impact of PACS on Clinical Practice

PACS has an impact on the clinical practice of radiologists and technologists, as shown in the interviews' results

Perceived Net Benefits of the PACS

From the interviews, it was easy to see that the PACS has increased users' productivity in comparison to the traditional filming system by minimizing their effort and time. In addition, the retaking of images is not required, as the PACS facilitates image storage and retrieval faster and over a longer period. "*We are happy with the PACS's benefits*," reported one interviewee, although the system has slowed in speed due to the huge number of cases, with the intervening procedures passing through several modalities, such as computed tomography and magnetic resonance imaging. There is also the possibility of missed images, especially concerning unknown IDs, although these could be traced using the patient's civil ID, the patient's PACS ID, or the excision ID of images.

User Satisfaction with the PACS

All the interviewees were apparently satisfied with the PACS; however, the technology-associated problems need to be addressed to optimize the system's versatility and performance.

Opinions on the PACS

Overall, from the interviews, the responses revealed that as long as the image is electronically collected, stored, and communicated to another system successfully, the productively of work will be increased, diagnosis will be precisely performed, the patient will be treated accurately and quickly, and health services will be improved.

Expectations of the Current PACS and Future Trends

The interviewees expressed satisfaction in using the PACS system but also highlighted the need for resolving the current problems, as well as to keep abreast of the latest advances in PACS operations, to meet the growing demands of the Kuwaiti health system. The emerging requirements for potential trends in the future concern the areas of: (1) teleradiology services (for radiologists to use the PACS anywhere and anytime); (2) mobile images viewer for faster accessibility to images; (3) speech recognition functions; (4) computer-assisted diagnosis (CAD); (5) advanced training; and (6) recruiting health informatics graduates to support the PACS administrators.

Discussion

In general, the study's findings revealed that the PACS has had a productive impact on the staff's clinical practice. Despite some of the technical limitations of the infrastructure, most of the respondents rated the system positively and as user friendly. The findings showed that the technologists were more satisfied than the radiologists were with using the PACS. Interestingly, there was a significant relationship between the perceived benefits of the PACS and the willingness of users to continue using it. It was also noteworthy that the problems associated with the PACS's integration with the RIS were the result of disorganized workflow.

The results of the study revealed that the users' demographic data, including computer experience, had no influence on their response patterns, being insignificant determinants of their predilection or preference for the PACS in enhancing their work efficiency. These findings were consistent with the study's results on PACS acceptance [7], but contradicted with the results of earlier studies that reported the significant influence of age and gender on users' choices concerning information technology, such as computer use patterns [20,21], particularly to adopting PACS [3,8].

Perceptions of PACS Quality, Information, Images, and Services

The study further revealed that both the radiologists and the technologists were satisfied with the quality of information and images produced and had positive views regarding the use of this technology. The PACS offered the users with the requisite information on a medical case and facilitated the accomplishment of several functions with efficiency and ease in producing high-quality images with precision and clarity. This positive relationship found between users' satisfaction and quality of information and images, produced by PACS was consistent with the findings of previous studies [1,22]. The results of the interviews further complemented these findings, with no mention of lost images posing a major problem, due to successful image retrieval by PACS administrators.

The study found that the technologists were more satisfied than the radiologists, concerning their current PACS use, attributing their satisfaction to 2 reasons, which had been confirmed in previous studies [2,6,23]: the technologists achieved their core objectives of using the PACS, including image access, storage, and retrieval and (2) the radiologists looked beyond these features for additional facilities and functions, such as the PACS being packaged with CAD, teleradiology, or speech recognition functions. As the radiologists had been using the PACS far longer than the technologists had, their understanding and familiarity with the PACS appeared to be relatively higher.

Concerning the quality of the services offered to support PACS technically, the findings showed that both users were satisfied with the technical support provided with regard to the promptness, reliability, and dependability of the services. However, the results of the interviews revealed that the radiologists and the technologists encountered organizational and infrastructure deficiencies. On the technical level, there was frequent breakdown of the system during rush hours; and on organizational level, there was negligence of some receptionists in recording patients' information from the RIS to the HIS. Interestingly, the respondents still showed satisfaction in confirming the benefits of the PACS over conventional radiology despite some deficiencies, as reportedly addressed in previous studies [3,22].

Perceptions of the PACS's Impact, Including Net Benefits and User Satisfaction

Regarding the PACS's net benefits, the findings demonstrated that both the radiologists and the technologists had used the PACS to enhance their work productivity with ease due to the swift storage, retrieval, and transfer of images along with reports. These findings were consistent with those reported in previous evaluative studies on the impact of PACS [6,24], confirming that work productivity in regard to the given effort, time, and accuracy of reporting, has obviously been improved. Furthermore, the PACS's benefits were found to have direct implications for user satisfaction, affecting their continued use of the PACS in the future [16]. These previous studies concluded that the more the users agreed with a PACS's effectiveness in their work, the more they were satisfied and willing to continue using it. The findings of the interviews further confirmed that both types of users benefitted from the PACS's advantages, expressing their readiness toward the technology's continuous use while looking ahead for additional functions, without deficiencies, which coincided with other studies [25-27].

Limitations

(1) This study was limited to radiologists and radiology technologists and did not involve other health care providers who are responsible for receiving patients' reports and images. Hence, there is a need for further research that would substantiate the study's findings by involving other stakeholders using the PACS facility, for the purpose of comparing research outcomes and enhancing the study's value. (2) The study also did not include socioeconomic and cultural factors, which are significant predictors of IT adoption in the Arab world [7,28,29] in comparison to Western countries. However, the respondents' willingness to use the PACS was a positive indicator of the technology's versatility, efficiency, and continuous use. (3) As the study was confined to one general hospital in Kuwait, there is a definitive need for future studies to enhance the study's scope by including other hospitals where PACSs are being used, for comparative purposes. (4) The study used specific criteria in evaluating IS success; hence, there is a need for using different models and tools for exploring and assessing PACSs and RISs from different dimensions.

Conclusion

Evaluating the applications of imaging informatics, such as PACSs, in hospitals is very crucial to ensure the successful implementation of the applications, to identify the systems' strengths and weaknesses during operation and to provide the opportunity for further improvements, strengthening the positive elements and minimizing drawbacks.

The evaluation of the existing PACS at Mubarak Al-Kabeer teaching hospital led to the successful assessment of the

technology's implications, based on which the study's conclusions are summarized: (1) the PACS exhibited a positive impact on the radiologists and the technologists in the diagnostic radiology department, significantly enhancing their work efficiency and productivity. Therefore, the impact of the technology was particularly visible in the context of its ability to store and retrieve images quickly, enabling the users to accomplish their tasks swiftly. In addition, the system facilitated the addition of an image to a report, expediting communication with another location with a keystroke; (2) the main concern reported by all the users was the frequent breakdown during rush hours at busy workstations, due to infrastructure deficiency; (3) both the technologists and the radiologists indicated the need for a more-advanced PACS in response to the growing demand of teleradiology, mobile image viewer, and voice recognition features; and (4) evaluating PACS's success is not confined to the technology itself but also concerns organizational and human factors that could limit the full integration with HIS.

Recommendations

To improve the work on the current PACS and overcome the deficiencies, the following recommendations could be considered at Mubarak Al-Kabeer general hospital: (1) the need to enhance the capacity of existing servers to accommodate the huge amount of data generated from the massive inflow of patients. (2) The need to develop an internal policy to facilitate the coordination with the hospital management for organizing hospital workflow with efficiency. This policy should be followed carefully by the department staff for achieving the full benefits of the PACS's integration with the HIS and the RIS. (3) The need to offer advanced training courses for fully using the PACS's functions. (4) The need to look forward for future trends of PACS, including teleradiology services, mobile images viewer, speech recognition functions, and CAD. (5) The need to hire health informatics specialists for providing the requisite administrative support on account of their knowledge in the field.

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Conflicts of Interest

None declared.

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Abbreviations

CAD: computer-assisted diagnosis
HIS: health information system
ID: identification
IS: information system
PACS: picture archiving and communication System
RIS: radiology information system

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Original Paper

Impact of Implementing a Wiki to Develop Structured Electronic Order Sets on Physicians' Intention to Use Wiki-Based Order Sets

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Abstract

Background: Wikis have the potential to promote best practices in health systems by sharing order sets with a broad community of stakeholders. However, little is known about the impact of using a wiki on clinicians' intention to use wiki-based order sets.

Objective: The aims of this study were: (1) to describe the use of a wiki to create structured order sets for a single emergency department; (2) to evaluate whether the use of this wiki changed emergency physicians' future intention to use wiki-based order sets; and (3) to understand the impact of using the wiki on the behavioral determinants for using wiki-based order sets.

Methods: This was a pre/post-intervention mixed-methods study conducted in one hospital in Lévis, Quebec. The intervention was comprised of receiving access to and being motivated by the department head to use a wiki for 6 months to create electronic order sets designed to be used in a computer physician order entry system. Before and after our intervention, we asked participants to complete a previously validated questionnaire based on the Theory of Planned Behavior. Our primary outcome was the intention to use wiki-based order sets in clinical practice. We also assessed participants' attitude, perceived behavioral control, and subjective norm to use wiki-based order sets. Paired pre- and post-Likert scores were compared using Wilcoxon signed-rank tests. The post-questionnaire also included open-ended questions concerning participants' comments about the wiki, which were then classified into themes using an existing taxonomy.

Results: Twenty-eight emergency physicians were enrolled in the study (response rate: 100%). Physicians' mean intention to use a wiki-based reminder was 5.42 (SD 1.04) before the intervention, and increased to 5.81 (SD 1.25) on a 7-point Likert scale (P=.03) after the intervention. Participants' attitude towards using a wiki-based order set also increased from 5.07 (SD 0.90) to 5.57 (SD 0.88) (P=.003). Perceived behavioral control and subjective norm did not change. Easier information sharing was the most frequently positive impact raised. In order of frequency, the three most important facilitators reported were: ease of use, support from colleagues, and promotion by the departmental head. Although participants did not mention any perceived negative impacts, they raised the following barriers in order of frequency: poor organization of information, slow computers, and difficult wiki access.

Conclusions: Emergency physicians' intention and attitude to use wiki-based order sets increased after having access to and being motivated to use a wiki for 6 months. Future studies need to explore if this increased intention will translate into sustained actual use and improve patient care. Certain barriers need to be addressed before implementing a wiki for use on a larger scale.

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KEYWORDS

knowledge translation; wiki; collaborative writing applications; decision support tools; health informatics; Theory of Planned Behavior; emergency medicine; computer physician order entry

Introduction

Clinical practice does not always reflect best evidence. High proportions of inappropriate care have been reported in different health care systems and settings and have a huge impact on both patient outcomes and health care costs [1]. Information and communication technologies (ICTs), such as computerized decision support systems, have been suggested as a possible solution for improving research uptake and increasing evidence-based practice [2,3]. However, these systems have yet to deliver the expected benefits despite the billions of dollars governments have invested in anticipation of improving care and reducing costs [4]. Moreover, some health care professionals have rejected these ICTs on the grounds that they are slow, incompatible with work processes, difficult to access, costly to implement, and cannot be adapted to local practices [4-8]. Furthermore, local initiatives to adapt the content of various clinical decision support systems seem to be restricted to a small number of hospitals, and tools are mostly designed for local use only [6]. Transfer of these local initiatives to the larger health care community is often slow and complex. Wikis are an open-source and low-cost means of accelerating innovation that could offer a solution to these problems by reducing duplication of effort, optimizing use of existing resources, and by engaging local stakeholders [6,9-12].

Wikis are knowledge management platforms that may empower stakeholders to implement evidence-based decision support tools in different areas of health care [13-15]. A wiki is a website that uses a novel technology to allow people to view and edit website content, with viewing and editing privileges determined by various levels of access. Many health organizations have started using wikis to manage knowledge and coordinate care [10,16,17].

In emergency departments (EDs), where shift work is prevalent, getting health care professionals to collaborate in creating, using, and updating decision support tools is particularly difficult [9,13,18]. EDs often translate clinical practice guidelines into order sets (ie, predefined groupings of standard medical orders for a condition, disease, or procedure) to remind their clinicians about best practice. However, these order sets must be adapted to local practice [19]. A wiki could permit multiple stakeholders in one or many EDs to collaborate asynchronously in the updating and creation of order sets, decreasing duplication, and reducing the time needed [9,11,20]. However, despite increasing evidence supporting the use of wikis in various settings, there is a lack of knowledge about the impact a wiki has on the implementation of best practices. Our overarching research program aims at evaluating the impact of a wiki containing various order sets on the implementation of best practices in trauma care [11,12]. However, before we can achieve this, we must identify the factors influencing professionals' use of the wiki [9,20,21] to facilitate its implementation. Many factors (eg, openness, instant publication, non-monetary incentives, group affiliation, motivation, strong leadership, active coordination) have been shown to improve contributions to wiki projects in other fields such as education [23,24], sociology [25,26], informatics [27-31], and management [32-34]. However, very few theory-based investigations have been led in the field of health care to understand how health professionals could use wikis' potential to improve collaborative knowledge implementation in interprofessional settings like EDs [9,22,35,36]. In addition to the importance of studying how to get health professionals to contribute to a wiki, it is also important to know how to get to use and trust collaboratively created content. Our hypothesis is that if we can optimize the clinical use of our wiki by developing a theory-based intervention that will target the behavioral determinants that influence wiki use by health professionals, we will be capable of developing an effective and low-cost intervention that will improve the implementation of best practices in emergency settings. To test our hypothesis, we wanted to assess the impact of actually contributing to a wiki on emergency physicians' (EPs) intention and behavioral determinants to using the wiki in clinical practice. Thus, our objectives were: (1) to describe the use of a wiki to create structured order sets for a single ED; (2) to evaluate whether the use of this wiki changed emergency physicians' future intention to use wiki-based order sets; and (3) to understand the impact of using the wiki on the behavioral determinants to use wiki-based order sets.

Methods

Setting

As of June 2013, the ED at Hôtel-Dieu de Lévis (HDL), a university-affiliated hospital in Lévis, Quebec, was moving into a newly renovated and much larger Emergency Department (4625 m^2compared to 1387 m^2). The ED was also planning an evolution away from paper-use with a new computer-physician order entry (CPOE) system (Med-Urge™, MédiaMed Technologies, Mont-Saint-Hilaire, Québec, Canada). This system allows local order sets to be entered in the system; however, it does not have an open collaborative writing application to help clinicians develop the order sets collaboratively. Thus, the department head in collaboration with our research team decided to use a wiki platform (a Google Sites™ wiki) to create the order sets collaboratively with the 28 EPs in the Emergency Department. This provided the opportunity to assess EPs' intention to use a wiki-based order set before and after 6 months of actually using the wiki to create and edit the order sets for the new CPOE system.

Study Design, Participants Recruitment, and Baseline Data Collection

This study is a prospective pre/post-intervention mixed methods study among the EPs at HDL. All EPs at HDL were eligible to participate except the principal author and the departmental head (PB). After receiving ethics committee approval in October 2012, we presented the research project to the EPs at HDL at

their monthly departmental meeting. All eligible participants were sent an invitation by email to respond to a previously validated Web-based survey [21]. This questionnaire contained an HTML link to a 6-minute YouTube video [9,21] depicting a physician using a wiki-based order set for the management of severe traumatic brain injury victims in the ED. Participants had to view this video before responding to the questionnaire. The video allowed participants to understand all the small implicit lead-in behaviors necessary to using a wiki-based order set in clinical practice (eg, logging onto the Internet, using a keyboard to type in the search terms to find the wiki-based order set, checking off the appropriate prescriptions suggested by the wiki-based order set). After viewing the video, the questionnaire, based on the Theory of Planned Behavior (TPB) [37], contained 55 items that measured the direct and indirect TPB constructs (intention, attitude, subjective norm, perceived behavior control, behavioral beliefs, control beliefs, and normative beliefs) including 10 sociodemographic items. The TPB is well known for its application to the study of health care professionals' behaviors [38,39]. Furthermore, the TPB questionnaire used for this survey has been formally validated for the behavior being studied in this study and has adequate test-retest reliability (Multimedia Appendix 1) [21]. Participants who preferred a paper-based questionnaire were sent a paper copy of the survey and an email containing the HTML link to the YouTube video. The video was also presented during the monthly departmental meeting in October 2012. After the initial invitation, participants received two reminders at two-week intervals to respond to the questionnaire between October and November 2012.

Intervention

The intervention consisted of making the Google Sites wiki available to all 28 EPs at HDL and receiving the instructions from the departmental head to use the wiki to create a series of order sets that would be transferred to the new CPOE system in June 2013. In December of 2012, the department head presented a brief overview of Google Sites' functionalities to the EPs at the monthly departmental meeting where all EPs were invited to attend. Google Sites was presented as the wiki platform that would be used to create the different order sets for the Department. Google Sites is a structured wiki- and web-creation tool offered by Google as part of the Google Apps for Work productivity suite. Google Sites allows anyone to create a team-oriented website where multiple people can collaborate and share files. We chose Google Sites because it was free (with a maximum of 100 MB of storage), easy to use, and most members of our ED already had Gmail accounts and were accustomed to using Google applications such as Google Docs. The advantages to using Google Sites were that we did not need users to know HTML or any wiki markup language and many different Webpage templates existed. The possibility to manage three different levels of user access was also an interesting feature that influenced our choice to use Google Sites. These three levels of permissions are: Owner, Editor, and Viewer. Owners have full permissions to modify design and content of the entire Google Site, whereas editors cannot change the design of the site. Viewers can only view the site and are not permitted to make any changes to text or otherwise. All the participants in this study were given editor-level access. Additional guidance regarding the steps involved for editing an order set were presented in person and on the home page of the wiki.

A Google Sites wiki page, called "Urgence HDL Informatisation" [40], was created and then presented to the group. This Google Sites wiki was created to contain collaboratively created order sets (written in French) and information related to the Department's transition towards the new CPOE system. The departmental head then asked all members to design at least one order set and then to review those made by their colleagues. The departmental head asked members to accomplish these tasks as part of their mandatory departmental responsibilities without any additional form of remuneration. An initial list of order set titles was created by the departmental head based on a list of the most frequent ED reasons for consulting the ED (eg, chest pain, gastroenteritis, sepsis). Members of the Department could also add to this list with their own order set topics. After this meeting, the EPs used the wiki to create and edit order sets for 6 months in preparation of their use of the new CPOE in June 2013. From December 2012 to May 2013, the departmental head reminded members at each monthly meeting to complete their wiki-based order set. All ED physicians had editing privileges during the duration of this trial. Although access to reading wiki content was available to anyone with the HTML link, wiki editing and pages revision history was only available to wiki editors. Once all members had completed their order sets, we systematically peer-reviewed them during a Department meeting and further improved them before the department head conducted a final review before exporting them manually into the new CPOE system by copying and pasting content into the new CPOE system. Participants were also encouraged by the departmental head to ask questions and add comments during or after meetings using the discussion thread function linked to each Google Sites page. Although our Google Sites wiki was planned to remain available after the study, it was only created for the purpose of this study and to create the order sets for the new CPOE system.

The purpose of getting emergency physicians to contribute content to this Google Sites wiki was to allow them to get to know how a wiki works and how its content is created collaboratively. As previously explained in the introduction, we wanted to explore the impact of this intervention on emergency physicians' future intention to use the wiki to inform decision-making in clinical practice. Even though our intervention is focused on "contributing to a wiki", it is important to understand that our pre and post-questionnaires only focused on participants' intention "to use a wiki-based order set" in clinical practice.

Outcomes and Post-Intervention Data Collection

The primary outcome measured following this intervention was the intention to use the wiki-based order set in a clinical context. Other secondary outcomes were also measured using our TPB questionnaire: attitude, perceived behavioral control, subjective norm, and the indirect TPB constructs (behavioral beliefs, control beliefs, and normative beliefs). We also used Google Analytics™ to collect daily wiki usage statistics. These statistics were only available after the wiki was launched. The

post-intervention questionnaire included open-ended questions to better understand participant's positive and negative views about using the wiki. We also asked participants to make suggestions to improve the wiki. Again, both Web-based and paper-based versions were available, but participants were not asked to view the video prior to completing the post-intervention questionnaire.

Data Analysis

We imported data from completed Survey Monkey questionnaires into an Excel spread sheet as well as daily usage statistics from Google Analytics. We compared the means, medians, interquartile ranges, and confidence intervals for each pre- and post- intervention question. Considering our small sample size, we conducted Wilcoxon signed-rank tests for continuous variables. We conducted a post-hoc analysis to compare the demographic characteristics and the measured behavioral determinants of participants who reported using the wiki during the 6-months study. For any missing data for single questionnaire items, we imputed the average of the other items measuring the same construct only if data was available from a minimum of two other items. A biostatistician performed the statistical analyses using SAS version 9.3 (SAS Institute Inc, Cary, NC, USA).

Two research assistants independently analyzed answers to open-ended questions by classifying the content by theme using two previously developed taxonomies (ie, positive/negative impacts, barriers/facilitators) [13]. They classified answers as a perceived positive and/or negative impact when a participant claimed that using the wiki had an impact on a clinical process or a clinical outcome. They classified answers as barriers/facilitators when the idea expressed by the participant was a barrier or facilitator to using the wiki. They then classified the comments in each theme by frequency of reporting.

Results

Participant Characteristics

Twenty-eight EPs from HDL completed both questionnaires, for a response rate of 100%. As seen in Table 1 , most participants were mid-career, male physicians with emergency medicine certification issued by the College of Family Physicians of Canada. Collaborative writing applications reported as having been previously used for personal reasons were: Wikipedia and Google Docs. One physician reported having previously edited a document using a collaborative writing application, specifically Google Docs. Other tools that clinicians mentioned as being used frequently were Dropbox and Evernote.

Table 1. Characteristics of participating emergency physicians (EPs).

Variables	EPs (n=28)
Age (years)	
Mean (SD)	40.7 (7.4)
Median (IQR)	41 (35-47)
Gender, n (%)	
Female	7 (25%)
Male	21 (75%)
Emergency medicine certification, n (%)	
Royal College of Physicians and Surgeons of Canada	7 (25%)
College of Family Physicians of Canada	21 (75%)
Previous professional use of a wiki, n (%)	7 (25%)
Previous personal use of a wiki, n (%)	19 (68%)
Previous editing of a wiki, n (%)	1 (3.5%)

Order Sets Developed

During the 6-month study, the wiki was used to create 68 order sets for a variety of conditions seen in the ED in the fields of anesthesia and critical care (n=9), neurology (n=9), gynecology-obstetrics (n=6), psychiatry (n=6), cardiology (n=5), pediatrics (n=5), trauma (n=4), rheumatology (n=4), ophthalmology/otorhinolaryngology (n=4), infectious diseases (n=4), gastroenterology (n=3), geriatrics (n=3), respirology (n=2), orthopedics (n=2), and hematology/oncology (n=2). A complete list of these order sets is available from the wiki itself [40]. In all, 15/28 (54%) participants created at least one order set and 13/28 (46%) did not create any (median of 0.5 order set per participant). The three most productive participants created more than 15 order sets each.

Post-Intervention Intention to Use Wiki-Based Order Sets

After 6 months of using the wiki to create order sets, participants were asked to respond to the post-intervention questionnaire on May 12, 2013 and the last participant responded on May 30, 2013. EPs' intentions to use a wiki-based order set to promote best practices in EDs increased from 5.42 to 5.81 on the Likert scale, representing a 0.39 point increase (P=.03) (Table 2). This difference in mean Likert scores is likely not to be clinically significant being that it is below the threshold of a 0.6 point increase (half of the standard deviation in our sample). Among

all the other direct and indirect TPB constructs, we also found that attitude and normative beliefs increased after the intervention. Finally, none of the constructs were negatively influenced by our intervention.

Table 2. Pre- versus post- intervention measurement of Theory of Planned Behavior constructs (measured on a 7-point Likert scale).

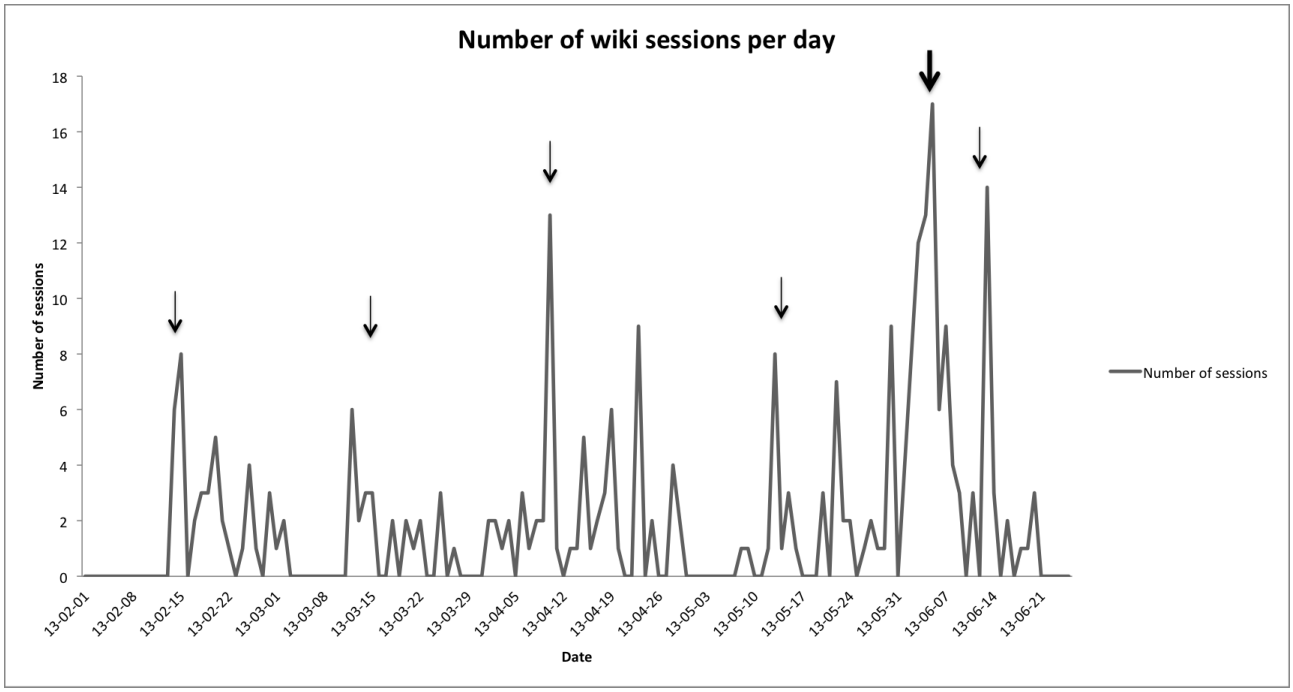
Constructs	Pre-intervention		Post-intervention		*P*
	Mean (SD)	Median	Mean (SD)	Median	
Intention	5.42 (1.04)	5.33	5.81 (1.25)	6.00	.03
Perceived behavioral control	5.46 (1.06)	5.67	5.80 (1.28)	6.00	.12
Subjective norm	4.21 (1.28)	4.33	4.58 (0.93)	4.67	.08
Attitude	5.07 (0.90)	5.00	5.57 (0.88)	5.75	.003
Normative beliefs	5.17 (0.96)	5.18	5.74 (0.75)	5.86	<.001
Control beliefs (facilitators)	6.49 (0.63)	6.64	6.68 (0.36)	6.82	.17
Control beliefs (barriers)	3.77 (1.33)	3.90	3.95 (1.18)	4.10	.40
Behavioral beliefs	6.00 (0.73)	6.13	6.20 (0.66)	6.31	.13

Data on Use of the Wiki

Once all participants had replied to our pre-intervention survey in November 2012, participants were given access to use the wiki starting in December 2012. The last participant receiving access to the wiki was on January 14, 2013. It was not until February 2013 that we created a Google Analytics account to monitor its ongoing use. With the usage data available (Figure 1), we observe that more sustained use began between February 2 to March 2. Then, its use increased over the period of March 12 to 19. There was a further increase of visits between the 30thMay and the 9thof June. Monthly departmental meetings were held on February 13, March 13, April 10, May 15, and June 12 (indicated by narrow arrows on Figure 1) during which the departmental head reminded the participants to contribute to the wiki. On June 5, the wiki experienced its greatest use with 17 visits. On this day, a simulation was held to practice using the new ED infrastructures including the new CPOE system (bold arrow in Figure 1). The new ED officially opened on June 17, 2013.

On average, the wiki was used 1.9 times per day by 54% (15/28) of the participants. Although there was a trend for non-users to be older, male, specialized EPs, there were no statistically significant differences between wiki users and non-users (Multimedia Appendix 2). Six participants used the discussion thread function to add comments to different wiki pages. This included one participant who made comments on 46 different order sets. The content of these comments concerned dosing of medications, suggestions to improve the order sets and ideas for other order sets.

Figure 1. Number of wiki sessions per day between February 1 and June 25, 2013 (narrow arrows: monthly departmental meetings; bold arrow: simulation in new ED).



Qualitative Comments About the Wiki

The most frequently mentioned positive perceived impact was that the wiki facilitated information and knowledge sharing (n=3) (Table 3). There were no negative perceived impacts mentioned. However, many different barriers were mentioned (Table 4). The top three barriers reported were: the organization of information needed to improve (n=7), the computers used were slow (n=6), and that access to the wiki was difficult (n=5). Even though restricted access was mentioned as a barrier to using our wiki, 4 participants also mentioned the opposite view that having an open access wiki would be a potential barrier for future clinical use. Although the wiki was consulted 23 times using an iPad, 16 times by an iPhone, and once by a Motorola XT720 MOTOROI device, there were no comments about difficult access using mobile devices. The most frequently reported facilitators to using the wiki were the wiki's ease of use (n=5), the support and promotion by colleagues (n=3), and also the administrative support (n=2) (Table 5).

Table 3. Perceived positive impacts about using the wiki-based order sets.

Perceived positive impact	n[a]
Information and knowledge sharing	3
Feedback (eg, "enables feedback from my colleagues")	3
Standardization of practices	2
Better access to information	1

[a]n=the number of single mentions by participants of each positive impact. Nine participants made comments about the wiki's perceived positive impact on their online survey.

Table 4. Barriers to using the wiki-based order sets.

Barriers	n[a]
Organization of information (eg, "layout and visual presentation")	7
Material resources - Slow speed of computers	6
Material resources (access to wiki)	5
Open access wiki (eg, "possibility that anyone can modify content")	4
Lack of webmetric tool to present recent changes	1
Time constraints to edit	1
Lack of familiarity with the wiki (ie, need to learn how to use the platform)	1

[a]n=the number of single mentions by participants of each barrier. Eight participants made comments about barriers to wiki use in their online survey.

Table 5. Facilitators to using the wiki-based order sets.

Facilitators	n[a]
Ease of use	5
Support and promotion by colleagues	3
Administrative/organizational support (eg, "department head")	2
Motivation to contribute consistent with clinical needs	1
Awareness of the existence of the wiki	1
Triability (eg, "trying the platform alone")	1
Easy access	1
Incentives (eg, "use made mandatory")[a]	1
Appearance of wiki	1

[a]This facilitator was not described in the taxonomy used; n=the number of single mentions by participants of each facilitator. Eleven participants made comments about facilitators for wiki use in their online survey.

Discussion

Principal Findings

Using a previously validated theory-based questionnaire, we determined that using a wiki to construct a series of order sets during a 6-month period increased the intention of using such a Web-based tool. Moreover, we also demonstrated that a wiki could be used to construct order sets in a single Emergency Department with 54% of our participants contributing at least one order set to the wiki during our study. Intention among EPs to use a wiki-based reminder increased by 0.39 points on a 7-point Likert scale (P=.03) after having access to the wiki for a period of 6 months. This increase was not clinically significant based on our cut-off for clinical significance (<0.6 points on our 7-point Likert scale) [41]. For the other TPB constructs, our intervention increased the attitude towards using a wiki-based order set to promote best practices. Interestingly, all these increases occurred even if the initial levels of intention and attitude were high.

We also identified specific aspects of the complex task of accessing and using a wiki that inform on improvements to be made and appreciated qualities to be maintained. For example, access to editing wiki content needs be controlled, but this needs to be balanced with better access to viewing wiki content (ie, better bedside access). Layout of information and computer performance need to be improved. Having the support and leadership from the departmental head was noted as an important facilitator for any future implementation. This support was instrumental to manage our wiki platform as our departmental head used monthly departmental meetings to stimulate collaborative writing periods among ED members with varying levels of comfort with wikis and technology in general. In this respect, the Google Sites wiki was perceived as easy to use, easy to access (eg, using mobile devices) and triable. These results lead us to the following observations.

To our knowledge, this study is the first to evaluate the effect of using a wiki on EPs' behavioral determinants of using wiki-based order sets to promote best practices. Other authors have used the Technology Assessment Model to explore how health professionals use and contribute to social media in general to share medical knowledge with other physicians in the medical community at one point in time [22]. Kohli et al [42] evaluated the use of a wiki for document sharing among residents in radiology and their contribution to updating and editing the wiki, but did not use any theoretical framework to assess the impact of this intervention on behavioral determinants. In contrast, our study measured the change in intention over time and provided an understanding about how our intervention acted on the behavioral determinants.

Although our intervention was not specifically designed to address any of the theoretical social cognitive determinants of the TPB, it did have a positive impact on three of these determinants (intention, attitude, and normative beliefs). Using intervention mapping [43] or the Theoretical Domains Framework [44,45], future theory-based interventions could be built to specifically address certain cognitive determinants. In particular, social norm and control beliefs were the lowest among the TPB constructs and we would need to specifically design an intervention targeting these constructs in a larger study. Even though the social norm construct did not increase significantly, the normative beliefs construct did increase significantly, meaning that our intervention had some social effect. By acting with the support of the departmental head and asking different colleagues to support each other and collaborate in creating their wiki order sets, we possibly unwillingly acted on certain normative beliefs. Surprisingly, none of the qualitative comments analyzed mentioned a negative referent that could be a target for a future intervention.

Although our participants' high previous personal and professional use of wikis did not seem to influence their 6-month use of our wiki, other authors have previously shown the importance of past behavior/habit in predicting behavior among health professionals [46,47]. Habit creation supported by reminders to use the wiki at our monthly departmental meetings likely increased reported 6-month use and future intention to use the wiki. This also resulted in a relatively high contribution rate with 54% of our participants contributing at least one order set to the wiki during our study. Although this contribution rate was unequally distributed among our participants (with some participants contributing many order sets and others not contributing any), this contribution rate is higher than contribution rates (3-22%) reported in other studies [36,48] and represents an increase compared to participants' self-reported baseline contribution rate prior to starting this study (3.5%). The mere measurement effect must also be considered as a potential explanation for the increase in intention, use, and contribution rate [49].

Limitations

Our study has some limitations. First, our sample of EPs at HDL may not represent the beliefs of EPs elsewhere. In particular, EPs in our sample reported lower prior wiki use for professional purposes than reported in a recent scoping review of wiki use in health care [13]. This review identified studies reporting a range of usage rates ranging from 55% for consultants and 80% for junior physicians [48,50]. Moreover, the social cognitive determinants of our study population may have been influenced by the fact that the study was being carried out in their hospital as well as by their proximity to the research physicians carrying out the study. The EPs were also aware that the ED was evolving away from paper use and were therefore possibly more inclined to use a wiki than physicians working in a paper-based center.

Second, we did not adjust our significance level for multiple comparisons. Rothman argues that not making adjustments for multiple comparisons leads to fewer errors of interpretation when the data under evaluation are not random numbers but actual observations on nature [51]. Furthermore, scientists should not be reluctant to explore leads that may turn out to be wrong because they might miss possibly important findings [52]. For this reason, further studies will still be needed to confirm our findings.

Third, our use of the TPB limits our capability to directly assess the importance of environmental factors such as organizational readiness for change. The use of the Theoretical Domains

Framework to inform our theory-based intervention could correct this [53,54].

Fourth, our questionnaire did not measure the determinants of contributing to the wiki, in addition to consulting it. By definition, a wiki is a product of its users and remains relevant only if its users continue to update it and create new content. Getting experts and other members of a wide community to contribute to a collaborative writing project is a difficult task and a theory-based approach will be needed to stimulate and promote this behavior [18,36,55]. Several further behaviors will need to be studied in the future, but we chose the one we felt to be the most important (using the wiki).

Fifth, our study did not evaluate the quality of the order sets created. Although all order sets were peer-reviewed by our departmental head and reviewed by all participants during our monthly departmental meetings, future studies will need to explore how to measure the quality of order sets and how a wiki collaborative writing platform can contribute to improving the quality of order sets currently in clinical use.

Finally, our use of Google Sites will potentially limit the future expansion of our wiki content and its integration into other health information technology to support clinical decision-making. Even though our content is free and open-source, the platform itself is not open-source meaning we cannot modify the wiki programming to integrate it directly into our CPOE, which was not an open-source program either. Therefore, there still remains a gap between the collaboratively created order sets in our wiki and their actual clinical use. Future explorations of completely open-source solutions and open-source CPOE could help solve this problem [11,56].

Future Studies

Future studies will also have to try to determine what represents a clinically significant increase of intention to use a wiki-based reminder. Moreover, rigorously designed implementation studies with larger samples are needed to determine the impact of wiki-use in trauma care. Better understanding of the impact of editing and using a wiki on the behavioral determinants for future wiki-use will also be important to explore in order to develop a sustainable and scalable knowledge translation intervention. Future studies also need to investigate how a collaborative writing platform can be used to produce high-quality evidence-based order sets and better integrate these collaboratively created order sets into CPOE systems that are more responsive and adaptive to local clinical needs.

Conclusion

Using wiki-based order sets in trauma care for the promotion of best practices seems possible given that EPs' intentions increased through its use. However, the clinical impact of this novel intervention remains to be verified using a rigorous study design with a larger population. Further development of our wiki will also need to consider the different barriers and facilitators identified by our users to build a highly usable and reliable evidence-based clinical resource.

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Conflicts of Interest

None declared.

Multimedia Appendix 1

Theory of planned behavior questionnaire.

[PDF File (Adobe PDF File), 393KB - medinform_v4i2e18_app1.pdf]

Multimedia Appendix 2

Comparison of wiki users and non-users at 6 months.

[PDF File (Adobe PDF File), 59KB - medinform_v4i2e18_app2.pdf]

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Abbreviations

CPOE: computer-physician order entry
ED: emergency department
EP: emergency physician
HDL: Hôtel-Dieu de Lévis
HTML: Hyper Text Markup Language
ICT: information and communication technologies
TPB: Theory of Planned Behavior

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