New Unintended Adverse Consequences of Electronic Health Records

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Summary

Although the health information technology industry has made considerable progress in the design, development, implementation, and use of electronic health records (EHRs), the lofty expectations of the early pioneers have not been met. In 2006, the Provider Order Entry Team at Oregon Health & Science University described a set of unintended adverse consequences (UACs), or unpredictable, emergent problems associated with computer-based provider order entry implementation, use, and maintenance. Many of these originally identified UACs have not been completely addressed or alleviated, some have evolved over time, and some new ones have emerged as EHRs became more widely available. The rapid increase in the adoption of EHRs, coupled with the changes in the types and attitudes of clinical users, has led to several new UACs, specifically: complete clinical information unavailable at the point of care; lack of innovations to improve system usability leading to frustrating user experiences; inadvertent disclosure of large amounts of patient-specific information; increased focus on computer-based quality measurement negatively affecting clinical workflows and patient-provider interactions; information overload from marginally useful computer-generated data; and a decline in the development and use of internally-developed EHRs. While each of these new UACs poses significant challenges to EHR developers and users alike, they also offer many opportunities. The challenge for clinical informatics researchers is to continue to refine our current systems while exploring new methods of overcoming these challenges and developing innovations to improve EHR interoperability, usability, security, functionality, clinical quality measurement, and information summarization and display.

Keywords

Electronic Health Records (EHRs), usability, confidentiality, quality indicators, data display, medical informatics

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Introduction

Over the past 25 years, we have made significant strides in using health information technology (HIT). Many national government-led initiatives have stimulated the adoption and use of electronic health records (EHRs) around the world [1, 2, 3, 4]. However, these initiatives have been met with mixed success in terms of increasing EHR adoption based on original budgets and time lines. Specifically, EHR adoption varied from 41% in Switzerland to over 98% in Norway and the Netherlands as of 2012 [5]. In the United Kingdom (UK), much of the £12 billion project [6] to promote HIT adoption was supposed to be completed by December 2010, but by then only 78/377 (21%) of the sites where implementation should have been finished had even begun the process [7]. Conversely, over the last six years, the percentage of clinicians using EHRs in the USA has increased from under 20% to well over 75%, brought on mostly by the USA's $30 billion, Health Information Technology for Economic and Clinical Health (HITECH) Act incentive program of 2009 [8].

Although we have made considerable progress, initial expectations have not been met [9]. We have not achieved what we originally envisioned [10], and there have been numerous unexpected adverse events and effects [11]. In 2006, we described a set of unintended adverse consequences (UACs) associated with the use of computer-based provider order entry (CPOE) (see Table 1) [12]. Briefly, we define UACs as unpredictable, emergent problems, associated with CPOE or EHR implementation, use, and maintenance. Many of the originally identified UACs have not been completely addressed or alleviated, and some have evolved over time (e.g., more/new work and workflow issues). Additionally, *new* UACs not just related to CPOE but to all aspects of EHR use have emerged. In this paper, we briefly describe these new UACs and illustrate why they must be addressed by EHR users, developers, implementers, researchers, and policy makers to help achieve the transformative effects of health information technology.

Why Have New Unintended Adverse Consequences Emerged?

The increased use of EHRs has led to a change in the types and attitudes of clinical users. As can be largely explained by Rogers' theory of the diffusion of innovations [13], "early adopters" of EHRs were mostly enthusiastic and proud to be a part of a new, innovative, and technological health care revolution. A number of these pioneering EHR users were working in academic institutions with home-grown EHRs that they developed and improved upon internally [14, 15, 16, 17]. Once enough people or organizations have adopted an innovation, adoption from then

on becomes self-sustaining. Rogers called this concept "critical mass," [13] which helps explain why there is a tipping point from which adoption becomes especially rapid [18]. However, the current "late majority" of users are different from early adopters in many ways. They use commercially available EHRs with variable and often suboptimal usability, and are much less understanding and forgiving of system limitations. In addition, during the early phases of EHR adoption, problems such as lack of interoperability and security issues remained hidden because there were not enough systems in existence outside the pioneering institutions to truly stress these systems' interoperability and security capabilities.

New Types of Unintended Adverse Consequences

Based on findings from the literature, our research projects, and field-experience from engaging with health care organizations actively developing HIT-enabled health care systems, we have witnessed several areas of concern, which we now organize into six new UACs for discussion. Knowledge was mainly gained from site visits, which included observation and interviews of key stakeholders. These visits focused on topics such as designing, developing, implementing, and evaluating clinical decision support [19]; exploration of the processes involved in identifying and communicating abnormal laboratory test results [20]; development and implementation of service-oriented clinical decision support [21]; and identification of recommended practices for ensuring safe and effective EHR implementation and use [22]. The following sections briefly describe each of these 6 new UACs along with new research opportunities and challenges they portend. We also highlight several future directions for research that need to be pursued as a direct result of these UACs.

Table 1 Previously identified unintended adverse consequences related to the use of Electronic Health Records (EHRs) by clinicians (adapted from Campbell et al. [12]).

More/new work for clinicians	EHRs often create new work for clinical and non-clinical staff, which is most prominent at the point of care (e.g., alerts, required data entry fields, and details of complex orders).
Unfavorable workflow issues	EHRs often highlight mismatches between *intended* and *actual* work processes in the clinical setting by adding to previously defined ineffective or dysfunctional workflows.
Never ending demands for system changes	As EHR use increases, it becomes increasingly difficult to standardize, update, test, and maintain the hardware infrastructure, application software, and clinical content.
Paper persistence	Paper continues to be used as a temporary, portable, disposable, data input and output medium.
Changes in communication patterns and practices	Use of EHRs often replaces synchronous, interpersonal conversations regarding provision of care with asynchronous computer-mediated messaging, often leading to an "illusion of communication."
Negative emotions	Specific EHR features, functions, or series of events that result in users succeeding or failing in reaching their goal(s), trigger emotions that can affect their ability to carry out complex physical and cognitive tasks.
New kinds of errors	New kinds of errors can result from problematic data presentations, confusing order options, inappropriate text entries, misunderstandings related to test, training, and production versions of the system, and workflow process mismatches, to name just a few.
Changes in the power structure	Clinicians experience a loss of power or professional autonomy when EHRs prevent them from ordering the types of tests or medications they prefer, or force them to comply with clinical guidelines they may not embrace, or limit their narrative flexibility through structured data entry.
Overdependence on technology	Health care organizations are becoming increasingly dependent on their EHR for many aspects of clinical care delivery. When the system is unavailable, chaos may ensue.

1 Complete Clinical Information Unavailable at the Point of Care

One of the biggest selling points for the adoption of EHRs was the tremendous increase in availability of patients' clinical data, anytime, anywhere [23]. This ubiquitous increase in data availability depended heavily on the assumption that once clinical data were routinely maintained in a computable format, they could seamlessly be transmitted, integrated, and displayed between health care systems' EHRs, regardless of differences in the developer of the EHR. Some progress has been made, for example, Epic Systems (Verona, WI) offers Care Everywhere (http://www.epic.com/CareEverywhere/), but it is currently limited to exchanging data between organizations in which either the sender or the receiver is using Epic's EHR, and both organizations have agreed to join the network. In addition, several other EHR developers have formed the CommonWell Alliance (http://www.commonwellalliance.org/) and are beginning to exchange data. It is obvious now that even though the majority of clinicians and health care organizations are using EHRs, complete clinical information is not yet available to them. There are a variety of reasons that unexpectedly emerged during the current rapid adoption phase including technical factors, such as incompatible data syntax, semantics, and pragmatics issues, as well as social constraints, such as data governance, ownership, and confidentiality concerns [24]. In fact, the inability to move patient data between health care organizations has given rise to a new term "information blocking" [25]. This term is used to describe some of the various socio-technical issues that often stand in the way of organizations that want to share patient information. Other issues that lead to problems in exchanging clinical information include the lack of agreement on specifications for implementing data interchange standards such as the HL7 v2.x family of standards [26] and the consolidated clinical document architecture (CCDA) [27]. While there are definitely technological challenges that limit EHR interoperability, there are also many internal, organizational, as well as external, regulatory, and socio-political challenges that also must be addressed if

we are ever to experience true clinical and administrative information interoperability required to deliver the highest quality and lowest cost health care.

Challenges related to interoperability are a prime opportunity for clinical informatics researchers [28]. Many unanswered clinical and scientifically-important research questions are on the table, including how to aggregate, organize, reduce/transform, interpret, and synthesize information from disparate organizations across time into a concise, yet complete, clinical summary [29]; how to display these summaries of vast amounts of data in an easy to read and comprehensible format [30]; and how to develop a set of key clinical workflows that involve information exchange to be used by EHR developers to design and test their systems' features and functionality.

2 Lack of Innovations to Improve System Usability Leads to Frustrating User Experiences

Although EHR usability has improved considerably since the days of hard-wired, keyboard-based, VT100 terminals connected to a mainframe computer (see figure 1), very little has changed since the current mouse-based, point and click, graphical user interfaces were introduced over the last 15 years. The lack of continued innovation in EHR interface design and the resulting "poor" EHR usability has only become a topic of widespread, national debate in the last 5 years [31]. Several reasons account for why this is a new concern. One, we are noticing it more substantially now as a reflection of the rapid increase in the number of new users, who are using overly complex systems, often with limited training or expertise [32]. Second, innovation in the human-computer interface, among many other facets of EHRs, has been stifled due to the rapidly changing Meaningful Use EHR certification criteria that have required EHR developers to make numerous changes to their system's user interfaces [33]. This has resulted in the dual disadvantages of increasing the complexity of these composite user interfaces while also reducing the number of people and the amount of time allocated to the needed system enhancements. Conversely, the recent introduction of hand-held tablet computers, with their high-resolution, multi-touch, gesture-controlled screens has significantly raised user expectations for what computer interfaces should look like and how they should behave.

Fig. 1 A Digital Equipment Corporation (DEC) VT100 terminal. (from: https://en.wikipedia.org/wiki/User_interface)

These usability challenges have created many opportunities for clinical informatics and human factors researchers to better understand the clinical tasks, regulatory constraints, and capabilities of current EHRs with an eye toward the usability innovations that contribute to developing the next-generation EHR user interfaces.

3 Inadvertent Disclosure of Large Amounts of Patient-specific Information

Over the last several years, the health care industry has been the victim of a large number of patient privacy breaches. Some of these are the result of external bad actors trying to take advantage of the increased monetary value of personally-identifiable health-related data, such as the breach of over 78.8 million patient files at Anthem [34]. Others are the result of health care organizations' failure to take the necessary precautions to protect their systems. Many breaches have resulted from lost portable computers [35] or system backup tapes [36] that were not properly encrypted [37]. We are also beginning to experience attempts to hack various network-attached devices and change important settings [38], efforts to hold an organization's entire patient files hostage by encrypting their files [39], and denial of service attacks [40].

Such problems offer opportunities for informatics researchers. These security issues call for new methods of encrypting [41], storing [42], linking [43], and transmitting [44] protected health information. In addition, we must develop stronger policies, rules, and regulations regarding the inappropriate secondary use of identifiable health-related data [45, 46].

4 Increased Focus on Computer-based Quality Measurement Negatively Affects Clinical Workflows and Patient-provider Interactions

The slow, but steady, move from fee-for-service to pay-for-performance payment models in health care has given rise to more EHR-based clinical quality measurement. This push for quality measurement has necessitated an increased need for capturing complete, accurate, structured data that can easily be extracted, aggregated, and reported to administrators, quality oversight organizations (e.g., University Health Consortium), and payers – both public and private. The need to capture structured data items such as "smoking status" [47], "pain scores" [48], venous thromboembolism prophylaxis, and documentation of the need for patient restraints every 24 hours has led to many convoluted clinical documentation workflows [49]. These new workflows are not only changing the way clinicians perform their work, but they are potentially interfering with their diagnostic and therapeutic critical thinking tasks leading to serious, preventable, adverse events [50], as well as having a negative impact on patient-provider interactions at the point of care [51].

However, new quality measure requirements are also creating numerous opportunities for clinical informatics researchers, including development of natural language processing methods to extract quality indicators [52]; development of new quality measure metrics [53]; and investigation of best practices for provider-computer interaction with the patient at the point of care [51].

5 Information Overload from Marginally Useful Computer-generated Data

As the breadth and depth of computer usage to record, store, display, and transmit clinical and administrative information have increased, so has the amount of information that clinicians are required to review and potentially act upon at the point of care. In addition to the traditional clinically-generated data, over the last few years the capability for patients to generate, capture, and transmit information about various physiological (e.g., blood glucose, heart rate, or blood pressure) or physical (e.g., number of steps walked or hours slept) processes further exacerbates the amount of information potentially available for clinicians, and more recently patients, to review. In addition, the computer itself, in the form of advanced clinical decision support (e.g., drug-drug, drug-allergy, and preventive care reminders), now routinely adds to the overwhelming clutter of information that must be addressed. Many clinicians complain that they are being overwhelmed with information [54]. In addition, the ease with which clinicians can "cut and paste" information from one part of the chart, or even another patient's chart, results in "note-bloat" and obscures relevant information [55]. Also, many EHRs have the capability to "generate" text based on structured data that has been entered by clinicians. Taken together, all these new computer-readable bits of information are overwhelming clinicians and causing them to miss important information which can lead to patient harm [56].

This information overload offers clinical informaticians an unparalleled opportunity to design and develop new methods of summarizing, as well as displaying, all this new information. In addition, we must develop methods to increase the specificity of the clinical decision support suggestions presented to clinicians to reduce alert fatigue [57].

6 Decline in the Development and Use of Internally-developed EHRs

Over the past five years or so, the number of EHRs developed and maintained by academics for their teaching facilities, or entrepreneurs for their small practices, has declined precipitously as large academic health centers increasingly adopted commercial EHRs [58] and acquired small practices [59]. We view this rapid decline as a result of several concomitant factors. First, commercial EHR developers with their comparatively vast technical and human resources, and their ability to defray their development costs across numerous clients, have for the most part duplicated the most important features and functions of internally-developed, state-of-the-art systems [60]. At the same time, these commercial systems offer health care administrators a relatively "fixed" cost for future EHR functionality [61]. Second, increasing regulatory oversight made it difficult for these internally-developed EHRs to meet the rapidly changing EHR certification requirements while also developing the new features and functions requested by their organizations and maintaining existing system functionality [62]. Finally, as small clinical practices (i.e., less than 10 physicians) began to recognize the difficulty in developing or selecting, configuring, implementing, and maintaining a state-of-the-art EHR along with the myriad of interfaces with external laboratories, hospitals to which they admit patients, referring physicians, and public health agencies, the idea of joining a local health care organization and using their commercially-developed and maintained systems became more palatable. In addition, with the relaxation of the Stark laws in the USA, hospitals were allowed to subsidize the cost of information systems [63]. Taken together, these complementary, socio-technical forces have resulted in a precipitous decline in the number of home-grown EHRs in use.

This major change in the nature of EHRs used by large organizations creates challenges but also introduces exciting new opportunities for partnerships between the academic and industry sectors [64]. For example, the development of the new HL7 FHIR (Fast Healthcare Interoperability Resources) [65] specification coupled with the SMART (Substitutable Medical Apps Reusable Technologies) [66] platform offers researchers and independent application developers the chance to create innovative apps that can be plugged in existing systems [67]. In addition, the widespread use of similar EHRs offers human factors and ethnographic researchers the opportunity to identify best practices for everything from screen design and layout [68] to organizational governance of key EHR features and functionality [69].

Conclusions

The health information technology revolution has already had a positive impact on the health of all citizens as well as on health care delivery systems around the world. Unfortunately, as with the application of any new technology, there have been numerous new UACs that have emerged. This is likely explained by us having reached what Rogers called the "critical mass," or tipping point ,of the adoption curve [13], at which point new, different, and unanticipated problems have emerged because the numbers of users have increased so dramatically. While each of the UACs identified in this manuscript poses significant challenges to EHR developers and users alike, they offer many types of opportunities for informaticians involved in multidisciplinary research. The challenge for clinical informatics researchers is to continue to refine our current systems while exploring new methods of overcoming these challenges and developing innovations to improve EHR interoperability, usability, security, functionality, clinical quality measurement, and information summarization and display. This will involve working in partnership with both clinical operations stakeholders as well as EHR developers. The opportunities to leverage HIT to impact the health of individuals around the world have never been greater. With a focused effort that addresses UACs and facilitates a safe, effective and efficient HIT infrastructure, we can expect to see high quality and low cost health care delivered to the right person, at the right time, in the right form, leading to improved health outcomes.

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