Mind the Gap

A systematic review to identify usability and safety challenges and practices during electronic health record implementation

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Summary

Objective: Decisions made during electronic health record (EHR) implementations profoundly affect usability and safety. This study aims to identify gaps between the current literature and key stakeholders' perceptions of usability and safety practices and the challenges encountered during the implementation of EHRs.

Materials and Methods: Two approaches were used: a literature review and interviews with key stakeholders. We performed a systematic review of the literature to identify usability and safety challenges and best practices during implementation. A total of 55 articles were reviewed through searches of PubMed, Web of Science and Scopus. We used a qualitative approach to identify key stakeholders' perceptions; semi-structured interviews were conducted with a diverse set of health IT stakeholders to understand their current practices and challenges related to usability during implementation. We used a grounded theory approach: data were coded, sorted, and emerging themes were identified. Conclusions from both sources of data were compared to identify areas of misalignment.

Results: We identified six emerging themes from the literature and stakeholder interviews: cost and resources, risk assessment, governance and consensus building, customization, clinical workflow and usability testing, and training. Across these themes, there were misalignments between the literature and stakeholder perspectives, indicating major gaps.

Discussion: Major gaps identified from each of six emerging themes are discussed as critical areas for future research, opportunities for new stakeholder initiatives, and opportunities to better disseminate resources to improve the implementation of EHRs.

Conclusion: Our analysis identified practices and challenges across six different emerging themes, illustrated important gaps, and results suggest critical areas for future research and dissemination to improve EHR implementation.

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1. Background and Significance

There is no dispute that electronic health records (EHRs) have the potential to improve the efficiency, safety, and quality of healthcare [1, 2]. However, to fulfill this potential, EHRs must be properly designed, developed, implemented, and used. Usability has emerged as a major factor limiting EHRs' realization of their full potential [3–5]. Suboptimal usability leads to inefficiencies, clinician frustration and stress — and poses serious hazards that have resulted in patient harm [6, 7].

Usability is formally defined as the effectiveness, efficiency, and satisfaction with which specified users achieve specified goals in a particular environment [8]. There is a common misconception that usability focuses solely on screen design elements such as color, font, and iconography. While good interface design is important, usability in the context of health IT extends beyond that and entails developing an in-depth understanding of how frontline health care professionals ("end users") perform their work, so that systems can be developed to support the user's cognitive needs [9–11.

Several aspects of the EHR product lifecycle can affect the EHRs' usability as experienced by end users. EHR system design and development is a major focus of the Office of the National Coordinator's certification program and a major focus area for researchers seeking to develop and provide tools for EHR developers to improve their systems' usability [12–15].

Implementation has received considerably less attention from policymakers and researchers. However, implementation is recognized as a time of tremendous risk, and decisions made after purchase during implementation have a direct impact on usability and safety [16]. During implementation, the product is configured and may be customized to meet particular needs based on workflow, preferences, and interoperability with other health information technology systems. End users must also learn how to use the system, and generally receive some form of training during implementation.

The American Medical Informatics Association's recommendations to improve EHR usability and safety highlight the need for both health IT developers and implementers to adopt best practices [17]. However, what these best practices are, and whether there are gaps between the challenges faced during implementation and best practices available to address these challenges, remains unclear. While most healthcare institutions have already adopted EHRs, one report suggests twenty percent of hospitals are considering switching to a different EHR product in the near future, and many small to midsize healthcare institutions are also considering different products [18, 19]. The quality of future implementations could be enhanced by identifying areas that need focused improvements.

2. Objective

The purpose of this review is to identify usability and safety challenges and best practices during EHR implementation, with a focus on gaps between the literature and key stakeholders. Our objectives were to (1) identify usability and safety practices and challenges during implementation as described in the published literature, (2) determine key stakeholder perceptions of current practices and challenges, and (3) compare these data to identify knowledge gaps and opportunities related to EHR implementation processes.

3. Materials and Methods

We conducted a systematic review of the literature and interviews with key health IT stakeholders. Each method is described separately.

Literature Review Methodology

The literature describing challenges and practices during EHR implementation is generally not based on empirical research trials describing effects, but rather on perspectives, case studies, and general assessments. Thus, we followed well-established systematic review methods used in reviews

with a similar purpose [20]. We adapted the Preferred Reporting Items for Systematic Reviews and Meta-analyses checklist to remove items that are focused on empirical studies with effects [21].

Search process

We searched PubMED, Scopus, and Web of Science in April 2016 using a combination of search terms to capture articles about safety and usability during EHR implementation. We included peer-reviewed articles in English that had been published from 2010 to May 16, 2016. We did not search earlier than 2010 because most EHRs were implemented on or after this year. ►Table 1 shows details of the search queries.

Selection process

For inclusion, articles must address EHR usability and safety as affected by implementation and describe practices, lessons learned, or challenges associated with implementation. Articles that focused on the development and implementation of specific algorithms or alerts, and articles measuring differences in clinician performance pre- and post- implementation were excluded unless the generalizable practices, lessons learned, or challenges were detailed.

Article selection started with three reviewers (KA, ES, RR) manually reviewing the titles and abstracts of all of the unique retrieved articles from the search query and excluding those not meeting our criteria. The full text of the remaining 86 articles was retrieved and three reviewers (KA, ES, RR) reviewed each article for inclusion in the final analysis. If it was unclear as to whether the article should be included it was discussed by the larger group of authors for a decision. Fifty-five articles were identified as meeting our criteria of highlighting a best practice or challenge during the implementation phase.

Data extraction and synthesis

Three members of the research team (KA, ES, RR) reviewed each article and extracted the challenges and practices. Many articles described multiple challenges or practices, so each of these was captured separately. We used a grounded theory approach to identify emerging themes and the practices and challenges within those themes [22]. Any disagreements amongst the three members were discussed with the larger group of authors to reach a resolution.

Stakeholder Interview Methodology

We conducted interviews with health IT stakeholders to identify current perceptions of the practices and challenges related to usability and safety during implementation.

Recruitment

Based on the authors' previous work, we identified five key stakeholder categories, and recruited eight to nine participants from each category using a purposive sampling method to recruit individuals with extensive knowledge of the perspective they would represent (►Table 2) [12, 23].

Process

We conducted semi-structured interviews lasting 30-60 minutes either in person or via telephone with knowledgeable individuals within each stakeholder category. Each stakeholder was asked open-ended questions about usability and safety practices and challenges during implementation. Prior to the interviews the research team discussed and agreed upon an initial set of questions (sample questions are in ►Table 2) and the purpose of each stakeholder group interview to maintain consistency across the interviews. Participants in each stakeholder category were asked questions relevant to their specific expertise; consequently, participants in each category were asked different questions. During each interview different follow-up probing questions were asked to pursue relevant topics and to obtain more specific information.

Data analysis

Responses were documented during each interview, and notes were transcribed and combined into a single data file immediately afterwards. Once all of the interviews were complete, six members of

the research team conducted a qualitative analysis. The data were sorted by topic and emerging themes were identified using a grounded theory approach, with a focus on the practices and challenges described during each interview.[21] Any discrepancies around the content and themes were discussed by the six-member team and if resolution could not be reached it was brought to the team of all authors for resolution.

Analysis to identify alignment between the literature and stakeholders

Six members of the research team examined the themes and content from the literature review and stakeholder interviews. The themes and content were synthesized to identify gaps between the literature and stakeholder interviews using a grounded theory approach. A gap was defined, a-priori, as a difference in knowledge content and focus between the literature and stakeholders. These gaps were often challenges expressed by stakeholders that did not have best practices or guidelines in the literature. If the literature mentioned the theme that was identified from the stakeholders, but did not provide concrete practices or guidance on how to overcome the challenge this was noted as a gap in the literature. Any discrepancies were discussed by all authors to reach resolution.

4. Results

Study Selection and Characteristics

The initial search resulted in 3676 articles. The flow diagram in ▶ Figure 1 details the selection process, which resulted in 55 articles. Of the 55 included articles, 29 were empirical articles presenting findings based on qualitative analysis of interviews and surveys of individuals involved in an implementation and 11 articles described case studies or lessons learned. Nine articles presented expert perspective or guidelines, and 6 articles were literature reviews focused on aspects of the overall process of implementation. Twenty-three of the articles were general articles that highlighted practices and challenges.

Synthesis of Results and Emerging Themes

The qualitative analysis of the literature search data and the interview data resulted in emerging themes in practices and challenges. The themes were cost and resources, risk assessment, governance and consensus building, customization, clinical workflow and usability testing, and training. ▶ Table 3 summarizes the literature review and stakeholder data by emerging theme with identified gaps. The general articles are briefly summarized, with greater focus on articles addressing specific aspects of implementation.

Cost and Resources

Findings in the Published Literature

One general article highlighted cost as a major issue, particularly for small healthcare institutions.[24] Two articles specifically addressed costs during implementation. One categorized the major costs during implementation; the usability and safety related categories included infrastructure such as hardware (monitors, PCs, etc.), software including integration engines, a category of "other costs and materials" including training materials and software testing, and personnel including trainers and usability experts [25]. This article states that training and implementation costs are the most likely categories for healthcare institutions to focus on when attempting to reduce costs. These areas are recognized as being important to successful EHR implementation and use. Costs associated with testing of the software system and additional staff to back-fill and allow for appropriate training were highlighted as areas that are typically underestimated by healthcare institutions. The other article described a cost savings strategy that was focused on collaboration and sharing of information across healthcare institutions. Critical access hospitals collaborated to reduce the resource burden of implementing a new EHR, including sharing information on workflow processes [26].

Key Stakeholder Perceptions

Small and large healthcare institutions, as well as researchers, discussed cost and resources as a major challenge. Health institutions - were concerned about the costs of making their systems more usable and safe. Small healthcare institutions commented that the products they were shown during demos were considerably different from those implemented, and that additional features to make the product more usable came with additional costs. Many small healthcare institutions also described the unexpected costs of training, including one who commented that the actual cost of a truly usable and safe system is unknown until implementation is complete. One researcher stated that health institutions are cost conscious during implementation, which poses challenges when usability and safety features may come at an additional expense. Association stakeholders also described the ambiguity over total cost of the implemented product. Health IT developers and consultants described how costs were dependent on the current infrastructure of the healthcare institution and that often times new hardware is required to improve usability and safety. Consultant stakeholders that focus on EHR optimization commented that despite their services being an added cost many large healthcare institutions are purchasing their services to focus on improving usability.

Gap

Few articles addressed the cost of implementation. There was alignment between the literature and stakeholders on general cost categories such as training and infrastructure. However, healthcare institutions desire a method for accurately estimating the total cost of implementation of usable and safe system. No articles addressed how to work with health IT developers and/or consultants to understand total costs of the implemented product.

Risk Assessment

Findings in the Published Literature

Five general articles stressed the importance of safety checks, having appropriate processes to communicate safety hazards, and conducting post–go-live audits [27–31]. Six articles specifically addressed risk assessment and included models for risk assessment and survey-based methods to identify areas for improvement within the EHR system. Four articles described models for risk assessment, three of which applied their models to CPOE. One approach used retrospective incident reports and prospective high-risk process identification to set priorities during implementation [32]. The second approach used a proactive risk assessment method using human factors and clinical experts and the third approach described a CPOE simulation tool to verify appropriate functionality [33, 34]. The fourth approach is a proactive risk self-assessment tool, called the Safety Assurance Factors for EHR Resilience (SAFER) guides, which can be used during implementation to identify areas of vulnerability including usability and optimization [35]. The SAFER guides enable health institutions to perform their own assessments with relevant health IT stakeholders, including developers.

Two articles described survey-based methods to identify problem areas during implementation and go-live. One survey tool, based on the Systems Engineering Initiative for Patient Safety model (SEIPS), focused on evaluating EHR implementation, and can be used to assess usefulness and satisfaction [36]. The other survey described focused on user experience to identify areas for improvement including the concept domains: training and competency, usability, infrastructure, usefulness, and end-user support [37].

Key Stakeholder Perceptions

Research stakeholders described the need for increased risk assessment and the challenges with identifying health IT related safety events. One association stakeholder remarked on the benefits of the SAFER guides, but mentioned that they are not widely known by the health institution community. Several health institutions described the need for practical tools to identify usability-related safety issues during clinician use of the EHR, such as processes for reporting of usability and safety related events. These tools need to be integrated during implementation so that they are readily

available during use, to streamline identification and remediation of issues. Consultants stated that few practical risk assessment tools exist. Proactive risk assessment was not a topic many health IT developer stakeholders discussed.

Gap

While the literature focused on the development of proactive risk assessment methods and tools, awareness and use of these tools by healthcare institutions and consultants was lacking. In addition, healthcare institution stakeholders focused on the need for methods to facilitate identifying, reporting, and addressing usability and safety hazards during product use.

Governance and Consensus Building

Findings in the Published Literature

Numerous general articles discussed the need to engage a diverse set of experts and end users, and the need for extensive planning with reasonable timelines [24, 27–31, 38–50]. Many of these articles highlighted the rushed timelines health institutions face; however, there were few concrete guidelines on how to address usability needs within compressed timelines.

Three articles specifically addressed governance structures and processes for building consensus during implementation. The implementation of the EHR requires making decisions on workflow processes, screen layouts, clinical decision support (CDS) rules, and other functionality – decisions directly tied to the usability and safety of the EHR. One article compared the governance structures and content management processes at five different institutions to compare CDS implementations, and provided recommendations including prioritization of work and providing a mechanism to gather user feedback [51]. Recommendations from an article describing use of Delphi methods to translate clinical policies into CDS include making CDS actionable, information easily consumable by clinicians, and allowing for clinician customization [52].

Key Stakeholder Perceptions

Small and large healthcare institutions described the need to have all staff on board for any EHR decision. Large healthcare institutions described their governance processes, which included clinical work groups, clinical informatics committees, and use of multidisciplinary expert teams during implementation. One consultant said that large healthcare systems have governing bodies that work well, but that small healthcare institutions struggle with governance and generally one or two individuals within the healthcare institution makes decisions without adequate end-user input. Small healthcare institutions and consultant stakeholders generally did not explicitly discuss governance structure and processes, but did discuss customization, which involves governance of the customization process. Small healthcare institutions described challenges with having the knowledge and expertise to make informed decisions about the product. Some associations stated that they provide recommendations for CDS and other features of the product to support healthcare institutions. Health IT developers described the importance of a rigorous governance process for successful implementation.

Gap

The literature focused on the need for multidisciplinary teams of experts during implementation. Stakeholders revealed that multidisciplinary teams are more commonly a best practice for large healthcare institutions that may have such expertise and resources available. Smaller healthcare institution stakeholders expressed that they lack the knowledgeable experts for effective governance. The literature does not provide concrete guidance and best practices for small institutions to overcome this barrier.

Customization

Findings in the Published Literature

Five general articles described the importance of allowing some level of customization to meet clinician needs [29, 38, 43, 44, 47]. Three articles focused specifically on customization. One described an EHR platform that allows individual users to configure the system according to their needs, with benefits over traditional EHR systems based on established theoretical concepts and research-informed usability guidelines [53]. The second was specific to alert fatigue with CDS and described an effective customization of alerts by engaging experts, reviewing the literature, and reviewing CDS with a different set of experts once established [54]. The final article described recommendations from a panel of experts regarding specific customizations to improve safety and utility in the pediatric setting [55].

Key Stakeholder Perceptions

Several stakeholders discussed customization, and both health institutions and developers described how customization decisions during implementation have a significant impact on usability and safety. One small healthcare institution expressed that the long-term costs of customization, only realized when upgrades or other system modifications are needed, are not fully understood by health institutions and are not clearly explained by developers. Similarly, some health institutions expressed the desire for developers to provide more guidance on customization given developers' extensive experience with implementation. Health institutions and associations described a move toward configuration rather than customization. Several health institutions and associations expressed that they were moving away from extensive local customization and are seeing improved usability. One described usability and safety challenges for health institutions that work at multiple sites, all on the same EHR, but experience different levels of usability because of variations in customization of that EHR. One health institution commented on the lack of usability expertise and standard processes during customization, and one health institution suggested looking to specialty associations for guidance.

Health IT developer feedback on customization varied. Some developers described extensive customization when working with health institutions, although only a few developers included usability experts during this process. Others described their processes as prescriptive, allowing little to no customization. Consultants described how healthcare institution customization that is not informed by human factors principles can lead to serious safety challenges. Associations discussed how many of their member healthcare institutions do customize, but did not offer any additional details on customization.

Gap

The literature focused on using experts to guide customization. Although some stakeholders preferred less customization, health institutions were looking for guidance when customizing, often from developers, on what aspects of the EHR should be customized, and the long-term costs and consequences of customization.

Clinical Workflow and Usability Testing

Findings in the Published Literature

Several general articles stressed the importance of usability assessment, pilot testing on end-users, and workflow design, including the impact of poor interoperability on workflow [24, 27–31, 38–40, 43, 46, 49, 56–58]. Nine articles specifically addressed aspects of clinical workflow and usability testing. Using a sociotechnical evaluation approach, one article identified clinical workflow as a key theme that can result in failure during implementation [59]. Similarly, another article stressed the need for cross-functional implementation teams including experts in workflow and design to ensure these critical aspects are part of implementation [60].

There were different methods described for analyzing workflow and conducting usability evaluations. One article described the use of technology mediators, who understand end user's workflows

and practices, to assist during implementation. The mediators establish credibility with the end-users and have knowledge of their technical abilities [61]. Another article focused on the study of communication patterns between physicians and nurses to better understand their needs and inform the implementation process to avoid negative impacts of technology on communication and workflow [62]. One article described a typology of temporary and routinized EHR workarounds [63].

Two articles described the use and importance of simulation during implementation and go-live to identify the impact of the EHR on workflow and determine whether clinicians can identify information critical to patient care via the HER [64, 65] and one described the processes required to transform a simulation center into an EHR testing laboratory to examine usability [66]. Several articles described different methods for testing usability, including simulation, verbal protocol, and heuristic evaluations of the test system with the intended users to identify critical issues [65, 67].

Key Stakeholder Perceptions

Health institutions described several challenges and practices around workflow and testing. Workflow decisions are uninformed because health institutions do not know best practices on workflows. Health institutions indicated that changes to workflow within the EHR are burdensome, and some described difficulties in working with their developer to institute changes. Health institutions discussed how challenges with interoperability affect workflow and usability, for instance requiring manual data re-entry or reducing the availability of key data.

Small healthcare institutions had some strategies for workflow design and usability testing. One described looking to other similar practices to understand how those health institutions' workflows are affected by use of the EHR and then adopting insights in their own practice, and one described analyzing their own workflows and conducting pilot testing with some health institutions before making any implementation decisions that would be rolled out to all staff. Several health institutions described going to EHR user conferences to meet and learn from other health institutions. One small healthcare institution described going through each click and each screen to adjust workflows and remove extraneous information. Several also described hiring consultants to perform workflow analyses and advise on optimization, but some noted that workflow consultants that understand a specific EHR product well were hard to find.

One consultant indicated that many health institutions are unaware of their EHR's complete functionality and may be using suboptimal workflows as a result. One researcher discussed how rushed implementation timelines present a major challenge for health institutions to analyze workflows and integrate them into the EHR. EHR developers described their usability testing processes during design and development, but stated that usability testing is not a focus during implementation.

Gap

The literature and stakeholders recognize the critical importance of workflow design and usability testing; however, many health institutions felt uncomfortable making workflow decisions without detailed knowledge of workflow patterns. Large healthcare institutions in particular have complex workflow processes, do not have the workflow knowledge, and look to EHR developers to support the process of understanding workflow needs and implementing products to meet these needs. Similarly, many health institution stakeholders did not have the knowledge of how to perform usability tests during implementation.

Training

Findings in the Published Literature

Several general articles highlighted training and support for clinicians as a critical component of implementation [24, 25, 27–31, 39–46, 50, 56, 57, 68–71]. These articles suggested tiered training approaches, varied training depending on clinician expertise, peer-training with clinical scenarios, and having 24-hour support available for health institutions [25, 29, 39, 43, 45].

Six articles focused specifically on training and described various aspects of training including training development and timing, and suggested best practices. One article focused on the development of training materials and highlighted the need for human factors techniques, such as task analysis, to identify the critical EHR tasks that should be the focus of training content [72]. One article described informatics and computer skill gaps as a major barrier to EHRs and suggested that EHR training should begin during formal medical education, prior to being a licensed clinician, to combat these barriers [73]. One article described the cost of training programs and detailed the high cost of education and identified barriers including hiring fill-in staff while others attend training [25].

Two articles focused on different training strategies, including simulation, resulting in positive effects such as increased self-confidence and preparedness [74]. One identified specific behaviors that increased super users' impact on peers' learning, such as being more engaged and proactive, providing comprehensive explanations for actions, and sharing information [75].

Two articles identified challenges and best practices. One focused primarily on the barriers and usability challenges in EHR education and training, including the burdensome length of training time, need for tailored training for specialist positions, lack of a systematic way to gauge learning, and inadequate resources such as experienced staff and time for retraining [76]. The other identified seven overall best practices in EHR implementation training, including: assess users' skills and needs, select appropriate trainers, and match training to users' needs, retrain, and optimize [77].

Key Stakeholder Perceptions

Several small and large healthcare institutions discussed training and its effects on end users' experiences and perceptions of EHR usability. One small healthcare institution described the challenge of having the right training for the right individual user, given differences in computer literacy and comfort. Health institutions discussed challenges posed by long delays between training and go-live, and one described how delivering large amounts of training in a short time resulted in poor learning. Several researchers discussed the need for continued training after "go live". Several health institutions had established their own training practices, including a continuous model with experts on site once a month, refresher training, and one on one peer consults. One consultant said that shadowing providers to see them use the system was very effective but costly and hard to scale. For nearly all health institutions, the high cost of training was a major issue. Several health IT developers expressed the importance of training on effective use of the product. Consultants described how many clinicians are unaware of core functionality within the EHR, which leads to inefficient workarounds, and how improved training could address this issue.

Gap

Several articles describe training methods, most of which are cost intensive and require specialized expertise and simulation. Stakeholders recognize the importance of training, but the cost of training was a significant challenge. While the literature provides information on the general costs of different training approaches, healthcare institution stakeholders are looking for clear guidance on effective low-cost training solutions and knowledge on how to train their staff on the implemented system in a time-frame that maximizes learning. Practical guidance on training strategies within the tight timelines of EHR implementation and cost-effective training solutions is currently unmet in the literature.

5. Discussion

EHR usability can dramatically affect clinicians' satisfaction with the system and the system's ability to enable consistently safe and high-quality care. Decisions made during EHR implementation can have a profound impact on the usability and safety of the system; improving implementation processes to optimize EHR usability and safety can help EHRs reach their full potential. We identified several gaps between the literature and the perspectives and practices of stakeholders working to improve the implementation process, making clear that additional research and resource development are needed to fill these gaps and to provide stakeholders with the knowledge and insight they need

to successfully implement EHRs. Specifically, concrete guidance and best practices are needed to support small healthcare institutions in finding the appropriate expertise during implementation, identifying aspects of the EHR that should be customized, identifying cost effective methods for training, and identifying and ameliorating usability-related issues in implemented systems. Improvements in usability should also improve the ability for users to learn how to use EHRs which could reduce the burden of training.

In addition to research, other initiatives currently underway can serve to fill existing gaps. Transparency around costs associated with improving usability and safety of products during implementation was a major concern for health institution stakeholders and was not addressed in the literature. The ONC Certified Technology Comparison Task Force and the Senate Health, Education, Labor and Pensions committee have discussed this particular gap and have both recognized and promoted the need for improved EHR usability comparison tools. Poor system interoperability also has a major impact on usability and poses several challenges to efficient workflow which can pose risks to patient safety. Improved interoperability initiatives, which are a major priority for the ONC and Health and Human Services (HHS), will have a dramatic impact on usability and safety by creating more seamless workflow experiences for clinicians and reducing the need for customization [66].

Three underlying themes bridged many of the identified gaps. First, when tools and processes are available in the literature, they are not always being effectively disseminated and/or translated for frontline implementer and end users. Second, costs during implementation remain a significant challenge, particularly for small healthcare institutions, and much of the literature does not consider it when offering best practices. There is the potential for significant return-on-investment for improving EHR usability during implementation to prevent downstream inefficiencies, clinician frustration, and safety hazards; however, these benefits must be more clearly demonstrated to healthcare professionals adopting the technology and developers should support improvements in usability. Finally, improved partnerships between health institutions, developers, and other stakeholders are necessary to improve EHR usability and safety. Addressing these challenges will require coordination and engagement form multiple stakeholders making the ONC proposed health IT safety collaborative a particularly appropriate venue [78].

6. Study Limitations

This study aimed to identify gaps in the published literature in areas important to key stakeholders in EHR implementation, and used established methods in literature review and qualitative analysis. There are limitations to this approach. The focus of our literature search and stakeholder interviews was on usability and we did not explicitly differentiate between usability and usefulness. The stakeholders may have conflated these two concepts in their responses. Stakeholder responses are the respondents' perception of usability and stakeholders have varying degrees of understanding and experience with usability assessments. As with any literature review, the choice of inclusion criteria has the potential to bias the results by unknowingly including less relevant data or excluding relevant data. This was minimized by selecting criteria based on established literature and by using three independent reviewers during the review process. The semi-structured interview portion of the study also has potential limitations. As with any purposive sampling strategy, we recruited participants most likely to be knowledgeable on targeted topics. Despite our best efforts, it is possible that some perspectives were not represented. However, we used well-established, rigorous qualitative research methods to minimize this risk. In addition, each stakeholder group was asked different questions about usability and safety during implementation given that each stakeholder group has their own unique expertise.

7. Conclusion

Decisions made during implementation directly affect the usability and safety of the EHR. We identified several usability and safety gaps affecting implementation by examining misalignments be-

tween the literature and key stakeholder perceptions. The major gaps were: transparency around cost and resources, risk assessment, governance and consensus building around EHR product options, customization, clinical workflow and usability testing, and training. Future research and resource dissemination should focus on these areas, and particularly on translation from the research realm to EHR implementation on the frontlines.

Conflicts of Interest
The authors have not conflicts of interest to report.

Human Subjects Protections
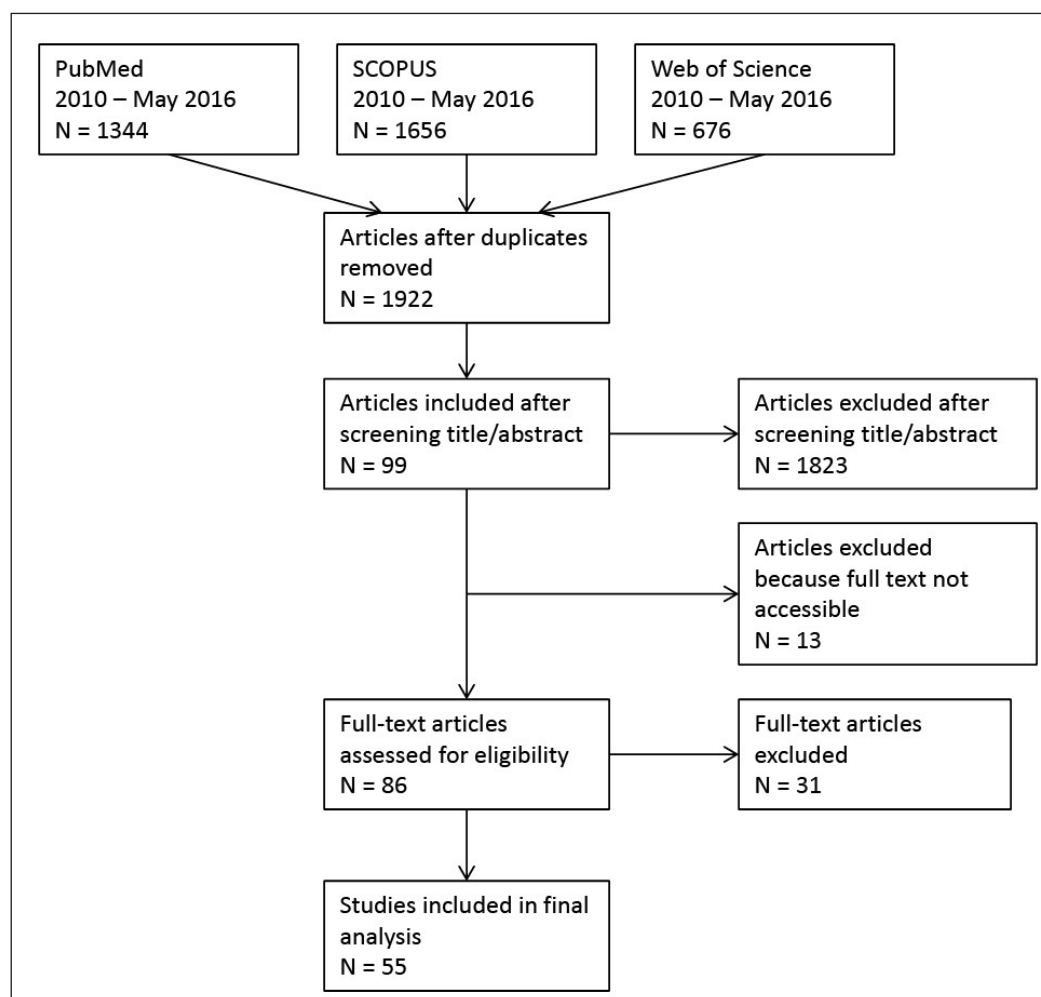This research effort was determined to be exempt by the institutional review board.

Fig. 1   Article selection process.

Concept 1		Concept 2		Concept 3
electronic health record *OR* EHR *OR* electronic medical record *OR* EMR *OR* CPOE *OR* clinical decision support *OR* CDS	*AND*	implementation* *OR* customization* *OR* training* *OR* configuration*	*AND*	safety *OR* usability

Table 1 Search queries and restrictions.

Restrictions: published 2010 – May 16, 2016; peer-reviewed journal; affiliated author country: Australia, Canada, United Kingdom, United States of America; * indicates the word was identified as a stem term during search

Table 2 Stakeholder categories.

Category of Stakeholder	Description of Stakeholder	Participating Individuals or Organizations	Stakeholder Background	Sample Questions
Academia & Research	Organizations that aim to do further research or analysis of health IT usability and safety.	8	3 focused on nursing informatics 2 focused on safety science 1 focused on physician informatics 2 focused on health IT	1. Do you know of any best practices around implementation strategies both internal and external to healthcare? 2. Do you know of case studies or research/planned research around how EHR purchasers implement new products and what recommendations vendors make?
Associations & Societies	Organizations that operate to represent the needs or further the interests of individuals with a common professional background.	8	6 Healthcare focused associations 2 Healthcare technology focused associations	1. Do you have or know of any current efforts around usability that your organization does on behalf of members? 2. Does your organization catalog UX efforts across quality and safety initiatives?
Consultants	Organizations that provide expert advice and services on EHR technology, such as implementation advisement and usability optimization.	8	1 focused on healthcare informatics 3 focused on implementation 4 focused on human factors/usability	1. How do you assist health institutions adapt their implementation process to improve usability and patient safety? 2. What workarounds or strategies have frontline staff implemented to improve their EHRs?

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Table 2 Continued

Category of Stakeholder	Description of Stakeholder	Participating Individuals or Organizations	Stakeholder Background	Sample Questions
Health IT Developers	Private companies that design, develop, and sell EHRs.	9	9 Health IT Developers	1. Do you know of any work to track or report health IT usability issues across purchasers or to vendors? 2. What does your organization do to improve the implementation process?
Health Institutions	Professionals and organizations that use health IT as part of their health care delivery process.	9	2 Nurses with IT role 3 Physicians with IT role 4 Physicians	1. Do EHR vendors provide you with information on the best ways to implement a new product? 2. Do you have other groups or organizations that you contact for implementation suggestions? 3. What resources would be helpful to your organization in making implementation decisions?

Table 3 Summary of literature, stakeholder data, and major gaps by emerging theme.

Themes	Literature	Stakeholders	Gaps
Cost and Resources	• Framework for major costs [26] • Cost saving strategy through collaboration [25]	• Unclear picture of total cost • Extra costs to improve usability and safety	Transparency around the total costs of a usable and safe EHR
Risk Assessment	• Models for risk assessment [32–35] • Tools to evaluate implementation [36, 37]	• Little awareness of risk assessment tools or models • Desire for seamless usability and safety reporting	Literature focused on proactive risk assessment and stakeholders desire practical risk assessment tools and method for seamless reporting of hazards
Governance and Consensus Building	• "Engage end-users" without suggestions of how to do so·Gather user feedback [51] • Actionable CDS recommendations [52] • Easily digestible information from developers [52] • Clinician customization [52]	• All staff involved in process • Large healthcare institutions have processes·Small healthcare institutions challenged to find needed expertise	Guidance and best practices need to be developed for small healthcare institutions who may not have multidisciplinary experts

Table 3 Continued

Themes	Literature	Stakeholders	Gaps
Customization	• Individual configuration can be effective [53] • Effective customization can be developed by using experts, literature [54] • Customization recommendations via panel of experts [55]	• Long term costs are not fully understood • Need more guidance from experienced developers or usability experts • Configuration over customization • Less local customization = increased usability	Guidance on what should be customized and costs associated with customization
Clinical Workflow and Usability Testing	• Need experts in workflow [60] • Workflow is key failure theme [59] • Methods for analyzing workflow [61–63] • Simulation to test workflow, usability [64–66] • Methods for conducting usability evaluations [65, 67]	• Workflow experts with product knowledge hard to find • Best practices unknown • Some small healthcare institutions have developed strategies for workflow analysis • Health institutions lacking full knowledge of EHR functionality • Rushed timelines	Methods to better understand current workflow processes and whether EHRs are meeting workflow needs; desire for greater engagement from HIT developers
Training	• Human factors techniques to identify critical training content [72] • EHR education and training earlier in medical career [73] • Successful use of super users [75] • Challenges [76] and best practices [75]	• Challenge to find right training for right clinician • Short timeline for absorbing content • Local established training practices	Need for guidance and best practices on low cost and effective training solutions that can be administered in short period of time

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