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Original Research Article

Is evidence of effectiveness a driver for clinical decision support selection? A qualitative descriptive study of senior hospital staff

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Abstract

Limited research has focused on understanding if and how evidence of health information technology (HIT) effectiveness drives the selection and implementation of technologies in practice. This study aimed to explore the views of senior hospital staff on the role evidence plays in the selection and implementation of HIT, with a particular focus on clinical decision support (CDS) alerts in electronic medication management systems. A qualitative descriptive design was used. Twenty senior hospital staff from six Australian hospitals in New South Wales and Queensland took part in a semistructured interview. Interviews were audio-recorded and transcribed, and a general inductive content analysis approach was used to identify themes. Participants acknowledged the importance of an evidence base, but reported that selection of CDS alerts, and HIT more broadly, was rarely underpinned by evidence that technologies improve patient care. Instead, investments in technologies were guided by the expectation that benefits will be achieved, bolstered by vendor assurances, and a perception that implementation of HIT is unavoidable. Postponing implementation of a technology until an evidence base is available was not always feasible. Although some technologies were seen as not requiring an evidence base, stakeholders viewed evidence as extremely valuable for informing decisions about selection of CDS alerts. In the absence of evidence, evaluation or monitoring of technologies postimplementation is critical, particularly to identify new errors or risks associated with HIT implementation and use. Increased transparency from vendors, with technology evaluation outcomes made directly available to healthcare organizations, may result in less reliance on logic, intuition, and vendor assertions and more evidence-based selection of HIT.

Keywords: evaluation, health information technology, evidence, implementation, clinical decision support

Introduction

Health information technologies (HITs) are becoming ubiquitous in healthcare, particularly to facilitate safety and efficiency in hospital settings [e.g. electronic health records (EHRs)] [1]. Evidence of their effectiveness to improve patient outcomes and streamline work processes is growing, but given the rapid pace at which HIT is being developed, introduced, and modified, evaluation of these tools is lagging behind implementation [2, 3]. Regulatory oversight of HIT is complex, with technology requirements dependent on if the tool is deemed a 'medical device' and the clinical context and potential risk posed [3, 4]. In recognizing the importance of testing a technology in practice to ensure that it is safe and used safely, the Centers for Medicare & Medicaid Services released a rule requiring that hospitals perform an annual safety assessment of their EHR using Safety Assurance Factors for EHR Resilience guides [5]. However, this requirement, or similar, is yet to be mandated outside of the USA.

Electronic medication management (eMM) systems (or computerized provider order entry systems), now used in many hospitals worldwide, replace paper-based medication

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charts and allow computerized prescribing, review, and administration of medications. A key component of eMM systems is the clinical decision support (CDS) they include [6, 7]. CDS is any feature or function that enhances decision-making by providing users with pertinent, organized clinical and patient information [8]. CDS can take many forms, with computerized alerts being one of the most common forms of CDS used and evaluated. There is evidence that CDS alerts can be effective in reducing medication errors, but studies are of variable quality, and limited research has examined clinical outcomes, such as medication-related patient harms [9–13].

The International Medical Informatics Association and the European Federation of Medical Informatics have argued for evidence-based principles to be applied to health informatics practice calling for HIT to be implemented only when shown to be safe and beneficial [4, 14]. Despite this, limited research has focused on understanding if and how evidence of HIT effectiveness drives the selection and implementation of technologies in practice, particularly decisions related to CDS [3, 4, 14–16]. The aim of this study was to explore the views of senior hospital staff on the role evidence plays in the selection and implementation of HIT, with a particular focus on CDS alerts in eMM systems.

Methods

Design

This study used a qualitative descriptive design [17].

Setting

Senior hospital staff from six Australian hospitals were approached to take part in a qualitative interview. Study sites were those participating in a large trial of CDS alerts and included five hospitals in New South Wales (NSW) and one hospital in Queensland (QLD). Hospital details appear in the Supplementary Material. Hospitals did not use the same eMM system. They used either different eMM systems or the same eMM systems (from the same vendor) but with different configurations/builds.

Recruitment and participants

A purposive sampling approach was initially used to recruit participants. In particular, department directors and individuals in HIT-related roles (e.g. Chief Information Officers and Directors of Medical Services) were sent an email inviting them to take part in an interview. Although not always directly responsible for HIT investment decisions, the opinions of senior hospital staff, including Chief Information Officers, Directors of Medical Services, and Department heads, are frequently sought by decision-makers to inform the selection and implementation of HIT in hospitals. A snowball recruitment approach was concurrently used to identify additional participants, with interviewees recommending colleagues in relevant decision-making roles who may be interested in taking part.

All participants provided written informed consent prior to commencing the interview. Participation was voluntary, and no compensation was provided. Participants were assured that no identifiable information would be collected or reported. The study received Human Research Ethics Committee approval by the Hunter New England Human Research Ethics Committee (18/02/21/4.07) and was also approved by all participating hospitals. The Standards for Reporting Qualitative Research Checklist was used to guide manuscript preparation and is given in the Supplementary Material.

Box 1. Interview guide.

(i) Do you think we need evidence that digital health interventions are effective before they are rolled out? Why?
(ii) What would constitute sufficient evidence of effectiveness for something like a decision support alert? Why?
(iii) Are healthcare organizations morally or ethically obligated to implement an intervention if there is a possibility that it *may* be effective? Why or why not?
(iv) Do you think a good evidence-base exists for drug–drug interaction alerts? Is there evidence that alerts improve prescribing and patient outcomes? What kind of evidence?
(v) What about evidence for decision support in general?
(vi) What do you think is the most appropriate way to evaluate digital health interventions, like electronic medication management systems and decision support alerts? Why?

Data collection

One-on-one, semistructured interviews were held via videoconference and conducted by a human factors researcher with expertise in HIT evaluation, CDS, and qualitative research (M.T.B.). The interviewer was independent (i.e. not employed or affiliated) from all study sites. Interviews were conducted between November 2019 and August 2020. Interviews formed part of a larger project focused on CDS alerts in eMM systems [13] and comprised two parts: questions related to (i) recruitment of hospitals into trials of HIT and (ii) evidence-based decision-making for CDS and HIT in general. Results from the latter component are reported in the current paper. The interview guide for Component 2 appears in Box 1. Participants were initially asked to reflect on whether evidence of effectiveness is required for HIT in general, before being asked specifically about CDS alerts. Questions were developed with input from researchers and practitioners with expertise in human factors, HIT evaluation, CDS, pharmacy, and clinical pharmacology and acted as guide only, with each functioning as a trigger for discussion.

Data analysis

Interviews were audio-recorded and transcribed, and transcripts were de-identified. A general inductive content analysis approach was used to identify themes [18]. Two researchers experienced in qualitative research and HIT evaluation (M.T.B. and B.A.V.D.) initially coded three transcripts independently, then came together to compare themes, and agreed on a coding framework for analysis of the remaining interviews. To ensure that analysis was reliable, the remaining interviews were independently coded by three researchers (M.T.B., B.A.V.D., and K.S.) using the framework. The three researchers came together to review codes, discuss discrepancies, and agree on key themes for reporting. Any disagreements in themes identified were resolved via a discussion process. Data collection and analysis continued until inductive thematic saturation was achieved [19]. Following analysis,

key interview findings were presented to three participants who confirmed that results were credible.

Results

Participants included 20 senior staff members, including five from QLD and 15 from NSW hospitals. Participants were Chief Information Officers ($n = 2$); Directors of Pharmacy, Nursing, and Clinical Pharmacology ($n = 7$); eMM system implementation leads ($n = 4$); Director of Clinical Governance ($n = 1$); Directors of Medical Services ($n = 3$); and Chairs of relevant committees/councils ($n = 3$). Each interview ran for an average of 30 minutes (range 17–55 minutes). Findings were consistent across participant subgroups, regardless of the role or level of seniority and have been combined later.

An evidence base to drive CDS selection

Most participants agreed that evidence of effectiveness is not only needed to inform the selection of CDS alerts and HIT more broadly but also reflected on the fact that many technologies are implemented without an evidence base.

> Evaluating what we do is really important […] making sure that we put in interventions that actually give value […] I think it's easy with technology for us just to assume that it's better because it's technology, isn't it? It's a computer, it's much better. (Site 1, Participant 1)

> We put a lot of things in place and a lot of interventions, you know, anything medical, we do rigorous research and interventions, you know, for new drugs, etc, to make sure they actually work […] but when it comes to electronic systems, there's not a lot of that around. (Site 2, Participant 1)

A number of participants highlighted the value of evidence to encourage end-user adoption of CDS. In particular, participants felt it would be very challenging to achieve high levels of acceptance and uptake of any technology among clinical groups without evidence that the technology improves patient care and safety.

> I'm a clinician by heart so if things are going to change, I think we've got to be convinced that they are good for the patient and more effective. I know, the biggest pushback from my staff is they don't understand if [why] the change has occurred, so why use it? (Site 2, Participant 2)

Despite this, some participants explained that although it is ideal to have evidence to drive the selection and implementation of HIT, waiting for an evidence base to be available would delay implementation, which is not always feasible.

> I think yes, ideally, of course, the struggle is in practice… But I'm also concerned about the amount of time that it takes to prove that everything that we can do in health is meritorious, will slow down actually implementing it at all… And I agree, like a full evidence-based approach would be great, but I just can't see there being enough time effectively to do that. (Site 2, Participant 1)

Participants also explained that evidence of effectiveness is needed for only some HIT, not all. For example, participants reported that replacing paper-based systems with eMM systems would result in immediate benefits like improved legibility and accessibility, with no evidence base needed to drive this implementation. On the other hand, particular features or functions, like CDS, where less is known about impact and outcomes, should be evaluated.

> What I would say is there are some interventions that you know are positive interventions such as […] making things electronic… So I would say implementing these interventions, knowing that they're mostly positive, no, you don't need evidence… So the research could be on the bits and pieces that we don't know or we are thinking whether they are positive or not. (Site 5, Participant 1)

A small number of participants also questioned the value of an evidence base for HIT, because implementation of technology is inevitable, with no possibility of reverting to paper-based processes.

> I mean it's always nice to have data for things but some things, I think, are just generally no brainers like eMeds [electronic medication management] for example, this is the way the system is going… In terms of having to go and do robust studies and controlled trials, like what value is that actually adding? So I sort of question the need to have a study to prove absolutely everything when something is just the progression in terms of society and the way things are going. (Site 3, Participant 4)

Mixed evidence of CDS effectiveness is available

When asked whether an evidence base exists for CDS alerts, specifically drug–drug interaction (DDI) alerts, participants had mixed perceptions. Some participants thought that there was limited evidence available to demonstrate that DDI alerts were effective in reducing DDIs. Others were not sure if there was evidence available.

> Without having looked into the evidence base. It's kind of hard to answer. (Site 3, Participant 5)

Interestingly, a number of participants assumed that an evidence base exists for DDI alerts because these alerts are promoted as key safety features in electronic systems. There was an expectation among participants that vendor decisions made during the development or design process of HIT are informed by available evidence.

> I'm sure because […] a lot of thought that has gone through to put these programs together. So there must have been something that is recommending them. (Site 5, Participant 1)

> I understand that, you know, the software design has to be reviewed at some point in terms of what's going to be clinically appropriate. But presumably, somewhere along the lines in the consultative process, someone has said this, we feel that this is an appropriate safety feature. (Site 3, Participant 5)

In the absence of evidence to inform selection, organizations should evaluate

In acknowledging some of the challenges associated with selecting CDS (and HIT more broadly) on the basis of an evidence base, most participants agreed that undertaking postimplementation evaluation of the technology was valuable.

> I think if you're going to implement something without evidence, you need to have a really robust audit process, evaluation process, so use the opportunity to get the evidence. (Site 6, Participant 1)

> I don't think it should be the decision not to put a system in or to avoid putting a system in until we do studies to prove it, which is only causing unnecessary delays… But I do think we should be tracking how those systems are performing and how we're then re-evaluating and improving on those systems once they are established. (Site 3, Participant 4)

When asked how HIT should be evaluated, most participants reported that conducting a randomized controlled trial (RCT) would be ideal.

> I'd prefer the RCT approach…I think for a very large or significantly sized investment, with significant risks and significant opportunity cost, having some evidence on it is very welcome. It's exceedingly rare in the informatics space. (Site 1, Participant 2)

However, participants also acknowledged that this would not always be easy and practical, particularly because technology is constantly being modified and updated.

> The practical world is that digital is changing so rapidly […] that you've done some research and you've gathered some auditing about, you know, usage of drugs, and something in the system has changed. There's not enough time to run a RCT. (Site 2, Participant 2)

Participants explained that both monitoring and measuring expected benefits and new safety risks of HIT were important. Expected benefits included improvements in patient care and patient outcomes, including reductions in medication errors and time for medication administration. Participants recognized the difficulty in identifying new risks and errors, particularly those that are unexpected.

> I think if I've learned anything in electronic systems, there always seem to be Spidey effects. In other words, when you change one thing, it tends to then have ramifications elsewhere and it's not all obviously directly a causal relationship, sometimes it's indirect, and that can be very difficult to really establish. (Site 2, Participant 3)

Voluntary incident reports were frequently mentioned as useful for identifying risks associated with HIT implementation, but some participants explained that current incident reporting systems are not designed to capture useful information about technology-related errors and risks.

> I think the incident management systems that we've got in place […] while there has been updated taxonomies around how we describe incidents, some of those health IT factors, really, I don't think they're even part of the […] information management system […] ultimately, if we're going to understand why these incidents are happening, or why they're coming through, we need a way of being able to describe them appropriately. And if we haven't got that, then we just, you know, how can we possibly look for trends? (Site 1, Participant 5)

Other suggestions put forward for evaluating CDS included observing user interactions with systems in practice, analyzing user interactions with the technology via back-end data (e.g. clicks and alert overrides), and seeking feedback from users.

Discussion

Statement of principle findings

This study explored senior hospital staff's views of evidence driving HIT selection and implementation. The majority of participants recognized the importance of an evidence base, but acknowledged that selection of CDS, and HIT more broadly, was rarely underpinned by evidence that technologies improve care in practice. Instead, staff explained that investments in technologies were guided by the expectation that benefits will be achieved, bolstered by vendor assurances, a perception that implementation of HIT is unavoidable. In the absence of evidence to drive CDS and HIT selection, almost all stakeholders advocated for organizations evaluating or monitoring their technologies postimplementation, particularly to identify new risks associated with HIT implementation and use.

Strengths and limitations

This study took a unique approach in interviewing senior hospital staff, who are key stakeholders in HIT selection and implementation. However, the study describes perceptions, not actual evaluation practices. A study strength was that data were collected from six hospitals across two Australian states, ensuring that a board range of views were captured; however, findings may not be generalizable to other countries or stakeholder types. Finally, although participants were asked about HIT in general, all were aware that interviews formed part of a larger project focused on CDS alerts, so responses were likely to predominantly reflect views on this type of technology.

Interpretation within the context of the wider literature

In line with previous research [14, 20], stakeholders acknowledged that implementation of CDS, and HIT more broadly, was primarily driven by the potential of technologies to improve care, not evidence that they actually do. A novel finding from this research was the perception that not all HIT requires evaluation. Stakeholders explained that benefits, such as improved legibility of prescriptions, would intuitively result from implementation of some technologies (i.e. 'no brainers'), removing the requirement for an evidence base. This was not the case for CDS, with most stakeholders acknowledging that less is known about CDS impact on prescribing and clinical outcomes. Some participants had assumed that the inclusion of a CDS feature, like DDI alerts, indicated that some level

of evaluation had been conducted by or for vendors, and evidence of effectiveness was available. This finding is consistent with previous research, which showed that trust in vendor recommendations is a strong driver for implementation of decision support alerts [21].

Many participants held the view that postponing implementation of a technology until an evidence base is available is not always feasible. This was primarily because of the time required to evaluate a system and the fast pace at which technology is changing. Given the length of time to conduct and publish research, evidence published would likely reflect a product that has been updated and refined multiple times. Technologies, including CDS, are typically embedded in complex, fast-paced sociotechnical systems, the result being that the outcomes of evaluation are likely to be context-dependent and unstable and may not be replicable [16, 22, 23]. With these challenges in mind, it has been suggested that traditional evaluation approaches, like RCTs, are replaced with more agile methods of evaluation for HIT [2, 23, 24]. Participants in our study reported several methods they thought may be suitable for evaluating CDS, including end-user feedback and utilization of technologies (e.g. alert overrides).

There is now a growing body of literature to show that HIT, although beneficial, can also result in unintended consequences, some of which can lead to patient harm [25–28]. Stakeholders in our study not onlyviewed the identification of new safety issues to be an integral part of technology evaluation but also highlighted several challenges associated with this. Voluntary incident reporting systems remain the primary means by which hospitals identify and reduce patient harm [29, 30], but participants described difficulties in garnering useful information about technology-related errors and risks from incident reports.

Implications for policy, practice, and research

Three key implications emerged from this research. First, increased transparency from vendors, with technology evaluation outcomes made directly available to healthcare organizations, may result in less reliance on logic, intuition, and vendor assertions and more evidence-based selection of HIT. Second, the establishment of appropriate HIT governance structures within an organization may facilitate systematic and transparent decision-making and ensure ongoing review and evaluation of technologies [31]. Finally, our study highlighted the importance of designing incident reporting systems so that they allow easy identification of technology-related incidents and the capturing of relevant details.

Conclusion

Interviews with senior hospital staff revealed that decisions to implement CDS, and technology more broadly, are viewed to be rarely evidence-based, but are also not haphazard, as driven by an expectation that benefits will be achieved. Although some technologies were seen as not requiring an evidence base, stakeholders viewed evidence as extremely valuable for informing decisions about selection of CDS, including CDS alerts in eMM systems. In the absence of evidence of effectiveness, postimplementation evaluation was highly valued, particularly for identifying technology-related risks.

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Supplementary data

Supplementary data are available at *INTQHC* Journal online.

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Data sharing statement

The dataset generated and analyzed during the current study is not publicly available.

Contributorship

M.T.B., S.H., R.D., J.W., W.Y.Z., and A.H. designed the study. M.B. conducted the interviews; M.B., B.A.V.D., and K.S. analyzed the interview data; M.M. and W.Y.Z. contributed to interpretation of interview data. All authors contributed to writing of the manuscript and approved the final manuscript.

Ethics and other permissions

All participants provided written informed consent prior to participating in an interview. The study received Human Research Ethics Committee approval by the Hunter New England Human Research Ethics Committee (18/02/21/4.07) and was also approved by research governance of all participating hospitals.

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