BMJ Open

"It's like turning all the features off in your car": A qualitative study of challenges with recruitment of hospitals into cluster controlled trials of clinical decision support

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-080610
Article Type:	Original research
Date Submitted by the Author:	05-Oct-2023
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Keywords:	QUALITATIVE RESEARCH, Hospitals, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS

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"It's like turning all the features off in your car": A qualitative study of challenges with recruitment of hospitals into cluster controlled trials of clinical decision support

Word count: 3079

ABSTRACT

Background and objective: We attempted to recruit six hospitals into a controlled cluster trial of drug-drug interaction (DDI) alerts but encountered significant challenges. No previous research has examined barriers to site-level recruitment into trials of clinical decision support (CDS). In the current study, we aimed to identify barriers to hospital participation in controlled cluster trials of CDS, and potential strategies for addressing barriers.

Methods: Senior hospital staff from six Australian hospitals were purposively approached to take part in a qualitative interview. Interviews were conducted via videoconference, audio-recorded, transcribed, and a general inductive content analysis approach used for analysis.

Results and discussion: Twenty senior hospital staff took part. Barriers to hospital-level recruitment primarily related to perceptions of risk associated with not implementing CDS as a control site. Perceived risks included reductions in patient safety, reputational risk, and increased likelihood that benefits would not be achieved following electronic medical record (EMR) implementation without DDI alerts in place. Senior staff recommended clear communication of trial information to all relevant stakeholders as a key strategy for boosting hospital-level participation in trials.

Conclusion: Hospital participation in controlled cluster trials of CDS is hindered by perceptions that adopting an EMR without CDS is risky for both patients and organizations. The improvements in safety expected to follow CDS implementation makes it challenging and counterintuitive for hospitals to implement EMR without incorporating CDS alerts for

the purposes of a research trial. To counteract these barriers, clear communication regarding the evidence-base and rationale for a controlled trial is needed.

What is already known on this topic

- Clinical decision support alerts are viewed as a key safety feature of electronic medical records, however, few controlled trials have been undertaken to assess the effectiveness of alerts
- Although there is considerable research exploring challenges associated with individual participant recruitment into trials, much less is known about barriers and facilitators to site-level recruitment into controlled trials
- No previous research has examined site-level recruitment into trials of clinical decision support

What this study adds

- Hospital participation in controlled cluster trials of clinical decision support is hindered by perceptions that not adopting decision support is risky for both patients and organizations
- An expected improvement in safety following alert adoption is a driver for implementation, making it challenging for organizations to omit alerts for the purposes of a research trial

How this study might affect research, practice or policy

- When recruiting hospitals into trials of clinical decision support, clear communication, particularly regarding the lack of evidence for clinical decision support effectiveness, may alleviate participant concerns and facilitate organization participation

1. Introduction

Controlled trials, where one cohort is exposed to an intervention and another cohort is not, are viewed as essential for determining effectiveness of an intervention. In trials of hospital-wide digital health interventions, like electronic medical records (EMRs), delivery of the intervention to selected individuals or groups, such as clinicians or patients, risks contamination and is practicably difficult, so intervention delivery is typically at the site or hospital level (1). In controlled cluster trials, individual participants are not recruited or consented but selected hospitals adopt a digital health intervention, while others refrain from or delay implementing the intervention during the data collection period (2, 3).

Clinical decision support (CDS) alerts are viewed as a key safety feature of EMRs. To date, however, few controlled trials have been undertaken to assess the effectiveness of alerts, and as a result, organizations have limited robust evidence to guide alert selection. For example, drug-drug interaction (DDI) alerts, which trigger at the point of medication order entry to warn prescribers of potentially dangerous drug combinations, are frequently used (4, 5), yet no controlled trials have examined the effectiveness of DDI alert sets (e.g. 'severe' or 'moderate' DDI alerts) to reduce medication errors and patient harms.

Our non-randomized controlled pre-post trial of DDI alerts in EMRs aimed to fill this evidence gap by comparing rates of DDIs and associated patient harms before and after implementation of an EMR, with (intervention) or without (control) DDI alerts.(6) We attempted to recruit six hospitals into our trial but encountered significant challenges in recruiting control hospitals. Hospitals were receptive to participating in a trial, but were opposed to implementing their EMR system without DDI alerts in place, despite the limited evidence available on DDI alert effectiveness.

Although there is considerable research exploring challenges associated with individual participant recruitment into trials (7-11), much less is known about barriers and facilitators to site-level recruitment into controlled trials, and no previous research has examined site-level recruitment into trials of CDS. In the few studies that have examined hospital recruitment, most barriers identified relate to challenges associated with intervention delivery. For example, in a study that attempted to recruit nearly 100 hospitals for a pragmatic cluster randomised trial of post-acute stroke services, the primary reason for hospitals declining to participate was insufficient staff or financial resources to deliver the intervention (12). However, for trials of CDS, like DDI alerts, this factor is unlikely to be a barrier, as intervention delivery typically consists of 'turning on' the CDS functionality in an EMR with some additional clinician training on its use.

In this study, we aimed to identify barriers to site-level participation in controlled cluster trials of CDS, and potential strategies for addressing these barriers. Based on the challenges we encountered in recruiting control sites for our trial, we expected to identify some unique recruitment challenges for trials of CDS. With the rapid acceleration of CDS implementation in hospitals, and digital health interventions more broadly, we hoped our findings would be of value to others attempting to generate a robust evidence-base for these important interventions.

2. Methods

2.1. Design

This study used a qualitative descriptive design.

2.2. Setting

Study sites included five hospitals in New South Wales (NSW) and one hospital in Queensland (QLD), Australia (see Supplementary material, Appendix 1). These sites were initially approached to participate in our trial of DDI alerts (6).

2.3. Recruitment and participants

Senior hospital staff from the six hospitals were purposively approached to take part in a qualitative interview to explore their views on evaluation of CDS alerts. Interviews formed part of our larger project focussed on determining effectiveness of CDS alerts in EMR systems (6) and were conducted after the commencement of our cluster trial, but before trial completion. The sample included department directors, Chief Information Officers, and those working in Health Informatics teams. A snowball recruitment approach was also used to identify participants, where interviewees recommended additional colleagues to be interviewed. All participants provided written informed consent prior to commencing the interview. Participation was voluntary and no compensation was provided.

The study received Human Research Ethics Committee approval (HREC 18/02/21/4.07) and site-specific governance approval from all participating hospitals. The Standards for Reporting Qualitative Research (SRQR) Checklist was used to guide manuscript preparation.

Patient involvement: A patient was involved in the conduct of this research. A member of the public joined our project steering committee during the early stages of our trial and provided input on study design, outcomes and dissemination opportunities for patients.

2.4. Data collection

Semi-structured interviews were conducted via videoconference. The interviewer was a human factors researcher with expertise in CDS evaluation and qualitative research (MB). The interviewer was independent (i.e. not employed or affiliated) from all study hospitals. Interviews comprised two parts: questions related to 1) recruitment of hospitals into trials of CDS, and 2) evidence-based decision making for selection and implementation of CDS and digital health interventions in general. Findings from the latter component were published previously (13), and the former component is the focus of the current paper. The interview guide for component 1 appears in Appendix 2. Participants were initially asked how and why their hospital decided whether to participate in the controlled trial of DDI alerts, and then to reflect on barriers and facilitators to hospital participation in CDS trials more broadly.

2.5. Data analysis

Interviews were audio-recorded and transcribed. A general inductive content analysis approach was used to identify themes from de-identified transcripts (14). Two researchers experienced in qualitative research and HIT evaluation (XXXX) initially coded three transcripts independently, then came together to compare themes and agree on a coding framework for analysis. The remaining interviews were then independently coded by three researchers (XXXX) 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 (15).

3. Results

In total, 34 potential participants were invited to take part in an interview and 20 participants agreed. This included five from QLD and 15 from NSW hospitals. Participants were Chief Information Officers (n=2), Directors of Pharmacy, Nursing or Clinical Pharmacology (n=7), EMR 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).

All senior hospital staff recognised that a key benefit of a controlled trial was the generation of evidence on DDI alert effectiveness. However, participants identified a number of barriers or challenges associated with participating in the research as a control site. As shown in Table 1, participants also proposed several strategies for addressing these barriers.

Table 1. Barriers to site-level participation as a control site in controlled trials of Clinical Decision Support (CDS) and potential strategies

Barriers	**Strategies to address barriers**
Risk of patient harm - End-users assume CDS alerts are operational - Transient workforce unaware of variability in CDS alerts between sites	Effective communication of trial information - To stakeholders at all levels within an organisation - Clear rationale for the trial

- Ethical and legal ramifications Reputational risk Risk of not demonstrating benefits from EMR Allure of new technology	Highlight value of research participation Explore additional safety measures

CDS=clinical decision support; EMR=electronic medical record

3.1. Barriers to participation as a control site

Risk of patient harm: The most frequently reported barrier was the potential risk to patients as a consequence of having the DDI alerts turned off at control hospitals.

You're at risk of nasty outcomes… there's been some deaths because of interactions…I was involved in a statin-voriconazole death.. an alert would have stopped that…if they read it. (site 2, participant 2)

People explained that this risk to patients was primarily because doctors would assume that CDS alerts were operational, and so would not double check for DDIs. Some participants reported that end-users' awareness of what alerts were operational in their EMR was poor, and this created a false sense of security.

My concern about the system is always that the clinicians always assume that the system will tell them when they're doing something wrong, and that it will inform them if there's a problem. If they see any alert at all, then they know that the system's watching out for them in some way. Their understanding of how much it watches out for them, obviously, is

completely inaccurate. And that's probably the biggest risk that I see of anything in the system, is that false sense of security. (site 1, participant 1)

With a transient workforce, participants were concerned that prescribers relocating from other districts would assume that DDI alerts were operational at control hospitals, as most other hospitals in Australia that used an EMR have DDI alerts.

We have medical staff come from every other LHD [local health district] and work here… So potentially that is a risk that they're thinking something's going to happen, but it's not going to happen in the system. (site 4, participant 1)

Reputational risk: Some participants explained that executive teams had a lower tolerance for risk than frontline staff, and this included tolerance for both patient risk and reputational risk.

People are really cautious, particularly higher ups who don't do clinical work so much and don't use the system so much...they tend to be very cautious around these things…and want every safeguard possible. Because…they don't want their system to be the one that caused harm to a patient. (site 2, participant 4).

Ethical and legal ramifications: Most participants were concerned about the legal and ethical ramifications of participating in the trial as a control site.

I guess it might be perceived as a bit of an ethical issue with… being in control site and not having that intervention. (site 6, participant 2)

Participants referred to CDS alerts as a safety feature or intervention, and most assumed that alerts were effective in reducing patient harms. Interestingly, some participants alluded

to alerts not being liked by end-users and many were aware of prescribers experiencing alert fatigue. Despite this, some senior hospital staff viewed removing DDI alerts as wrong because it constituted removing an effective safety intervention.

What if the media got hold of this if someone was harmed, and they sued the hospital and it came out that we were participating in a trial, and elected not to turn on this safety feature… And we would not, they felt we would not have, I think that we wouldn't have a leg to stand on because we have got the functionality built in, but we didn't turn it on. (site 1, participant 4)

Look, I think one of the things that people look at is that they realize that even though they may not like it, the alert functionality is actually safer…if I turn that off, I've actually created an environment that's actually going to put us back to causing harm… It's a bit like turning all the features off on your car…so I take all the safety features off. I take all the beeps and all the other bits off the cameras. Why would I do that? (site 2, participant 5).

Risk of not demonstrating benefits from EMR: A small number of participants also raised political barriers, explaining that there was significant political pressure to show benefits from EMR and CDS. Participants perceived that acting as a control site in a trial, and not turning on DDI alerts, could result in benefits not being demonstrated from EMR implementation at that particular site.

There was huge political pressure to show benefit… Because of, you know, it's almost a billion dollars of investment that's gone. So I think that's, that'd be number one… they really want to see results for their investment (site 2, participant 3)

Allure of new technology: A frequently raised barrier was the attraction of new technology, with participants explaining that hospitals are often waiting for these "brand new toys" so a decision to delay implementation for the purposes of a controlled trial would not be supported by executive and front-line staff.

Everyone wants the latest tech, part of the allure of digital. (site 2, participant 1)

3.2. Strategies to boost hospital participation

Effective communication: The mostly frequent strategy reported by participants to facilitate hospital recruitment as a control site was effective communication of trial information to the site, particularly to front-line clinicians, as end-users of CDS. Most senior staff who were also clinicians were not consulted as part of their site's decision to participate in the research, and this was viewed as highly problematic.

We needed much more engagement from all our clinicians… And indeed, not only communication, it's actually that they're part of the decision making, to be engaged in such a project, which would mean that demonstrating the potential benefit would be very important. (site 3, participant 3)

I think, ultimately, the executives need to make the decision, but you definitely need input from the end users. Because as we all understand, the executives don't necessarily use the system and know how it impacts their workflow. So you would need advice or guidance from your end users. (site 5, participant 2)

To avoid any misunderstanding, participants suggested that researchers directly communicate with clinicians about the trial, rather than information being delivered to

front-line staff from executive teams. Trial information should include clear background and the rationale for the study, so that all stakeholders understand the current evidence base and why a controlled trial is needed.

I think just kind of that discussion around "look, guys, you know how irritating these [alerts] are, we're not sure they're safe, so this is what we're thinking, and this is how we're going to measure it". (site 3, participant 2)

Once I understood that basically there was equipoise between the two, that it probably didn't really matter which was the control arm and which was the treatment arm. (site 3, participant 5)

Highlight value of participation: Some participants explained that it was advantageous for hospitals to be seen as participating in research, particularly novel or ground-breaking research, so this could be used as an argument to facilitate recruitment.

The chief executive plus the rest of executive were very much driven around that this was a good opportunity to be involved in some, at that point of time, cutting edge research to actually help prove some of the value around what digitalization brings. (site 2, participant 5)

Extra safety measures: Finally, a small number of participants proposed that extra safety measures could be introduced to reduce risks associated with being a control site. With respect to CDS alerts, participants suggested interventions like passive CDS tools (e.g. DDI interaction checkers) and turning DDI alerts on in the background so that DDIs could be monitored by researchers or pharmacists without alerts being visible to prescriber end-users.

4. Discussion

This qualitative study revealed that hospital participation in controlled cluster trials of CDS is hindered by perceptions that adopting an EMR without CDS is risky for both patients and organizations. The allure of technology and the expected improvements in safety following CDS implementation are drivers for adopting an EMR, making it challenging and somewhat counterintuitive for hospitals to implement EMR without incorporating these safety features for the purposes of a research trial. Senior staff recommended clear communication of trial information to all relevant stakeholders as a key strategy for boosting hospital-level participation in trials.

Previous research has shown that the primary reason for hospitals declining to participate in trials is limited resources to carry out the intervention (12), but this did not emerge as a result in our study. However, we uncovered similar concepts to those described in previous studies on individual recruitment into trials but found that these barriers manifested in a unique way for trials of CDS. For example, perceived risk of participation has been identified as a barrier to individual participant recruitment, with individuals less likely to take part in a trial if they perceive exposure to an experimental or untested intervention as too risky (11). Risk emerged as a key theme in our results, however, we observed that the risks to patients, reputation and benefits realization related to the *absence* of the intervention, not the intervention itself, reflecting participants' underlying assumption that CDS alerts improve patient safety. Similarly, barriers related to the intervention in previous research typically relate to sites being unconvinced of the added value of an intervention, over and above unusual care processes (12), however, we observed the reverse for CDS, with the value of CDS viewed as too great to participate in a trial as a control site.

The perception that fewer alerts increase risk to patients, and concerns about the legal ramifications of this, has been identified as a factor contributing to organizations over-alerting users in EMRs (16). This, and our findings highlight the importance of consultation and clear communication between research teams and prospective organisations, particularly regarding the evidence-base and rationale for controlled trials of CDS. Improved communication was the primary strategy proposed to boost hospital recruitment by participants in our study. This also aligns with a key facilitator to individual participant recruitment, as identified in previous research. Clear trial information delivered both face-to-face and in written format, by a trustworthy and knowledgeable individual with good communication skills, has been shown to increase individual participant recruitment into trials (11). Implementation of CDS, like many digital health interventions, is often driven by the potential benefit achieved, rather than actual benefits demonstrated (13, 17-20), and increasing stakeholder awareness of this, and the equipoise that currently exists with respect to CDS effectiveness, may abate any major concerns held by both frontline clinicians and executive teams.

To minimise any risk to patients from the absence of CDS, participants suggested additional monitoring for adverse safety events by pharmacists and systems. Consistent with previous research (21, 22), interviewees identified a risk of over-reliance on alerts by prescribers not being aware of which CDS functionalities are in place in the EMR. This study highlighted that this over-reliance is particularly a problem for controlled trials of CDS if a specific intervention is a frequently used form of CDS, like DDI alerts, or if the user has transferred from a different organization, which is not uncommon. Ensuring end-users are aware of available CDS within an EMR, via good alert design (e.g. visibility of available alerts in an

EMR to end-users) (23) and training, is critical for minimizing inappropriate over-reliance on CDS.

4.1. Limitations

This study describes senior hospital staff's perceptions of barriers to hospital recruitment. Not all participants were actively involved in their organization's decision to participate in our trial of DDI alerts. Complementing interviews with document review (e.g. committee meeting decisions) and consultation with all stakeholders involved in trial participation decisions would strengthen these results and potentially identify other barriers to trial participation. Data were collected from senior staff at six Australian hospitals and findings may not be generalizable to other countries or stakeholders.

5. Conclusions

Barriers to hospital-level recruitment into controlled cluster trials of CDS related primarily to perceptions of risk associated with not implementing CDS as a control site. These perceived risks included reductions in patient safety, reputational risk, and increased likelihood that benefits would not be realized following EMR implementation. To counteract these barriers, consultation and clear communication between research teams and prospective organisations is needed, particularly regarding the evidence-base and rationale for conducting a controlled trial of CDS, and any ethical concerns surrounding trial participation.

DECLARATIONS

Funding

This work is supported by the National Health and Medical Research Council (Partnership Grant XXXX) in partnership with XXXXX.

Conflicts of interests

The authors have no competing interests to declare that are relevant to the content of this article.

Availability of data

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

Ethics approval

The study received Human Research Ethics Committee approval (HREC 18/02/21/4.07) and site-specific governance approval from all participating hospitals.

Consent for publication

Not applicable

Code availability

Not applicable

Author contributions

XXXXX

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Appendix 1. Setting details

Hospital type*	State	Beds (approx.)	Remoteness
Principal referral	NSW	700	Major city
Public acute Group A	NSW	450	Major city
Principal referral	NSW	550	Major city
Public acute Group A	NSW	300	Inner regional
Public acute Group A	NSW	250	Inner regional
Principal referral	QLD	1000	Major city

*Principal referral hospitals provide a very broad range of services, have a range of highly specialised service units and very large patient volumes. Public acute Group A hospitals do not provide the breath of services of a principal referral hospital but include 24-hour emergency, an intensive care unit, coronary care and oncology unit.[33]

Appendix 2. Interview guide

1. How did you hear about our study being run on drug-drug interaction alerts?
2. Do you know how and why your hospital decided to participate in the study? For example, who was consulted, what factors were taken into consideration?

3. What were your initial impressions of the study? Have these changed over time, after learning more about the study? If yes, why?
4. What do you think were the main barriers or challenges to recruiting hospitals into this study? What about trials of digital interventions more broadly?
5. What about facilitators? Can you think of anything that would have facilitated participation of hospitals in this study?
6. Can you describe the main risks and benefits of the research study?

Standards for Reporting Qualitative Research (SRQR) Checklist

Title and abstract	**Page number**
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Integration with prior work, implications, transferability, and contribution(s) to the field	
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BMJ Open

A qualitative study of challenges with recruitment of hospitals into a cluster controlled trial of clinical decision support in Australia

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2023-080610.R1
Article Type:	Original research
Date Submitted by the Author:	06-Feb-2024
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Primary Subject Heading:	Health informatics
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Keywords:	QUALITATIVE RESEARCH, Hospitals, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS

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A qualitative study of challenges with recruitment of hospitals into a cluster controlled trial of clinical decision support in Australia

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Keywords: recruitment, cluster trial, clinical decision support, hospital

Word count: 3346

ABSTRACT

Objective: To identify barriers to hospital participation in controlled cluster trials of CDS, and potential strategies for addressing barriers.

Design: Qualitative descriptive design comprising semi-structured interviews.

Setting: Five hospitals in New South Wales (NSW) and one hospital in Queensland (QLD), Australia.

Participants: Senior hospital staff, including department directors, Chief Information Officers, and those working in Health Informatics teams.

Results: Twenty senior hospital staff took part. Barriers to hospital-level recruitment primarily related to perceptions of risk associated with not implementing CDS as a control site. Perceived risks included reductions in patient safety, reputational risk, and increased likelihood that benefits would not be achieved following electronic medical record (EMR) implementation without DDI alerts in place. Senior staff recommended clear communication of trial information to all relevant stakeholders as a key strategy for boosting hospital-level participation in trials.

Conclusion: Hospital participation in controlled cluster trials of CDS is hindered by perceptions that adopting an EMR without CDS is risky for both patients and organizations. The improvements in safety expected to follow CDS implementation makes it challenging and counterintuitive for hospitals to implement EMR without incorporating CDS alerts for the purposes of a research trial. To counteract these barriers, clear communication regarding the evidence-base and rationale for a controlled trial is needed.

Strengths and limitations of the study

- This was a multi-site study, with data collected across six Australian hospitals.
- Data analysis was completed independently by three researchers who came together to review codes, discuss discrepancies, and reach a consensus on key themes for reporting.
- Although purposive sampling was used, and all participants were senior staff, not all participants were actively involved in their organization's decision to participate in the trial of clinical decision support, so barriers and strategies identified may not be exhaustive.

1. Introduction

Controlled trials, where one cohort is exposed to an intervention and another cohort is not, are viewed as essential for determining effectiveness of an intervention. In trials of hospital-wide digital health interventions, like electronic medical records (EMRs), delivery of the intervention to selected individuals or groups, such as clinicians or patients, risks contamination and is practicably difficult, so intervention delivery is typically at the site or hospital level (1). In controlled cluster trials, individual participants are not recruited or consented but selected hospitals adopt a digital health intervention, while others refrain from or delay implementing the intervention during the data collection period. (2, 3)

Clinical decision support (CDS) alerts are viewed as a key safety feature of EMRs.(4) To date, however, few controlled trials have been undertaken to assess the effectiveness of alerts,(5, 6) and as a result, organizations have limited robust evidence to guide alert selection. For example, drug-drug interaction (DDI) alerts, which trigger at the point of medication order entry to warn prescribers of potentially dangerous drug combinations, are frequently used, (7, 8) yet no controlled trials have examined the effectiveness of DDI alert sets (e.g. 'severe' or 'moderate' DDI alerts) to reduce medication errors and patient harms.(9, 10)

Our non-randomized controlled pre-post trial of DDI alerts in EMRs aimed to fill this evidence gap by comparing rates of DDIs and associated patient harms before and after implementation of an EMR, with (intervention) or without (control) DDI alerts.(11) We attempted to recruit six hospitals into our trial but encountered significant challenges in recruiting control hospitals. Hospitals were receptive to participating in a trial, but were opposed to implementing their EMR system without DDI alerts in place, despite the limited evidence available on DDI alert effectiveness.

Although there is considerable research exploring challenges associated with individual participant recruitment into trials,(12-16) much less is known about barriers and facilitators to site-level recruitment into controlled trials, and no previous research has examined site-level recruitment into trials of CDS. In the few studies that have examined hospital recruitment, most barriers identified relate to challenges associated with intervention delivery. For example, in a study that attempted to recruit nearly 100 hospitals for a pragmatic cluster randomised trial of post-acute stroke services, the primary reason for hospitals declining to participate was insufficient staff or financial resources to deliver the intervention.(17) However, for trials of CDS, like DDI alerts, this factor is unlikely to be a barrier, as intervention delivery typically consists of 'turning on' the CDS functionality in an EMR with some additional clinician training on its use.

In this study, we aimed to identify barriers to site-level participation in controlled cluster trials of CDS, and potential strategies for addressing these barriers. Based on the challenges we encountered in recruiting control sites for our trial, we expected to identify some unique recruitment challenges for trials of CDS. With the rapid acceleration of CDS implementation in hospitals, and digital health interventions more broadly, we hoped our findings would be of value to others attempting to generate a robust evidence-base for these important interventions.

2. Methods

2.1. Design

This study used a qualitative descriptive design.

2.2. Setting

Study sites included five hospitals in New South Wales (NSW) and one hospital in Queensland (QLD), Australia (see Supplementary material, Appendix 1). These sites were initially approached to participate in our trial of DDI alerts.(11) At the time interviews were conducted, two hospitals had no DDI alerts in place, and four had DDI alerts operational in their EMRs. The number of DDI alerts that were available varied between sites.

2.3. Recruitment and participants

Senior hospital staff from the six hospitals were purposively approached to take part in a qualitative interview to explore their views on evaluation of CDS alerts. Interviews formed part of our larger project focussed on determining effectiveness of CDS alerts in EMR systems (11) and were conducted after the commencement of our cluster trial, but before trial completion. The sample included department directors, Chief Information Officers, and those working in Health Informatics teams. A snowball recruitment approach was also used to identify participants, where interviewees recommended additional colleagues to be interviewed. All participants provided written informed consent prior to commencing the interview. Participation was voluntary and no compensation was provided.

The study received Human Research Ethics Committee approval (HREC 18/02/21/4.07) and site-specific governance approval from all participating hospitals. The Standards for Reporting Qualitative Research (SRQR) Checklist(18) was used to guide manuscript preparation.

Patient involvement: A patient was involved in the conduct of this research. A member of the public joined our project steering committee during the early stages of our trial and provided input on study design, outcomes and dissemination opportunities for patients.

2.4. Data collection

As data collection occurred during COVID-19 pandemic restrictions and across multiple states in Australia, semi-structured interviews were conducted via videoconference. The interviewer was a human factors researcher with expertise in CDS evaluation and qualitative research (MB). The interviewer was independent (i.e. not employed or affiliated) from all study hospitals. Interviews comprised two parts: questions related to 1) recruitment of hospitals into trials of CDS, and 2) evidence-based decision making for selection and implementation of CDS and digital health interventions in general. Findings from the latter component were published previously (19), and the former component is the focus of the current paper. The interview guide for component 1 appears in Appendix 2. Participants were initially asked how and why their hospital decided whether to participate in the controlled trial of DDI alerts, and then to reflect on barriers and facilitators to hospital participation in CDS trials more broadly.

2.5. Data analysis

Interviews were audio-recorded and transcribed. A general inductive content analysis approach was used to identify themes from de-identified transcripts (20). Two researchers experienced in qualitative research and HIT evaluation (MB, BV) initially coded three transcripts independently, then came together to compare themes and agree on a coding framework for analysis. The remaining interviews were then independently coded by three researchers (MB, BV and KS) 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 (21).

3. Results

In total, 34 potential participants were invited to take part in an interview and 20 participants agreed. This included five from QLD and 15 from NSW hospitals. Participants were Chief Information Officers (n=2), Directors of Pharmacy, Nursing or Clinical Pharmacology (n=7), EMR 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). Despite the range of expertise of participants, we found no major differences in the views expressed, so results are presented for all stakeholder groups together.

All senior hospital staff recognised that a key benefit of a controlled trial was the generation of evidence on DDI alert effectiveness. However, participants identified a number of barriers or challenges associated with participating in the research as a control site. As shown in Table 1, participants also proposed several strategies for addressing these barriers.

Table 1. Barriers to site-level participation as a control site in controlled trials of Clinical Decision Support (CDS) and potential strategies

Barriers	**Strategies to address barriers**
Risk of patient harm - End-users assume CDS alerts are operational	Effective communication of trial information

- Transient workforce unaware of variability in CDS alerts between sites - Ethical and legal ramifications Reputational risk Risk of not demonstrating benefits from EMR Allure of new technology	- To stakeholders at all levels within an organisation - Clear rationale for the trial Highlight value of research participation Explore additional safety measures

CDS=clinical decision support; EMR=electronic medical record

3.1. Barriers to participation as a control site

Risk of patient harm: The most frequently reported barrier was the potential risk to patients as a consequence of having the DDI alerts turned off at control hospitals.

You're at risk of nasty outcomes… there's been some deaths because of interactions…I was involved in a statin-voriconazole death.. an alert would have stopped that…if they read it. (site 2, participant 2)

People explained that this risk to patients was primarily because doctors would assume that CDS alerts were operational, and so would not double check for DDIs. Some participants reported that end-users' awareness of what alerts were operational in their EMR was poor, and this created a false sense of security.

My concern about the system is always that the clinicians always assume that the system will tell them when they're doing something wrong, and that it will inform them if there's a problem. If they see any alert at all, then they know that the system's watching out for them in some way. Their understanding of how much it watches out for them, obviously, is completely inaccurate. And that's probably the biggest risk that I see of anything in the system, is that false sense of security. (site 1, participant 1)

With a transient workforce, participants were concerned that prescribers relocating from other districts would assume that DDI alerts were operational at control hospitals, as most other hospitals in Australia that used an EMR have DDI alerts.

We have medical staff come from every other LHD [local health district] and work here… So potentially that is a risk that they're thinking something's going to happen, but it's not going to happen in the system. (site 4, participant 1)

Reputational risk: Some participants explained that executive teams had a lower tolerance for risk than frontline staff, and this included tolerance for both patient risk and reputational risk.

People are really cautious, particularly higher ups who don't do clinical work so much and don't use the system so much...they tend to be very cautious around these things…and want every safeguard possible. Because…they don't want their system to be the one that caused harm to a patient. (site 2, participant 4).

Ethical and legal ramifications: Most participants were concerned about the legal and ethical ramifications of participating in the trial as a control site.

I guess it might be perceived as a bit of an ethical issue with… being in control site and not having that intervention. (site 6, participant 2)

Participants referred to CDS alerts as a safety feature or intervention, and most assumed that alerts were effective in reducing patient harms. Interestingly, some participants alluded to alerts not being liked by end-users and many were aware of prescribers experiencing alert fatigue. Despite this, some senior hospital staff viewed removing DDI alerts as wrong because it constituted removing an effective safety intervention.

What if the media got hold of this if someone was harmed, and they sued the hospital and it came out that we were participating in a trial, and elected not to turn on this safety feature… And we would not, they felt we would not have, I think that we wouldn't have a leg to stand on because we have got the functionality built in, but we didn't turn it on. (site 1, participant 4)

Look, I think one of the things that people look at is that they realize that even though they may not like it, the alert functionality is actually safer…if I turn that off, I've actually created an environment that's actually going to put us back to causing harm… It's a bit like turning all the features off on your car…so I take all the safety features off. I take all the beeps and all the other bits off the cameras. Why would I do that? (site 2, participant 5).

Risk of not demonstrating benefits from EMR: A small number of participants also raised political barriers, explaining that there was significant political pressure to show benefits from EMR and CDS. Participants perceived that acting as a control site in a trial, and not turning on DDI alerts, could result in benefits not being demonstrated from EMR implementation at that particular site.

There was huge political pressure to show benefit… Because of, you know, it's almost a billion dollars of investment that's gone. So I think that's, that'd be number one… they really want to see results for their investment (site 2, participant 3)

Allure of new technology: A frequently raised barrier was the attraction of new technology, with participants explaining that hospitals are often waiting for these "brand new toys" so a decision to delay implementation for the purposes of a controlled trial would not be supported by executive and front-line staff.

Everyone wants the latest tech, part of the allure of digital. (site 2, participant 1)

3.2. Strategies to boost hospital participation

Effective communication: The mostly frequent strategy reported by participants to facilitate hospital recruitment as a control site was effective communication of trial information to the site, particularly to front-line clinicians, as end-users of CDS. Most senior staff who were also clinicians were not consulted as part of their site's decision to participate in the research, and this was viewed as highly problematic.

We needed much more engagement from all our clinicians… And indeed, not only communication, it's actually that they're part of the decision making, to be engaged in such a project, which would mean that demonstrating the potential benefit would be very important. (site 3, participant 3)

I think, ultimately, the executives need to make the decision, but you definitely need input from the end users. Because as we all understand, the executives don't necessarily use the

system and know how it impacts their workflow. So you would need advice or guidance from your end users. (site 5, participant 2)

To avoid any misunderstanding, participants suggested that researchers directly communicate with clinicians about the trial, rather than information being delivered to front-line staff from executive teams. Trial information should include clear background and the rationale for the study, so that all stakeholders understand the current evidence base and why a controlled trial is needed.

I think just kind of that discussion around "look, guys, you know how irritating these [alerts] are, we're not sure they're safe, so this is what we're thinking, and this is how we're going to measure it". (site 3, participant 2)

Once I understood that basically there was equipoise between the two, that it probably didn't really matter which was the control arm and which was the treatment arm. (site 3, participant 5)

Highlight value of participation: Some participants explained that it was advantageous for hospitals to be seen as participating in research, particularly novel or ground-breaking research, so this could be used as an argument to facilitate recruitment.

The chief executive plus the rest of executive were very much driven around that this was a good opportunity to be involved in some, at that point of time, cutting edge research to actually help prove some of the value around what digitalization brings. (site 2, participant 5)

Extra safety measures: Finally, a small number of participants proposed that extra safety measures could be introduced to reduce risks associated with being a control site. With respect to CDS alerts, participants suggested interventions like passive CDS tools (e.g. DDI interaction checkers) and turning DDI alerts on in the background so that DDIs could be monitored by researchers or pharmacists without alerts being visible to prescriber end-users.

4. Discussion

This qualitative study revealed that hospital participation in controlled cluster trials of CDS is hindered by perceptions that adopting an EMR without CDS is risky for both patients and organizations. The allure of technology and the expected improvements in safety following CDS implementation are drivers for adopting an EMR, making it challenging and somewhat counterintuitive for hospitals to implement EMR without incorporating these safety features for the purposes of a research trial. Senior staff recommended clear communication of trial information to all relevant stakeholders as a key strategy for boosting hospital-level participation in trials.

Previous research has shown that the primary reason for hospitals declining to participate in trials is limited resources to carry out the intervention (17), but this did not emerge as a result in our study. However, we uncovered similar concepts to those described in previous studies on individual recruitment into trials but found that these barriers manifested in a unique way for trials of CDS. For example, perceived risk of participation has been identified as a barrier to individual participant recruitment, with individuals less likely to take part in a trial if they perceive exposure to an experimental or untested intervention as too risky (16, 22). Risk emerged as a key theme in our results, however, we observed that the risks to

patients, reputation and benefits realization related to the *absence* of the intervention, not the intervention itself, reflecting participants' underlying assumption that CDS alerts improve patient safety. Similarly, barriers related to the intervention in previous research typically relate to sites being unconvinced of the added value of an intervention, over and above usual care processes (17), however, we observed the reverse for CDS, with the value of CDS viewed as too great to participate in a trial as a control site.

The perception that fewer alerts increase risk to patients, and concerns about the legal ramifications of this, has been identified as a factor contributing to organizations over-alerting users in EMRs (23). This, and our findings highlight the importance of consultation and clear communication between research teams and prospective organisations, particularly regarding the evidence-base and rationale for controlled trials of CDS. Improved communication was the primary strategy proposed to boost hospital recruitment by participants in our study. This also aligns with a key facilitator to individual participant recruitment, as identified in previous research. Clear trial information delivered both face-to-face and in written format, by a trustworthy and knowledgeable individual with good communication skills, has been shown to increase individual participant recruitment into trials (16, 22). Implementation of CDS, like many digital health interventions, is often driven by the potential benefit achieved, rather than actual benefits demonstrated (19, 24-27), and increasing stakeholder awareness of this, and the equipoise that currently exists with respect to CDS effectiveness, may abate any major concerns held by both frontline clinicians and executive teams. We recommend engaging with organisations early, and tailoring study information to highlight the potential benefits of trial participation to each user group. Understanding the needs and values of stakeholders is viewed as critical for successful

recruitment into a trial.(28) A recent Delphi study recommended making clear to prospective participants not only the potential benefits and harms of trial participation but how these compare with what would happen if the participant did not take part in the trial.(29)

To minimise any risk to patients from the absence of CDS, participants suggested additional monitoring for adverse safety events by pharmacists and systems. Consistent with previous research (30, 31), interviewees identified a risk of over-reliance on alerts by prescribers not being aware of which CDS functionalities are in place in the EMR. This study highlighted that this over-reliance is particularly a problem for controlled trials of CDS if a specific intervention is a frequently used form of CDS, like DDI alerts, or if the user has transferred from a different organization, which is not uncommon. Ensuring end-users are aware of available CDS within an EMR, via good alert design (e.g. visibility of available alerts in an EMR to end-users) (32) and training, is critical for minimizing inappropriate over-reliance on CDS.

4.1. Limitations

This study describes senior hospital staff's perceptions of barriers to hospital recruitment. Not all participants were actively involved in their organization's decision to participate in our trial of DDI alerts. To preserve anonymity, limited demographic information was collected from participants, however we acknowledge that some characteristics, like age, and career experience, may have impacted the perceptions held and expressed by participants in this study. Complementing interviews with document review (e.g. committee meeting decisions) and consultation with all stakeholders involved in trial participation decisions would strengthen these results and potentially identify other barriers to trial

participation. Data were collected from senior staff at six Australian hospitals and findings may not be generalizable to other countries or stakeholders.

5. Conclusions

Barriers to hospital-level recruitment into controlled cluster trials of CDS related primarily to perceptions of risk associated with not implementing CDS as a control site. These perceived risks included reductions in patient safety, reputational risk, and increased likelihood that benefits would not be realized following EMR implementation. To counteract these barriers, consultation and clear communication between research teams and prospective organisations is needed, particularly regarding the evidence-base and rationale for conducting a controlled trial of CDS, and any ethical concerns surrounding trial participation.

DECLARATIONS

Funding

This work is supported by the National Health and Medical Research Council (Partnership Grant APP1134824) in partnership with eHealth NSW and eHealth QLD.

Conflicts of interests

The authors have no competing interests to declare that are relevant to the content of this article.

Availability of data

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

Ethics approval

The study received Human Research Ethics Committee approval (HREC 18/02/21/4.07) and site-specific governance approval from all participating hospitals.

Consent for publication

Not applicable

Code availability

Not applicable

Author contributions

MB, SH, RD, JW, WYZ, LL and AH designed the study. MB conducted the interviews, MB, BVD, and KS analyzed the interview data, MM, WYZ contributed to interpretation of interview data. All authors contributed to writing of the manuscript and approved the final manuscript.

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Appendix 1. Setting details

Hospital type*	State	Beds (approx.)	Remoteness
Principal referral	NSW	700	Major city
Public acute Group A	NSW	450	Major city
Principal referral	NSW	550	Major city
Public acute Group A	NSW	300	Inner regional
Public acute Group A	NSW	250	Inner regional
Principal referral	QLD	1000	Major city

*Principal referral hospitals provide a very broad range of services, have a range of highly specialised service units and very large patient volumes. Public acute Group A hospitals do not provide the breath of services of a principal referral hospital but include 24-hour emergency, an intensive care unit, coronary care and oncology unit.[33]

Appendix 2. Interview guide

1. How did you hear about our study being run on drug-drug interaction alerts?
2. Do you know how and why your hospital decided to participate in the study? For example, who was consulted, what factors were taken into consideration?

3. What were your initial impressions of the study? Have these changed over time, after learning more about the study? If yes, why?
4. What do you think were the main barriers or challenges to recruiting hospitals into this study? What about trials of digital interventions more broadly?
5. What about facilitators? Can you think of anything that would have facilitated participation of hospitals in this study?
6. Can you describe the main risks and benefits of the research study?

Standards for Reporting Qualitative Research (SRQR) Checklist

Title and abstract	**Page number**
Title	1
Abstract	2
Introduction	5-6
Problem formulation	6
Purpose or research question	6
Methods	
Qualitative approach and research paradigm	6
Researcher characteristics and reflexivity	7-8
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