

Scoping Reports

Report 1: Literature review findings regarding the development and implementation of electronic health record technology in the perioperative care of patients undergoing major surgery?

Project: Developed in the Open: Sustainable digital health-tech enabling transformed patient care

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Table of Contents

Introduction	3
Methodology	4
Findings.....	5
Sources of observation data.....	5
Data quality	6
Implementation.....	8
Reporting	10
Technological infrastructure	10
Acceptance	11
Workflow and workload	11
Alerting.....	13
Open Standards, Open Data, Open Source	14
Research and development issues.....	15
Interface recommendations from existing research	18
Questions to guide further tasks and work packages	20
References	22

Introduction

Many patients still experience sub-optimal care leading to adverse clinical outcomes such as unplanned ICU admission, emergency surgery, cardiac arrest, and death. An estimated 7% of in-hospital deaths are preventable (NCEPOD 2007). There is therefore, a healthcare need consistent with the (NHS Improvement 2016), to:

- Reduce avoidable mortality and morbidity of deteriorating patients
- Improve identification, diagnosis and management of sepsis
- Implement NEWS2

There is also a business need procure digital technology to manage care pathways where:

- Clinicians manage the roadmap, prioritise features, commission and approve product changes
- A competitive supplier market place exists without vendor lock-ins
- Supplier exchange is possible
- Appropriate governance for healthcare technology safety, ownership, sustainability and control

The current NHS approach delivers very low value and high unsustainable costs, plus barriers to iteration and evolution required for utility needed to deliver outcomes and advance clinical progress. There is a business need from the supplier end to engage with the NHS without incumbent lock-in and dysfunction procurement routes making the market inaccessible. Technological challenges exist around interoperability, lack of use of mandated open standards, and no sustainable proven model for continuous improvements of applications used for healthcare needs. There is therefore a market opportunity to deliver step-change improvement in deteriorating patient care that is achievable AND addresses shortcomings of current NHS digital technology procurement via an open standards approach.

The aim of the InnovateUK DITO project is to digitally transform the management of care systems for deteriorating patients, without changing clinical pathways. A novel, open, Electronic Health Record (EHR) system will be developed that enables an open approach to digital innovation to deliver electronic observation and rapid response system technology whilst mitigating perceived implementation risks.

This literature review aims to explore current knowledge regarding EHR digital technologies (including but not limited to eObs, Clinical Decision Support (CDS) Systems, and Rapid Response Systems (RRS)), prior to further explorations and development of the new Open EHR technology solution. The potential scope of the DITO project leads to a very broad research question. Intervention terminology is (still) poorly described and publications are not well indexed in the medical literature. The pace of digital innovation and evolution renders even the more recent reviews as out of date. This review will focus on perioperative care pathways to explore what is known from the existing literature about the clinical benefit of electronic health record technology in the perioperative care of patients undergoing major surgery. The review will therefore aim to:

- Describe benefits of EHRs within the perioperative population (to understand how EHRs may address the healthcare need described)
- Describe features of existing EHRs (to understand what has already been developed and what is already being used)
- Describe methodologies used in the literature for the testing of EHRs, and any benefits and challenges described by the authors (to understand how we can test the new eObs/EHR being developed as part of the DITO project)
- Describe sociotechnical opportunities and challenges of EHRs described in the literature (to understand challenges of integrating the new eObs software into healthcare settings)

There are five generations of Electronic Health Records (Cheungpasitporn and Kashani 2016), and all will be considered in the review to ensure breadth of learning.

Table 1. Summary of EHR generations

First generation (The Collector)

Simple systems that implement a site-specific solution for the need to obtain clinical data, which is imported through scanning or other forms of collection

Second generation (The Documenter)

Basic systems that providers use at the point of care to sufficiently document, rather than solely access, clinical data

Third generation (The Helper)

Systems that episodically incorporate and encounter data, use decision support tools for providers, and are functional in both outpatient and inpatient settings at a minimum

Fourth generation (The Partner)

Advanced systems that implement additional decision support capabilities, are operational and available across the continuum of care, and provide satisfactory credibility for becoming the patient's legal medical record

Fifth generation (The Mentor)

Complex and fully integrated systems that incorporate all previous capabilities and that are a principal source of decision support in guiding patient care for both providers and consumers

Figure 1: Summary of EHR Generations, from Cheungpasitporn and Kashani (2016), p.75

Methodology

A Scoping Review methodology was chosen, as the research question is so broad. Arskey and O'Malley guidelines for conducting a literature were followed, according to the following six steps (Arksey and O'Malley 2005):

1. Identify research question
2. Identify studies
3. Select studies
4. Chart results
5. Collate, summarise, report results
6. Optional consultation

Two research questions guided the review:

1. What is known from the existing literature about the clinical benefit of electronic health record technology in the perioperative care of patients undergoing major surgery?
2. What is known from the existing literature regarding the development and implementation of electronic health record technology in the perioperative care of patients undergoing major surgery?

The following search terms were used:

- EHR (excluding Personal Health Records and Anaesthesia Information Management Systems); clinical noting; clinical decision support; electronic observations; Computerised Physician Order Entry

The "PICO" criteria included:

- **Patient group:** Patients undergoing major surgery (excluding cardiac surgery – an augmented care pathway), or any surgery in children
- **Intervention:** EHR at hospital level, or implementation of a specific EHR function during the perioperative period (excluding ePrescribing only, or a specific focus on Anaesthesia Information Management Systems)
- **Comparisons:** No EHR vs any EHR vs EHR upgrade vs full EHR

- **Outcomes:** as this is a scoping review, all outcomes will be reported to serve as a pointer towards relevant outcomes, both regarding clinical benefit and measurement of successful development and implementation.

This document describes the findings of the second research question: “What is known from the existing literature regarding the development and implementation of electronic health record technology in the perioperative care of patients undergoing major surgery?”. The findings regarding clinical benefit will be reported separately, and is intended for publication in an informatics journal.

Findings

The literature compared the use of EHRs versus traditional, paper-based records. Part of the drive of this project stems from the shortcomings of paper observations which are well documented by previous authors, and include:

- Errors in Early Warning Score calculations (Subbe, Gao and Harrison 2007, Wilson et al. 2013)
- Omission of data (Subbe, Gao and Harrison 2007, Wilson et al. 2013)
- Illegible handwriting (Subbe, Gao and Harrison 2007, Wilson et al. 2013)
- Difficult to share opinion amongst experts (Anton and Anton 2016)
- Time taken to complete manual risk calculations (Aakre et al. 2017)

eObs and EHRs can improve patient outcomes, and are associated with improvements in a variety of outcomes including quality of care, medication errors, test result administration and communication (Nguyen, Bellucci and Nguyen 2014). However, for these patient outcomes to be realised, any EHR software must be successfully implemented. This report describes findings from the literature regarding the opportunities and challenges for successful implementation of EHR technologies within perioperative settings.

Sources of observation data

There are a variety of methods that can be used to input observations into an EHR, beyond the usual method of a user having to manually type in the data, thus only offering a moderate improvement in human error than paper-based methods. For example, data may be inputted via speech, and then sent to a Speech to Text service to translate verbal clinician notes (Anton and Anton 2016). Other modalities include dictation, typing, use of mouse to select items, and handwriting recognition (Kaufman et al. 2016).

Ultimately, offering a range of data entry options may improve usability as clinicians can choose an entry modality that suits their workflow. Integration of Natural Language Processing to dictation options can also provide the opportunity to reduce workflow time for clinicians whilst increasing the quality of the notes collected (Kaufman et al. 2016).

Continuous monitoring technologies are currently being developed, which until recently have been limited to use on critical care wards, however on general wards will take away the need for repeated intermittent measurements of vital signs, which are not only time consuming but are also open to recording errors, calculation errors and interobserver differences (da Costa et al. 2018, Downey et al. 2018, Weenk et al. 2018). Downey et al found that ambulatory post-surgical patients who wore a continuous vital signs monitoring device received antibiotics sooner when showing evidence of sepsis, had a shorter length of stay, and were less likely to be readmitted in thirty days (Downey et al. 2018). The development of continuous monitoring technologies could be supported by Internet of Things infrastructures, allowing interconnected devices to monitor patient health continuously, however currently many devices are locked to the use of particular vendor software/hardware and thus not interoperable (da Costa et al. 2018). This is discussed in more detail below.

There is also the opportunity to combine traditional clinical observations with other sources of data to improve predictive ability, for example, the combination of eObs data with social media data. Ram et al

described emergency department visits for asthma exacerbations can be predicted using Twitter and air quality data (Ram et al, 2016, cited in Leff and Yang 2015). However, such approaches have also been criticised, including the often cited example of Google's 'Flu Trends', which claimed to be able to predict and track flu epidemics over time based on Google searches, however it was later found that prevalence of flu had been overestimated due to data analysis errors (Ghassemi, Celi and Stone 2015).

The collation of eObs allows the use of Big Data to inform improvements to evidence-based guidelines and thus patient care, whilst also providing data regarding costs and spending (Simpao, Ahumada and Rehman 2015), although this Big Data approach should also be combined with the use of visual analytics to make the data easy to understand at the point of care, and to reduce to requirement of clinicians to manually query databases (Simpao, Ahumada and Rehman 2015). The use of Big Data can also support demand planning, for example, in the area of blood transfusions (Pendry 2015). Big Data also has the potential to add to our evidence base regarding treatments. The gold standard of medical research is often considered to be the Randomised Control Trial (RCT), however the cost and time required to run such trials means that in practice, only up to 20% of medical decisions are backed by this 'gold standard' supported evidence, as well as the fact that to control variables in the trial many participants will be excluded (e.g. ethnic minorities, children, etc), therefore we cannot say if the results equally apply to all patients (Smith et al, 2013, cited in Ghassemi, Celi and Stone 2015). Findings using Big Data within single institutions are beginning to evidence effects of treatment on clinical outcomes in varying patient populations, however challenges described within this paper regarding interoperability and standardisation need to be overcome so that such findings from individual contexts can be validated with Big Data from other organisations (Ghassemi, Celi and Stone 2015). The use of patient data, and in particular identification of outlier data regarding unusual treatment decisions can also be used for learning, and thus either detect errors, and/or improve the system over time, for example the identification of processes which might require an interruptive or hard stop alert (Hauskrecht et al. 2013). However, there are challenges to the use of Big Data, and as of 2018, the potential benefits (and cost-effectiveness) have not been fully realised or evidenced – further, healthcare organisations will have to invest in skilled analysts to meaningfully interpret findings and associations within the data (Mehta and Pandit 2018), and to deal with the "volume, velocity, veracity, variability and value" inherent in Big Data (Leff and Yang 2015).

Data quality

Whether or not eObs are more accurate than paper-based observations is unclear. A retrospective study examining accuracy of physical examinations as documented by paper or eObs found that inaccurate documentation was significantly higher in eObs (24% compared to 4.4% paper), although paper notes were more likely to contain omissions (41% compared to 17.6% eObs), and it was suggested that some of the inaccuracies in eObs may result from level of training with the EHR system, use of templates or copied notes, and delays to making the notes leading to lack of recall (Yadav et al. 2017). The design of the eObs interface may also lead to mistakes in the patient observations, for examples, typos, omissions of data, copy and pasted error from another record – although better designed interfaces can reduce these errors, or integration of Clinical Decision support can help to identify potential errors (Bologva et al. 2016). Completeness of vital signs data, key data for management of patient deterioration, may lack completeness, correctness, and if completed manually may not correspond with the correct timestamp (di Martino et al, 2011:, Genes et al, 2013:, Ward et al, 2013, cited in Skyttberg et al. 2016). Skyttberg et al (2016) conducted a qualitative exploration of clinician views of what affects vital sign quality in Sweden (where EHR penetration is 100% in emergency care hospitals). Factors included: lack of standardised triage and repeated measures processes, staff not following standardised procedures, lack of feedback from management, change management issues, knowledge regarding plausibility of vital signs, documentation support, workflow support, and interoperability. Despite 100% penetration of EHRs in Sweden, some of the clinicians spoke of using paper records to calculate warning scores due to lack of completeness of data in the EHR.

There are areas of data quality where eObs and EHRs are reported to be superior. Ghani et al (2014) found that the use of electronic operation notes improved legibility and led to notes closer to Royal College of Surgeons of England (RCS) guidelines for Good Surgical Practice and Cresswell et al (2014) found that the adoption of Clinical Decision Support systems reduced time staff spent deciphering handwriting.

The consequences of poor data quality include poorer patient outcomes (as incorrect information is used to inform treatment decisions), increased workflow issues as users must seek out data from other sources or repeat readings, and malpractice issues (Wilbanks et al. 2018). Views on whether the use of digital systems improves data quality are mixed, a systematic review conducted by Nguyen et al (2014) found that use of electronic health records improved data quality with regards accuracy, access and availability and removed the problem of illegible notes, however the amount of information presented to the user could be overwhelming. How do we then improve data quality and accuracy in the EHR? The list below details for suggestions regarding improving data quality, and the evidence for and against such interventions.

- **Reduce number of patient records a user can open at one time:** one argument is that restricting the number of records open at any one time reduces the likelihood of inputting data into the wrong patients record, however there is no evidence that this practice does reduce errors, and may increase workflow times for clinicians who would be required to constantly log into and out of different patient records, or workarounds to avoid logging in and out (e.g. use of multiple computers) could increase the risk of error further (Adelman et al. 2017). Ultimately, there is a balance to be made between safety and efficiency (Adelman et al. 2017).
- **Using default values to reduce time needed to type and possible typos:** however this can lead to errors in the medical record, as busy staff may not be able to correct them in a timely manner, when face to face care or treatment is the priority (Wilbanks et al. 2018), or users may miss changing the default value as it already looks like it has been completed.
- **Use of templates to structure data entry:** There are no evidence based guidelines regarding optimal templates to structure data entry to ensure data quality (Ellsworth et al, 2016, cited in Wilbanks et al. 2018), and heterogeneity in existing literature means it is difficult to draw conclusions regarding how electronic health records should be structured (Hyppönen et al. 2013).
- **Use of continuous monitoring to reduce need for manual entry:** The use of continuous monitoring is described in more detail above, and can improve data quality due to improved accuracy of the readings, lack of human error, as well as the continuous, not intermittent nature of the readings (Wilbanks et al. 2018), although such equipment is not error free nor one hundred per cent reliable (Venugopalan et al. 2019).
- **Allow users to amend data entries at a later date:** Whether or not incorrect data can be amended at a later date is also an issue, and Hunt et al (2017) reported clinicians signing off charts they knew were not accurate because their EHR system would not let them amend otherwise (Hunt et al. 2017).
- **Make it easier for the user to complete data entry at the point of care:** Completing data entry at the point of care improves documentation accuracy (Wilbanks et al. 2018).

Data completeness is important, and the use of standardised high quality data has potential for re-use in reporting and research contexts, yet too much structure can lead to a system that limits the users “expressivity” (Kuhn et al, 2015, Embi et al, 2013, Cimino, 2013 & Rosenbloom, 2011 cited in Jamieson et al. 2017). However, the use of full narrative, unstructured data also means that the data is less usable for secondary data analysis and research purposes, and can render notes unreadable, or not easy to read (Jamieson et al. 2017, Wilbanks et al. 2018), and can leave medical records lacking detail in some areas, with too much detail in other areas (Jennings et al. 2017). There is a balance therefore to be made between fully structured and unstructured, and indeed Jamieson et al (2017) found that use of a semi-structured electronic documentation system (‘History of Present Illness’ and ‘Impression & Plan’ were fully free text, other sections were structured with options for free text annotation) improved quality of admission notes,

including the content of sections allowing free narrative, and the authors argued that this suggests that imposing structure on notes is not necessarily related to data quality. This could also have a relation to patient outcomes. Stafos et al (2017) found that an electronic risk assessment tool (using fall risk, skin assessment scores, antiemetic and anticoagulant administration, laboratory values, surgical interventions, restraints, need for intubation) did not improve identification of patients at risk of harm over face to face safety huddles combined with noting patients at risk on a whiteboard (in a surgical unit, a progressive care unit and an orthopaedic unit). The authors suggested that nurses would have knowledge of psychosocial and behavioural aspects of the patients not available to the electronic health record which would allow them to make informed decisions regarding which patients to mark as high risk – again, supporting the notion that too much structure may miss information vital to the patient’s care.

The importance of narrative

Authors have argued that the data required from electronic health records is focused on organisational priorities, and the voice of the clinician, and thus the patient and their narrative has been lost since the introduction of digital records – patients are reduced to their observations alone (Hunt et al. 2017). Overly structured interfaces miss key narrative information which can be “scribbled... into the margins” of paper notes (Hunt et al. 2017).

*“It is well documented that ‘the practice of medicine is built upon and conducted through narratives: telling stories, editing, translating, and manipulating stories’ (Waymack, 2009, p.18). When a patient presents with a complaint, the physician will listen to the patient’s story, ...conduct a physical examination, and in doing so transform the patient’s initial story into a **medical** narrative emphasising possible diagnosis and action (Berg, 1992; Davenport, 2011) ...the lab data never speak for themselves. Those various data are delivered framed by some sort of narrative about this patient, however truncated, however impersonalised a form it might take. (Waymack, 2009, p.220)”*
(Bansler et al. 2016 p.507-508).

Further, Brown et al (2014) found that clinicians spend more time looking at narrative “Impression and Plan” sections of electronic notes, and less time on laboratory results and medication profiles. Nurses have also reported finding it difficult to find free text team notes, which they found limited communication within the team (Kossmann, Bonney and Kim 2013). This lack of free text to build a narrative, in favour of standardised check boxes may also constrain critical thinking (Kossmann, Bonney and Kim 2013). There is clearly then a balance to find between “information chaos” (Beasley et al, 2011 cited in Bansler et al. 2016) and full lockdown and standardisation of data (Bansler et al. 2016, Cillessen, Felix H. J. M., de Vries Robbé and Biermans 2017). Clinicians also report that use of the EHR can disrupt the normal rhythm of conversation they might have with a patient, and instead the interaction is reduced to a tick box exercise – “Patients would commonly stare in silence at the floor or clock as the clinician typed away...” (Hunt et al. 2017 p.415).

Providing standardised blocks of narrative may seem a solution to the balance between providing unstructured narrative and standardisation of data, however users may not have time to make manual adjustments at the time of data entry, as their priority is the face to face care and treatment of the patient (Wilbanks et al. 2018).

Implementation

Varghese et al (2017) argue that the successful implementation of Clinical Decision Support Systems can be improved by consideration of two sociotechnical characteristics : 1) usage of existing disease related knowledge bases (for example, well-known evidence-based patient risk variables, incorporated into algorithms) and 2) integration with all relevant hospital stakeholders – including local clinicians, quality management staff, and IT staff. Before full-scale roll out, all necessary staff should be educated and trained in the use of the system.

Some eObs and EHR systems are developed locally, and these have the advantages of being heavily customised to the local setting, however they require high levels of local support. This high level of support and cost may be mitigated by outsourcing such systems, however there may be difficulties in implementing software from outside vendors, or there may be interoperability issues with remaining home grown software packages (Cresswell et al. 2014). Demoed versions of software may be different to what is actually implemented, with customers having to purchase additional functionalities they did not realise do not come as standard and clinicians have raised concerns that procurement teams may be cost-sensitive during implementation, and may not opt to purchase all features at the outset (R. Ratwani et al. 2016). Further, moving from a specialised locally developed system, to a commercial, proprietary system may cause decreases in satisfaction in areas such as having more time for patients, coordination of care and monitoring patients, possibly because new software is less suited to the particular setting in question, or because of technical and usability issues – added value of larger, more commercial software settings maybe therefore not be immediately apparent in the initial implementation phase (Krousel-Wood et al. 2018).

Although switching to a new EHR system can very disrupting, Colicchio et al (2018) identified patterns of disruption across four hospital sites post-EHR implementation. For example, increased length of stay and wait time until treatment was observed across emergency departments in the immediate aftermath of technology implementation, suggesting the need for hospitals to consider providing extra support to emergency departments when rolling out a new EHR system. There were mixed and inconsistent patterns of disruption across other areas of the hospital (for example, CDifficile infections decreased in two hospitals following implementation, however increased in one), suggesting that there are many context-driven confounding variables that will affect successful technology implementation.

How technology threatens the role of clinicians can also have an impact on the success of any implementation. As well as challenges to the accuracy of findings, there are challenges to the use of EHR systems and their associated CDS system and add-ons. For example, clinicians may feel that implementation of information technology threatens their role in the healthcare system, there may be usability issues with the technology, concerns about cost-benefit ratios, and return on investment all leading to a lack of user acceptance (K. Kashani 2016, Nguyen, Bellucci and Nguyen 2014).

There also the concern that adoption of technologies will reduce face to face time with patients, for example Hunt et al (2017) found that clinicians could spend several minutes interacting with the computer screen rather than the patient to ensure the right items were selected from various drop-down boxes, however (Schenk et al. 2018) found that nurses spent significantly more time in patient rooms following implementation of EHR, although they also found a slight decrease in time spent explaining care plans and medications to patients. The authors postulated that this may be due to the challenge of EHR introduction, and called for further studies into this effect.

Related to successful implementation, is training. Vendors often produce training for their products, often training in-setting employees to a level where they can train other employees after initial implementation. There is a tension between clinician users of software and the vendor providers, with users sometimes critical regarding the quality of training, and vendors displeased that organisations are reluctant to invest money in training (Ash et al. 2015). Good quality training is related to improvements in staff proficiency when using the system, and if training is perceived to be inadequate then this will impact upon whether users will realise the full potential of the software (Nguyen, Bellucci and Nguyen 2014). Ongoing IT support also supports successful implementation (Alsohime et al. 2019). Jalota et al (2015) found that providing education to physicians improved their performance with an EHR system compared to just receiving 12 hours of EHR classroom training followed by access to e-learning modules and a test site, as measured by time take to complete a progress note in the new system. The education provided consisted of information

regarding best techniques observed in other physicians, and received teaching sessions led by fellow physicians.

Reporting

EHRs have the potential to answer questions regarding patterns in healthcare costs over time, impacts of policy changes on costs, clinical outcomes and clinician behaviour, geographical patterns, organisational patterns, and detection of potential epidemics (Mehta and Pandit 2018). eObs systems also provide audit trails for the organisation and can provide data to be used for quality improvement activities, or identification, reporting and trend analysis of patient safety events (Bodagh et al. 2018, Cresswell et al. 2014, Gallego et al. 2015). eObs and results from the consultation process can be printed “there and then” and given to patients as a record of their consultation, or sent quickly to primary care physicians, rather than the consultant having to write a letter outside of the patients appointment, thus saving time (Bodagh et al. 2018). Some commercial vendors require payment for customised data reports, or may hold their data in a proprietary format leaving the user unable to export data into a different software package. Conversely, vendors may offer data analytics modules or services for free, but they may be seen as non-essential reports to clinicians, and therefore this service may remain underused (Ash et al. 2015).

Technological infrastructure

Unplanned downtime of technologies has the potential to seriously adversely affect patient outcomes, particularly where systems are fully implemented and clinicians are reliant upon the technology (Larsen et al. 2018). Downtime incidents from Wi-Fi outages, system crashes, computer errors or the need to reboot a machine (Nguyen, Bellucci and Nguyen 2014) may cause delays with test orders, medication administration, care, patient transfer, imaging appointments, medication errors, inability to register patients or complete documentation, and inability to view a patient’s history (Larsen et al. 2018). The causes of technology downtime are varied, and malfunctions can be caused by: build errors, clinical conceptualisation and algorithm development errors, coding errors during updates, source code errors, migration errors (test software to production software), changes to allowable values or lack of, external software issues, inappropriate manual enabling or disabling of rules (Wright et al. 2017). How and where the malfunction are detected may also have an impact on patient safety, especially if the error is not immediately spotted at point of patient care. Errors may be detected and reported by end users, during review of alert firing, during review of manual override reasons, during routine testing or development, reviewing input data at a later stage, whilst demonstrating the system, or whilst investigating other similar errors (Wright et al. 2017). Guidance and frameworks should therefore be provided with regards how organisations can identify and respond to malfunctions which may impact patient safety in a timely manner (Meeks et al. 2014). Menon et al (2017) demonstrated that daily safety huddles consisting of clinical, IT, and administrative representatives could be a useful strategy to identify EHR errors and concerns.

Local technology infrastructure issues may also affect the success of implementation, if users of any new system are confronted with problems regarding finding computers to use, or mobile devices with sufficient battery life (Alsohime et al. 2019). Mobile devices may be convenient for staff but may get misplaced (Nguyen, Bellucci and Nguyen 2014) Poor Wi-Fi or internet access, or computers not fit for purpose may also cause frustration and lead to increases in workload from waiting for screens to load (Alsohime et al. 2019, Cresswell et al. 2014).

With regards technological support, some vendors embed at least one employee per organisation to provide support for their software, however their utility may be questioned as hospital staff may feel that their loyalties will side with the vendor company and not of the needs of the particular hospital setting. There may be feelings of misunderstanding between vendor stakeholders and clinical stakeholders. Clinicians may also be concerned that the vendor employees do not understand enough about clinical and patient needs to be of optimum use, although vendor employees with a clinical background are more valued (Ash et al. 2015).

Acceptance

Where aspects of an EHR system replicate that of existing technologies (e.g. pagers, emails), this functionality may not be as widely used, for example, Dalal et al (2017) found staff were less likely to use a new microblogging site which synchronised with their patients' EHRs if they were unfamiliar with the new site, and already had access to existing communication technologies. Further, Skyttberg et al (2016) found that despite 100% penetration of EHR in Sweden, clinicians reported still relying on paper based charts when calculating warning scores as they found vital signs recorded in their EHR systems incomplete or unreliable. Even if the EHR is complete and correct, there may be difficulties in connecting the Obs data with CDS systems, where data entry is not standardised (Skyttberg et al. 2016). The portability of electronic systems, compared to existing paper based methods, may also be a barrier to use, and clinicians may view paper observations and documents as more lightweight and portable, with clinicians using paper based charts or even scraps of paper to write down observations to enter into the system at a later date – and where paper based observations are converted to electronic observations at a later time, error may be introduced, and clinician workload is increased (Skyttberg et al. 2016)

Smooth integration with existing systems is likely to improve uptake, for example by using single log-in infrastructures (Dalal et al. 2017). Where CDS systems are integrated to utilise eObs to support clinical decision making, there is the question over whether the CDS systems can be directly incorporated into the existing eObs system, or whether it is a standalone product which requires staff to export observations into the CDS system (Kopanitsa 2017). The latter may have implications for acceptance, as the export of clinical data may increase workload and time to treatment for the patient. Indeed, the majority of reasons for clinicians not accepting CDSS recommendations are often pragmatic in nature, such as time, or organisational and logistical barriers (Jeffery 2015). Even if different systems can interoperate with each other, the use of differing keywords and nomenclature between systems may cause frustration and delays in workflow (Skyttberg et al. 2016).

Although findings regarding concerns about privacy and confidentiality were not found in the papers describing EHR use in the perioperative setting, a systematic review of EHR use in wider healthcare settings did show that some users held such concerns (Nguyen, Bellucci and Nguyen 2014). This should be explored further before implementation of a system, not only to ensure acceptance within an organisation, but also adherence to data protection laws.

Workflow and workload

Findings regarding whether the introduction of digital systems improves workload and workflow for clinical tasks are mixed, although results in the literature show that there are positive improvements in efficiency for administrative tasks (Nguyen, Bellucci and Nguyen 2014). Wong et al (2017) found that introduction of the SEND eObs system was associated with a statistically significant reduction in time taken to measure and document vital signs that fed into an automatic calculations of an Early Warning Score, and was also associated with a decrease in variability in time take to record observations amongst nurses. Such systems may also reduce time taken to prescribe, due to the use of automated order sets (simultaneous ordering of all necessary medications for a particular diagnosis) and remote ordering (Cresswell et al. 2014). As well as improving workflow, EHRs can reduce the need for unnecessary testing, for example, Deleger et al reported how a CDS system which analysed EHR records (laboratory results and free text analysed by Natural Language Processing) to risk stratify patients with abdominal pain had the potential to accurately classify risk in paediatric patients, and potentially reduce the number of diagnostic imaging orders.

Where workload or workflow is increased by the EHR, or perceived to be increased, this can be a major barrier to successful implementation (Nguyen, Bellucci and Nguyen 2014). Some studies have found that physicians take longer to complete EHRs compared to paper records (Perry et al. 2014), therefore work should be conducted when developing an eObs system to ensure that only necessary data is collected (or

clinicians have options over whether or not they enter particular variables -although this can also have impacts on data completeness for Big Data purposes, and the usability of the interface is optimal (see “Interface Recommendations below for further details). Workload can also be increased indirectly by aspects of the software design or technology infrastructure such as security requirements, security measures required with such systems that hold large amounts of patient data may increase workload for users who are constantly required to log out and in again (Adelman et al. 2017, Cresswell et al. 2014). Poor usability arising from searching for information or through menus, or from the action of scrolling or switching between screens (display fragmentation) may also increase workload (Cresswell et al. 2014, Roman et al. 2017). Workflow frustrations may occur when users are not able to amend entries and orders at a later point in time, and so to improve usability, and indeed safety, the system should offer flexibility, and enable users to undo actions or modify orders, prescriptions or data entries where needed (K. Miller et al. 2018) There also exists the “data-rich, knowledge-poor oxymoron” (Tsoukalas, Albertson and Tagkopoulos 2015), and this increase in information available to the user may also increase workload (Cresswell et al. 2014), without necessarily improving patient outcomes. The plethora of graphs and data on offer for physicians to look at may be ignored by those in a hurry, thus missing vital information (Cresswell et al. 2014). It is vital to consider the, what data is needed, and what is superfluous.

Where digital tools increase workload, users may develop workarounds in order to complete their tasks, for example, e.g. users taking notes to upload onto a computer at a later date, or users sharing the same log in to avoid having to spend time constantly logging in and out of one machine (Adelman et al. 2017, Cresswell et al. 2014, Kossman, Bonney and Kim 2013). These workarounds have the potential to compromise patient safety, e.g. if written notes are not entered into a CDS in a timely manner (Cresswell et al. 2014, Kossman, Bonney and Kim 2013). Ultimately, there is a balance to be made between safety and efficiency (Adelman et al. 2017). When rationalising the reasons for workarounds, users give a variety of reasons including:

- Not knowing how to complete a task (from lack of training) (Blijleven et al. 2017)
- Knowing but not feeling proficient enough to complete a task (unable to retrieve training) (Blijleven et al. 2017)
- Poor usability (Blijleven et al. 2017)
- Adding information in the wrong boxes as the “right” box does not exist (Blijleven et al. 2017)
- Technical issues (e.g. software crash, hardware failure) (Blijleven et al. 2017)
- Unable to enter data into EHR (e.g. unable to enter 3.75mg of a drug, rather than 2.5mg – clinician therefore selects 2.5mg and enters a free text note stating the dosage should be 3.75mg) (Blijleven et al. 2017)
- Workaround is a more efficient route to completing task (e.g. writing down observations whilst with the patient, to upload into EHR later) (Blijleven et al. 2017)
- Have seen colleagues complete workaround (social norms) (Blijleven et al. 2017)
- Entering “dummy” data as not able to progress with task until something is entered (e.g. because neither the clinician nor the patient know the answer) (Blijleven et al. 2017)
- Valuing patient over computer interaction (Blijleven et al. 2017)
- Using non-hospital wi-fi networks due to wi-fi access issues (Lee et al. 2017)

Although workarounds can increase efficiency for one team, they can have unintended consequences for other teams, or further down the workflow line. For example, Blijleven et al (2017) reported how a workaround for one team, who were unable to add free text notes to their patient EHRs, impacted another team in the hospital:

“...physicians were unable to add additional free text alongside each patient entry in the top-level overview. Physicians argued this hampered them in efficiently searching through their patient lists, as they had to look into each patient entry one by one. A

physician heard from a colleague that the neonatology group managed to add free text to each patient entry by looking into the property menu of each patient entry and selecting “NICU Note” – a functionality developed by the ...vendor as requested by the neonatology group. Free text could then be entered into a field that would be shown alongside each patient in a top-level overview. The physician managed to find this hidden functionality and shared her knowledge of this workaround with her colleagues working outside of the neonatology department. These colleagues in turn rapidly copied this workaround behaviour, much to the annoyance of the neonatology staff, who consider this abusive use of their data field polluting their own patient records.” (from Blijleven et al. 2017)

Whilst standardisation is important, some level of flexibility and customisation should also be incorporated where possible to allow settings to modify the software to suit their local workflows (Ash et al. 2015), or provide the opportunity for “workarounds”, for example clinicians using “other” or free text entry boxes to expand upon data entered, or prescription information inputted where standardised menus limit options (Slight et al. 2016), however such workarounds need to be monitored to ensure they are not affecting patient safety, or are indicators that customisation of the software needs to be carried out.

Alerting

The design of system and clinical alerts can have an impact on the EHR system – poor sensitivity and specificity of alerts will reduce performance and satisfaction (Manaktala and Claypool 2017). Despite advantages of various types of alerts (immediate notification, compliance recording, adverse event identification, alerts regarding clinician to patient trial participation eligibility (Benthin et al. 2016)) over asynchronous unautomated alert modalities, e.g. a telephone call (Slovis et al. 2017), alerts may be seen as repetitive, redundant or a distraction when a user is speaking with a patient (A. Miller et al. 2015). Clinicians can receive up to 77 alerts per day, and up to two hours of related desk-based work per patient following the implementation of health information technology (Murphy et al 2016 and Sinkys et al, 2016 cited in Richardson et al. 2019).

Algorithms used in CDS systems may lack maturity, and not enable users to include all the information they would like into a clinical decision (A. Miller et al. 2015), or may not be able to deal with slightly more complex patient situations, for example a system that cannot recognise that asthma patients may be prescribed more than one inhaler appropriately and thus displays unsuitable alerts (Russ et al, 2009, cited in A. Miller et al. 2015). Too many of these unsuitable alerts will impact satisfaction with the system, and potentially patient outcomes. Appropriate timeliness of alerts needs to be carefully considered – too far in advance may be confused with a false positive and thus ignored, and too late could lead to untimely clinical responses. Too many alerts that are not clinically useful can lead to alert fatigue, and missed warnings can lead to poor patient outcomes, including increased mortality (Scully and Daluwatte 2017).

How do we improve the acceptability of alerts? Bates et al found that by prioritising high risk alerts, or changing the “interruptability” of low risk alerts can reduce the risk of alert fatigue, and the likelihood of overriding or ignoring higher risk alerts (Bates et al, 2003, cited in Finkel and Galvin 2017), this could be achieved for example by having alerts appear “in-line” on the screen, therefore being present and visible but not interrupting the clinician’s workflow (Roman et al. 2017) and users may be given the opportunity to override an alert (and indeed in some cases this may be appropriate) (Finkel and Galvin 2017), however the question that remains is, in what cases is it appropriate to override an alert, and does this change between settings? Whilst in the majority of cases, overrides are appropriate, Wong et al (2018) reported that where they are inappropriate, they can increase the risk of adverse drug events by six times.

Some vendors may include a “hard stop” option which does not allow a user to override the alert (user cannot proceed further, or needs further authorisation to proceed further). The inclusion of a hard stop in certain settings may improve patient outcomes, for example reduction in Deep Vein Thrombosis rates in trauma following a hard-stop risk assessment tool and suggestions for appropriate prophylaxis (Haut et al,

2012, cited in Powers et al. 2018). However, unintended consequences may arise from the use of hard stops, for example, a Computerised Physician Order Entry (CPOE) system with a “hard stop” alert to avoid drug interactions. Nanji et al (2018) found that 40% of hard stop alert overrides were not appropriate and could have implications for patient safety. Strom et al conducted a randomised control trial of a hard-stop drug-interaction alert for warfarin and trimethoprim/sulfamethoxazole where the hard stop could only be overridden by calling a pharmacist directly – however the RCT was halted due to delays in treatment, suggesting that sometimes physicians may need to override an alert for the safety of individual patients (Finkel and Galvin 2017). Reasons for wanting to override an alert may include: clinician deems low risk of allergic reaction, clinician would prefer to monitor for drug interactions, suggested dosage needs to be amended, an alerted duplicate drug is not actually a duplicate (Nanji et al. 2018), for example in the previously described case of asthma drugs (Russ et al, 2009, cited in A. Miller et al. 2015). Not providing an override to stop screens also has implications for auditing. Without an override option, for many actions there may be no way to ensure that the physician actually followed up on such alert (Finkel and Galvin 2017), and may just state so as a way of overriding the alert. Not only does this have implications for safety, but also does not collect accurate data on alert overrides which may be useful when reviewing the utility and risk profile of particular alerts. Where hard stops are deemed necessary to ensure patient safety, then they should be accompanied with the option for the clinician to view information supporting the hard override (e.g. reasons, research evidence, clinical guidance and advice on next steps – (K. Miller et al. 2018) a free text box allowing the user to enter their reason for override should be provided – not only does this enable the justification of the override for communication and audit purposes, but it also allows the identification of hard stop alerts that may not be fit for purpose (Aaron et al. 2019). Ultimately, developers must learn from working with clinicians and other stakeholders, and through the use of system data to improve alerts and dedicated committees, reduce the number of inappropriate alerts delivered (Slovits et al. 2017, A. Wong et al. 2018).

Open Standards, Open Data, Open Source

It is a source of frustration that commercial EHR vendors have made little progress regarding interoperability and use of standardised protocols (Ash et al. 2015). Lack of standardisation and time taken to convert data to fit with the requirements of a new vendor’s software is one of the reasons that some organisations feel locked-in with particular suppliers, however it is this very lack of interoperability that leads to repeat businesses for the EHR vendors (Ash et al. 2015). Concern about interoperability with existing software and hardware is a concern (Nguyen, Bellucci and Nguyen 2014).

Open Standards will hopefully allow the interoperability of EHR and eObs systems with apps that can provide additional functionality required by particular settings, and integration with patient health records on their own Smartphones. As newly developed smart devices that support a Health Internet of Things become more available, the issue of interoperability will become more pertinent (da Costa et al. 2018) as organisations will want to acquire devices that can ‘plug and play’ with their chosen EHR software – however currently many devices are proprietary technologies. Indeed, Ash et al (2015) explored clinician perspectives of CDS systems, and found that there was an appetite to share systems and algorithms developed, however currently in practice this was difficult and often led to duplicated effort: *“Some things are hard to share. So you just get like a bunch of screen prints... Somebody has to actually go and program that or configure, and it may be a six month effort”* (Ash et al. 2015 p.6)

Whether or not an eObs system records data in a standardised manner such as OpenEHR (Atalag et al, 2011, cited in Kopanitsa 2017) is also key, as standardised meta-data will improve ease with which the product can integrate with other products and services, although the use of OpenEHR standards in existing CDS systems is not widespread (Marcos et al, 2013, cited in Kopanitsa 2017). The interoperability of software and standardisation of data entry and concepts will support the sharing of Big Data for use in health care (M. K. Ross et al. 2014). Open data methodologies such as crowdsourcing data and holding hackathons could enable the bringing together of large datasets and multiple stakeholders, including

clinicians and data scientists – all of whom have been excluded by traditional methodologies of evidence gathering, such as the randomised control trial, and publication of results in peer reviewed journals (Ghassemi, Celi and Stone 2015). However, for the merging of large datasets, there is also the consideration of interoperability of clinical language between systems, otherwise known as semantic interoperability (Legaz-García et al. 2016), not only does this allow for users to more easily to switch between systems and import data (arguably, this is something that proprietary vendors do not want to make easy), but it also allows for the secondary use of data, such as research purposes (Legaz-García et al. 2016). However, attempts to fully standardise language in the electronic medical record have met some resistance, as it has been argued that this does not allow clinicians to detail nuance and detail in a patient case, and does not allow for the building of a narrative. The importance of being able to build a narrative, despite concerns of standardisation, is discussed in more detail above (See “The Importance of Narrative”).

“As large amounts of shared data become available from different geographical and academic sources, there will be additional benefit from the collection of data from sources with different viewpoints and biases. While individual researchers may not be aware of their own biases or assumptions that may impact imported results, shared exploration of Big Data provides us with an inherent sanity check that has been sorely lacking in many fields.” (from Ghassemi, Celi and Stone 2015)

There are perceived challenges with the Open approach. There may be a question over liability, where knowledge regarding eObs and associated clinical decision support is shared. Dixon et al suggested that as well as CDS developers validating eObs inputs with CDS outputs, liability frameworks stipulate that CDS systems are not a replacement for clinical judgement (Dixon et al. 2013). The safety of Open Source software may also be a concern where organisations need to customise or adapt software. It is currently unclear who would be responsible for this, and whether they would have awareness of downstream effects of adding customised modules to the Open Source software, and any resulting patient risks (Finkel and Galvin 2017).

Research and development issues

It is difficult to ascertain evidence regarding the effectiveness of technological interventions including eObs and associated clinical decision support symptoms. The evidence base is difficult to integrate due to heterogeneity of methodologies and variations in study quality, and many studies only test technology in a single-site setting (Varghese et al. 2017). Often lack of information regarding algorithms or observations, or where there is information it is not detailed enough, or standardised to enable comparison with other interventions means that we are unable to examine why an electronic tool may or may not have worked (Colicchio et al. 2016). Due to eObs and CDS technologies existing within a sociotechnical system, there are many confounding variables present that may affect the successful implementation of such technologies, such as exposure to numerous clinicians (Jeffery 2015, Thompson et al. 2015, Varghese et al. 2017). Although Randomised Control Trials are often considered the gold standard of evidence, pragmatically it is difficult to test eObs and associated technologies using this methodology. Firstly, it is impossible to blind clinicians and patients to the presence or not of technology, and secondly ethical issues arise regarding blinding clinicians to probabilities of adverse events (as per information provided by CDS systems and alerts), therefore other methodologies for example, prospective before and after technology implementation studies may be more appropriate (Jeffery 2015).

Often there is little evidence of usability and efficacy testing ahead of deployment in real-life settings, in particular with the full range of staff who will ultimately be using these technologies on the front-line (R. M. Ratwani, Hettinger and Fairbanks 2017), yet studies of clinician and organisational views on EHR technology often cite the importance of user involvement in the development of EHRs (Nguyen, Bellucci and Nguyen 2014). There are usability requirements in the United States, however research has suggested that these requirements are not always adhered to (R. M. Ratwani, Hettinger and Fairbanks 2017). Whilst

the market could encourage the influence of usability on purchasing decisions, traditionally it has not as usability mostly affects clinicians who are not on the frontline of purchasing and not always involved fully in product development. Recommended (but not standardised) testing scenarios have been developed for EHRs, however these are not always used by vendors. The use of recommended scenarios and associated statistics would allow for more meaningful usability comparisons across different EHR products (R. M. Ratwani, Hettinger and Fairbanks 2017). Further, Roman et al have argued that GUI navigation of EHR software has not received sufficient attention (or is attended too but consistent language is not used to described navigation concepts, thus making comparisons difficult), yet as described above, has an influence on usability (Roman et al. 2017). Sousa et al (2015) argued that standardised methodologies for exploring acceptance of EHR technologies with nurses was required. There is little guidance regarding conducting usability and acceptability studies of EHR technologies (Ellsworth et al. 2017). Typically, where usability studies are conducted, it is late in the design and development life cycle, at a point where it is more difficult or costly to implement changes (Ellsworth et al. 2017). Within the proprietary vendors, less than half perform industry standard usability evaluations, and often these are not conducted by usability experts, and questionnaires and surveys are heavily relied upon. Where more detailed usability methods are employed, such as heuristic evaluation, little methodological detail is provided, including study-specific heuristics used, and the participants/stakeholders employed in the testing (Ellsworth et al. 2017).

Even if usability studies are conducted, it is difficult to compare the usability of particular software systems when compared at different sites – as each site will customise the software to their own requirements, thus it is not comparing like for like (R. M. Ratwani, Hettinger and Fairbanks 2017). Some advice was found regarding usability studies in Khajouei et al's 2017 paper. They found that when conducting a usability study of an EHR system, 3 to 5 participants are considered sufficient for methodologies such as Heuristic Evaluation (HE) and Cognitive Walkthrough (CW) (Nielsen 1992, cited in Khajouei, Zahiri Esfahani and Jahani 2017). Khajouei et al (2017) found that despite some authors arguing that HE is more likely to identify usability issues than CW (as there is more task guidance than CW, which is scenario led), there was no statistically significant difference between number of usability issues identified by either. However, they also noted that there were some differences, with CW being more likely to identify learnability issues, and HE being more likely to identify user dissatisfaction. CW therefore may be more suitable for studies looking to explore usability issues with novel users of a system.

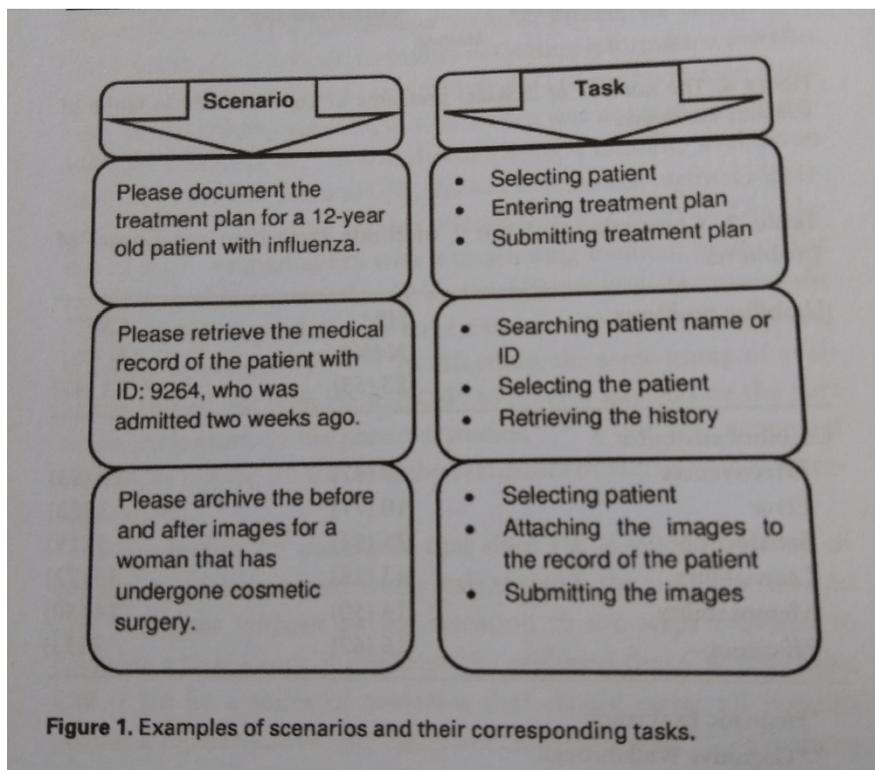


Figure 2: Examples of scenarios/tasks for CW and HE usability processes from (Khajouei, Zahiri Esfahani and Jahani, 2017)

Higher level requirements can be gathered from user stories, for example, clinicians explain what they want to do, why, and what this will achieve, followed by elaboration of tasks to determine what steps are needed to realise this requirement (Basit et al. 2018).

“As an emergency room nurse, I want to be alerted before I administer an oral medication to a patient with known or suspected stroke if they’ve not yet had their Swallow Screen performed, so that my patient can receive their medications by the most safe and effective route” from Basit et al (2018)

Whether or not the right stakeholders are involved in product development and testing is an also issue. There may be differences between the identified team, and the actual team that use the software in a real life setting, meaning that key voices and lessons may be missed (Kricke et al. 2017). There is also a chicken and egg scenario here – although it is vital that all key stakeholders are involved in development to ensure successful implementation, the resulting software, if used correctly can also be used to identify who the actual users are for further development, and can provide data regarding what “actually” happens in a clinical situation to compare with team-written process maps (Kricke et al. 2017).

Simulation facilities, originally intended for training use, can be easily adapted to test eObs and EHR software in a setting with higher levels of ecological validity, in particular with regards to workflow analysis and usability testing (Landman et al. 2014). Sousa et al (2015) reported utilising a “life-sized simulated nursing station, including sights and sounds typical for a busy hospital unit, and a computer containing the functional EHR prototypes into which the participants could enter decisions” (Sousa et al. 2015 p.468), and argued that the use of simulation should be used before CDS systems are deployed in practice. When developing technologies with clinicians in a participatory research setting, scenarios including patients at risk of rapid deterioration lend themselves more easily to research and testing as this minimises the potential for confounding variables to affect the clinicians’ performance when using the technology, or their perception of the technology (Jeffery et al. 2017).

Interface recommendations from existing research

- The language of aspects of the software needs to be taken into account and tested with the various users who will interact with the product. Alerts developed with pharmacists may not be language appropriate for physicians and vice versa, or scales that are not routinely used in clinical practice may cause confusion (A. Miller et al. 2015)
- The choice of how to present risk in alerts may also be confusing, and for example providing statistical probabilities may not be a quick way of communicating risk to the physician, and a traffic light system or use of easy to understand categories (low, med, high risk) may be preferable (Jha et al, 2009, cited in A. Miller et al. 2015, K. Miller et al. 2018)
- Text should not be relied upon to present information, and graphs, tables and symbols should be considered where appropriate (K. Miller et al. 2018) The screen design should be as simple as possible, including only necessary elements, and readable, utilising appropriate fonts and font sizes and contrasts (K. Miller et al. 2018)
- Lack of consistent colour usage, or lack of use of cultural colour conventions for colour-coded alerts, or other types of symbols and indicators may also cause confusion between systems if there is a lack of standardisation (Finkel and Galvin 2017, Rojas and Seckman 2014), particularly for bank staff who may work between a number of different settings, or when an organisation moves from one vendor's software to another. Icons should be intuitive and consistent throughout the software screens (Rojas and Seckman 2014)
- With regards inputting information, the data entry should be set up to ensure minimal time possible is spent entering information (K. Miller et al. 2018), for example, by allowing predictive text to find menu items rather than requiring the user to scroll down a long list of drugs, or tick-boxes instead of drop-down menus where only a confirmation of an action is required (Rojas and Seckman 2014). Only essential information should be requested. Number of screens should also be minimised, and the need to switch between different screens to complete one task should also be minimised (K. Miller et al. 2018)
- Where alerts or messages given require further information to be given, acceptance is more likely if the clinician is able to access that information quickly, for example, is there a hyperlink within the text (Dalal et al. 2017)
- When inputting data, many EHRs automatically timestamp the data entry – however, where users are inputting data retrospectively, the option to amend the timestamp for accuracy of records needs to be clearly visible (Kirkendall et al. 2019). It is unclear from the literature how this could be achieved at present, whilst a pop-up alert could request to user to confirm the date and time, in a setting where most data entry is conducted in real time, this would unnecessarily increase workload.
- The preferred time-stamp format for each setting needs to be determined (Kirkendall et al. 2019). Indeed, in many critical cases, the ability to enter data retrospectively will be required (e.g. in a situation where a patient is rapidly declining)
- Where free text boxes are present, this may present a problem for future auditing and research purposes, or even for searching patient notes due to the heterogeneity present in language and lack of standardisation of terms, and spelling mistakes
- Consistency between layout of different screens is also important, to reduce cognitive load and time spent seeking particular on-screen details (K. Miller et al. 2018, Rojas and Seckman 2014).
- Juxtaposition of necessary clinical information onscreen, without the requirement of a clinician to move between different screens (display fragmentation) can reduce cognitive load on a clinician and improve their workflow and reduce likelihood of errors (Roman et al. 2017)
- Provide clinical data close to decision (Russ et al, 2014, cited in Finkel and Galvin 2017)
- Provide alert data in a table to allow for easy reading/processing (Russ et al, 2014, cited in Finkel and Galvin 2017)

- Remove or shorten alerts which require the user to scroll to read (Russ et al, 2014, cited in Finkel and Galvin 2017)
- Do not repeat alerts unnecessarily (Russ et al, 2014, cited in Finkel and Galvin 2017)
- Pull down menus may lead to users selecting the wrong drug (e.g. may accidentally click on adjacent drug) (Cresswell et al. 2014)
- Ensure language of all text on screens is appropriate for the widest number of potential users possible (A. Miller et al. 2015, K. Miller et al. 2018)
- Include clear level of risk in alerts in a visual manner, using easy to understand categories (e.g. high, medium, low or traffic light system) (A. Miller et al. 2015)
- Ensure easy to read font and font sizes are used (K. Miller et al. 2018)
- Ensure screen contrast is easy to read, or adjustable for individual needs and preferences (K. Miller et al. 2018)
- Use tables, graphs and symbols where relevant (K. Miller et al. 2018)
- Too much information can be overwhelming (Nguyen, Bellucci and Nguyen 2014), user test for usability and adherence to clinical guidelines to ensure balance of information quantity, quality and ease of use of the system
- A further point related to usability comes with regard how the system deals with daylight savings time, and whether this updates automatically, or whether the user has to do this (Kirkendall et al. 2019).

Questions to guide further tasks and work packages

Questions for Work Packages/interviews/HFS and recommendations for further development

- Do we want to run a usability simulation just on the newer iterations, or provide paper Obs and a control eObs (previous version) as a comparison?
- The Hi-Fi Sim at Coventry would not naturally include interruptions to tasks that would inevitably occur in real-ward settings – do we include an interruption as part of one of the scenarios to ensure nurses are able to return to their task in the software easily? (i.e. could be issues with having to log in again after a certain time, may not remember which menu item they were looking for...)
- Can we time tasks using the eObs software we are testing? Or will we need to time manually? Do we need to observe manually too – e.g. why did an operation take so long to complete – was the user trying to remember the process? Was there a loss of internet connection? Did the eObs software freeze? Was there an outside interruption?
- Does the eObs software work offline?
- How to ensure our measurements of time taken to complete task are correct – 2 observers and interobserver variability calculation? Or one observer plus comparison with eObs software timings?
- Is there an associated training package with the software?
- What usage statistics will we have access to?
- What level of information is provided by alerts? If the alerts signpost users to further information, is that information easily accessed, i.e. is it provided within the alert via a hyperlink?
- How do individuals log in? How long does this take? Is it a new and separate password to other work passwords? What happens if they forget their password?
- What would you want to “do” with the data? What are the possibilities?
- Build in processes for organisations to deal with technology induced errors (e.g. allow reporting of errors, auditing of errors)
- Consider how technology induced errors will be eliminated in future – will this be a vendor issue to deal with or organisational (or other due to Open source nature of software)
- How do users share identification of technology induced errors with other users/organisations/the vendor?
- Usability test and safety test all workflows
- Are there standards with regard colours and symbols for EHR interfaces and alerts? These should be followed to avoid confusion for organisations moving from another vendor’s product, or for staff who may work at different settings and with software from other vendors.
- What is a justifiable override for an alert?
- How often do users need to log-in? Balance between data security and not increasing workload.
- What graphical screens are necessary? Should they be shown as default?
- How to select or input drugs? Drop down menus may lead to error where a user clicks on an adjacent drug by accident
- Distinguish between essential functionalities and nice to have functionalities.
- Include use of visual analytics where possible to make data easy and quick to understand at the point of care
- What is preferable... within-screen or between-screen navigation?
- How do we time-stamps of data entry are correct when data is being added in retrospectively? (e.g. may miss option to adjust time and date, and pop up questions to remind during each data entry task will lead to alert fatigue in settings where data is entered in real time in most occasions).
- Which time-stamp format is most preferable? (DD-MM-YY/DD-MM-YYYY/MM-DD-YY?)
- How does the system adjust for daylight savings?

- Provide guidance on how to monitor system for malfunctions and errors – how do we identify malfunctions and respond to them in a timely manner?
- Allow free text narratives to be included as well as standardised inputs – as these medical narratives can be important for clinical judgement
- How many patient records should be accessible at one time? How do we ensure that we are not amending the wrong patient's record?
- Ensure eObs does not take longer to enter than paper obs
- Have we included all relevant stakeholders in the research and development?
- Concerns about downtime and procedures for downtime
- Preferred design elements

Possible measures for high-fidelity observations

- Structure measures into Technology Acceptance Model criteria (Fishbein & Ajzen) – perceived usefulness – or UTAUT?
- Time spent taking and documenting vital signs
- Demographic data required – include seniority
- Time taken to complete a note
- Satisfaction data
- Response to alerts
- Accuracy of observations (%) – paper vs. eObs
- Error rate
- Types of errors
- Task based observations should include (from Sousa et al (2015)): consequences of ignoring or deleting alerts and recommendations and acceptance of CDS suggestions
- Does each feature work as intended?
- Possible clinical scenarios – hypovolemic shock, cardiac arrest
- Views on alert notifications
- Views on colour scheme
- Number of clicks/taps to achieve a task
- Is the text/nomenclature appropriate?
- Perceived workload
- Usability testing of alerts

Possible outcome measures for CWP and SLAM trials

- Patient groups and effect size needs careful consideration to ensure detection of clinical benefit, for example Kashani et al (K. B. Kashani 2018) recommend initially testing with higher need patients, as this requires a smaller sample size
- Compare workflow times for eObs vs usual practice to ensure the introduction of eObs does not cause delays which may affect patient outcomes

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