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AN INTERDISCIPLINARY SYSTEMATIC REVIEW: DOES ALIGNMENT BETWEEN SYSTEM AND DESIGN SHAPE ADOPTION AND USE OF BARCODE MEDICATION ADMINISTRATION TECHNOLOGY?

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AN INTERDISCIPLINARY SYSTEMATIC REVIEW: DOES ALIGNMENT BETWEEN SYSTEM AND DESIGN SHAPE ADOPTION AND USE OF BARCODE MEDICATION ADMINISTRATION TECHNOLOGY?

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ABSTRACT

Aim: To identify how human factors influence the usability and adoption of barcode medication administration (BCMA).

Objective: To describe how human factors related determinants for BCMA have been researched and reported by healthcare and human computer interaction disciplines. **Method**: Computerised systematic searches were conducted in four databases covering April 2000 to April 2020. Search terms were developed to identity different disciplinary research perspectives which examined BCMA use, used a human factors lens and were published in English. Thematic analysis was carried out for included papers.

Setting: Secondary care.

Primary outcome: Reported factors associated with successful BCMA adoption. **Results**: Of 3,707 papers screened, eleven were included. Studies did not fit neatly into a clinical or HCI perspective but instead uncovered a range of overlapping narratives, demonstrating consensus on the key themes despite differing research approaches. Prevalent themes were misaligned design and workflow, adaptation and workarounds, factors which mediate successful BCMA use, safety, users' perceptions, and design and usability. Many of the studies identified complementary themes such as misaligned design and clinical workflow, and identifying a gap in understanding between system designers and end users. Workarounds were frequently identified as an outcome of inadequate design and a safety risk. Reported mediating factors included clear understanding of user needs, pre and post implementation evaluations to guide design and redesign, the study of workarounds to highlight design flaws and organisational commitment to appropriate technology selection, infrastructure and staffing.

Conclusion: Evaluating the literature from interdisciplinary perspectives including a human factors approach identified similar and complementary enablers and barriers to successful technology use. Many of the mediating factors were developed to compensate for unsuitable design; a collaborative approach to future research that includes the system designer and end users is necessary for BCMA to achieve its true safety potential.

Keywords: Human factors, Human computer interaction, usability, workarounds, design, Barcode medication administration, patient safety.

ARTICLE SUMMARY

Strengths and limitations of this study

Strengths:

- The search strategy captured literature from both healthcare and human computer interaction perspectives, providing a rich understanding of the factors.
- A second reviewer repeated the initial search with a high level of agreement and reviewed the data extraction process and theme selection to ensure findings were representative.
- The PRISMA checklist was used to design the study protocol.

Limitations:

- Most studies included were relatively small in terms of number of participants and usually conducted in just one or two hospitals, primarily in the United States.
- Qualitative methodology was prevalent in the selected studies, making it difficult to generalise findings.

FUNDING STATEMENT

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COMPETING INTERESTS STATEMENT

There are no competing interests to declare.

BACKGROUND

The prevalence and subsequent harm caused by medication errors has galvanised efforts to develop systems, policies and technologies to prevent medication errors (1–5). Medication administration errors are the most common adverse events in hospitals; it has been estimated that a patient will experience one medication error

per 24 hours as an inpatient (6,7). Annually, an estimated 237 million 'medication errors' occur in the NHS in England; 72% do not cause harm but 66 million are clinically significant. Avoidable adverse drug reactions contribute to 1700 and cause an estimated 700 death per year, at a financial cost of £98.5 million (4).

Medication management and administration in the hospital setting encompass a complex and interlinked series of events and individuals, including pharmacists, doctors, nurses, stock managers and patients. There are many opportunities in this chain to intercept errors which may lead to adverse events, and it is hard to estimate how many potential errors are intercepted before they reach the patient (4). However, medication administration has been identified as the phase where intercepted at the point of administration (7–10). To mitigate some of these risks, bar code medication administration (BCMA), usually in conjunction with an electronic medication administration record (eMAR), has been promoted to reduce the prevalence of medication administration errors (1,11,12).

Bates argues that the causes of frequent medication error are relatively simple: the bulk of the systems in place were not formally designed, and are not subject to the stringent regulation processes used in other high risk industries such as aviation (13).
Furthermore, healthcare is complex: it is highly regimented and systematic whilst also being unpredictable, requiring clinicians to constantly learn alongside their practice, often adapting to conform to local policies; this presents many challenges for clinicians navigating safe practice (14). Health information technologies (HIT), such as BCMA, seek to ensure safety for both patient and clinician.

BCMA technology incorporates the "five rights of medicines administration" (right drug, right time, right patient, right dose, right route) into an automated system (15,16). BCMA automates and records each medication administration and prompts the user to ensure it meets the required safety standard, warning the user if any discrepancy between prescription and administration detail is identified. For example, if the barcoded patient identification band does not match the selected electronic medication chart, an alert will notify the user of the mismatch, and prompt them to check they have the right medication for the right patient, potentially avoiding a "wrong patient" error (1,11). Whilst BCMA technology can reduce some medication errors, it can exacerbate others, or even cause new types of error to occur (11–13). The literature presents a complex picture of unintended consequences following BCMA implementation, indicating that the overall effect of a new health information technology, such as BCMA, is often difficult to predict (13,17).

From a human factors perspective, the belief that adopting health information technologies such as BCMA will lead to improved safety outcomes is termed 'magical thinking'; rather, successful adoption is complex, reliant on many mediating factors

and context dependent (18,19). The introduction of any new work system will have a transformative effect on the established workflow; successful adoption is not guaranteed, but a positive outcome may result from the comparison and clarification of the established and proposed systems (19–22). However, unintended consequences such as workarounds may also occur.

Human factors models such as systems engineering in patient safety (SEIPS) have been instrumental in understanding the factors that influence successful implementation of BCMA and other HIT (23). Such models examine the wider context in which work takes place, acknowledging that adverse events are rarely caused by one individual, but from a series in interconnected events (24). A human factors lens can be used to examine multiple factors such as environment, organisation, technology and tasks, to gain understanding of why errors occur and how to prevent them (24).

This literature review identifies factors which enable and limit the use of BCMA, during the implementation phase and beyond, by using a human factors lens to capture primary research from both users and implementers of the technology. Human factors approaches can often expose the root causes of undesirable outcomes, and by using a search strategy that captures research from across the spectrum of those designing and using the technology, it may be possible to develop implementation strategies that enable effective BCMA implementation and long-term use.

METHOD

Search strategy

Multiple key words were developed using terminology that would identify literature from healthcare, design, and informatics perspectives using a human factors lens. The preferred reporting items for systematic reviews and meta-analyses (PRISMA) was utilised as a guide for literature review protocol development (25). The Cumulative Index of Nursing, and Allied Health literature (CINAHL), PubMed, OVID MEDLINE and Google scholar were systematically searched for literature produced between April 2000-April 2020. Search terms were combined with Boolean operators and were adapted to match database terms.

Selection process

The selection process is displayed in figure 1. Full text, English language, peer reviewed papers of primary research were included; grey literature and literature reviews were excluded. The results from each database were compared and duplicates removed. Abstracts of the remaining papers were reviewed against the

 inclusion criteria and if the study included BCMA, usability and a human factors approach it was considered eligible and the full text was reviewed for inclusion. The paper did not have to explicitly state human factors in the title, as long as human factors principles were evident in the methodology. For example, workarounds are frequently studied in relation to BCMA; studies using human factors principle to understand the causes of workarounds were included, but studies examining workaround prevalence, in relation to error, without examining underlying causes were excluded.

PRISMA flow chart- Figure 1

Data Extraction process

A second reviewer (RA) repeated the search and study selection process, resulting in a high level of agreement (76%) for study eligibility through titles review. The level of agreement for final inclusion was very high, with both reviewers agreeing on 10 of the 11 studies following discussion all 11 were included in the review. Thematic data extraction was performed by RW, with the emergent themes developed iteratively through discussion with AB and YJ. RA reviewed a selection of the papers and associated thematic extraction and agreed that the identified themes were appropriate and representative of the study findings.

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Patient and Public Involvement

No patient involved.

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CHARACTERISTICS TABLE: EXTRACTED CHARACTERISTICS OF SELECTED STUDIES

Table 1

BCMA = Barcode medication administration, CPOE=Computerised physician order entry, STROBE=Strengthening reporting of observational studies in epidemiology, PIS= Pharmacy information system, eMAR= electronic medication administration record, PICU=paediatric intensive care unit, HIMSS= Health information and management systems society, EHR= electronic health record, ICU= Intensive care unit

Author, year	Aim	Study design	Research methods	Framework	Setting	Technology ad ed	Research Focus
Holden et al. 2013. (27)	To Study of workflow alteration following BCMA implementation.	• Comparison groups- Pre/post BCMA implementation.	 Observation of nursing practice (post- 47hrs, Pre- 89.5 hrs.) Interviews with 45 nurses post BCMA Implementation. Data collection Feb-Mar 2008. 	Cognitive systems engineering approach (2).	 Paediatric hospital. 236 bed. United states. ICU, haematology/ oncology unit and a general medical/surgical unit. 	Software vendor: Centricity pharmacy (G Healthcare). Integrated BCMA with CPOE, PIS and eMAR. Implemented Dec 2016: Software vendor:	 Notes BCMA research often focused on distal outcomes (adverse events). Often BCMA research does not explore underlying causes. Does not focus on impact on safety as an outcome. Usability and design focus.
Holden et al. 2011. (19)	To Study how BCMA may improve or worsen outcomes using a human factors lens.	• Comparison between BCMA and non-BCMA hospitals.	 Nurse survey conducted pre/post implementation. Additional data of 200 hrs of nurse practice observation, and 68 short interviews with BCMA users. Additional data collected during a previous study. 	The human factors model of health IT impact	•Two large paediatric hospitals. •United States.	Unclear. Integrated O BCMA and CPOE with A pharmacy checking of Til orders in place (PIS). 28 BCMA accessible via eMAR. 2020 Implemented Dec 2000	 States that safety is not the outcome of interest. Focus on nursing workflow, usability and design issues.
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Novak et al. 2012. (28)	To Identify strategies that mitigate the risks associated with BCMA implementation.	•An ethnographic case study.	•50 hrs observation of mediator/nurse interaction during BCMA implementation. •Additional data: Unstructured interviews, training, meeting minutes and emails.	Technology use mediation (TUM) framework.	One US hospital with an Informatics support team (IST).	Software vendor: 44 Unclear. CPOE and EH in use prior to BCMA 90 implementation. 1 Unclear. BCMA and ed	 Implementation process may influence safety outcomes, but no examined by this study. Highlight s that clinical staff can communicate design issues ident with designers.
Novak et al. 2013. (26)	To study of collisions between nursing orientation (Practice frame) and the technology orientation (the system frame) and resulting adaptions.	• Mixed methods study.	 Study a) 120 hrs observation during implementation of BCMA, interviews with 27 nurses post implementation and notes from meetings and emails. Study b) 90hrs observation pre and 47 hrs post BCMA implementation. Interviews with 45 nurses postimplementation. 	Frames of reference- Author discussed finding in terms of system frame and Practice frame.	• Two large paediatric hospitals. • United states.	Software vendor: Unclear. BCMA and CPOE with pharmacy checking of orders in place (PIS). BCMA accessible via eMAR. Study a) 2007 BCMA rollout, study B) 2006 BCMA rollout.	 Implementation and design the not safety. Designs impact on workflow and workarounds discussed. Current separation in the resear between user concerns (patient sa and design concerns (Usability). A balance of user and design perspectives could improve overa design.
Rack et al. 2012. (30)	To determine the existence, frequency, and potential causes of workarounds, and to determine whether workarounds were a factor in serious medication error, to determine if BCMA could have prevented the error.	Mixed method study.	 Survey (n=220 respondents). Focus groups with nurses. (6 conducted, 12 nurses in each). Review of medication errors and how they related to BCMA. Interviews with nurses responsible for medication errors. 	Complexity theory	 One 765 bed Hospital. United States. Three different BCMA systems implemented in three years. 	Software vendor: unclear. BCMA implemented in 2004, CPOE introduced in 2004, 2024 by guest. Protected by copyright.	 Need for design and clinical collaboration highlighted. Focus on how poor design lead nurse workarounds. Safety not the outcome of inter

Stagger s et al. 2015. (32)	To understand how BCMA effects situational awareness in nurses and to identify the usability issues	Evaluation.	 Evaluators completed the BCMA wed based training for nurses in order to develop a list of usability problems. BCMA co-ordinators reviewed and refined usability issues. 	 Heuristic evaluation (Zhang). Severity rating (Nielsen). 	 One Veteran's hospital United states. Hospital included ICU, medical and surgical units. 	Software vendor: VistA4419 Include EHR, computerised patient 19 record system (CPRS),01 rated stage 7 HIMSS. BCMA and eMAR implemented in early 2022.	 Focus on usability problems, design improvement recommended. Poor design could impact on patier safety but that was not a primar outcome of this study. Designers need to better understan clinic task prior to design.
Van der Veen et al 2018. (29)	responsible. To study the association between workarounds and medication administration errors when using BCMA, and to determine frequency, type of workaround and type of error.	A prospective observational study.	Direct observation of 5793 medication administrations on 1230 inpatients.	No theoretical framework used.	Four Dutch hospitals of varying size.	BCMA and CPOE implemented in all 4 hospitals using a varie of software.	 Safety as outcome measure. Association between med error and workarounds studied. General Design issues identified as possible cause of workarounds but no specifically studied. Need for collaboration not discussed.
Holden et al. 2012. (33)	To identify predictors of nurses' acceptance of BCMA.	A cross sectional survey	Survey (n=83). •August- Nov 2007.	Technology acceptance model (TAM)	Paediatric hospital • Recently implemented BCMA. 236 bed United States. PICU, haematology/onco logy/ bone marrow transplant unit and a medical/surgical unit surveyed.	Software vendor: Centricity pharmacy, GE healthcare). BCMA, S CPOE, PIS and automated medication dispensing cabinets. & Implementation 2007 2024 by guest. Protected by copyright.	• Study of predictors of technology acceptance to influence design. Safety not an outcome of interest

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et al. 2008. (7)occurrences, causes and (7)study· Shadowing N=31. · Semi-structured interviews N = 29. · 13 specialists, including pharmacists, and nurse leaders interviewed. · Additional analysis of BCMA override data. · Data collection 2003-2006.engineering in patient safety (SEIPS) model · United States.Siemens medication 4 administration check 50 and McKesson, BCMA7 and McKesson, BCMA7 and display eMAR. · United States.lead to workarounds. · Description and McKesson, BCMA7 and McKesson, BCMA7 and display eMAR. · United States.lead to workarounds. · Description and McKesson, BCMA7 and McKesson, BCMA7 and McKesson, BCMA7 and McKesson, BCMA7 and McKesson, BCMA7 and display eMAR.lead to workarounds. · Description and user · Importance of collaboratio between designer and user · Direct observation in total. · Opportunistic interviews with observees'. · BCMA override data analysed.engineering in patient safety (SEIPS) model · United States.Siemens medication factors administration · United States.Ilead to workarounds. · United States.Van der Veen et al 2020.To identify possible risk factorsA prospective observational study.A prospective observation of 5793 on 1230 inpatientsSTROBE checklist for reporting data.Four Dutch hospitals of hospitals of varying size.Workarounds as risk to safe · System design not discusse.				ВМЈ Ор	en	36/bmJopen	
n et al. 2006. (31)types and extent of workaround strategies with the use of BCMA.ethnographic studyacute care and n=13 long term care nurses. · 79 hours of observation in total. · Opportunistic interviews with observees'. · BCMA override data analysed.activity protocol.and large veteran's administration hospitals. · United states.Unclear. BCMA in use since 2000. CPOE and PIS.• Practical hardware design i · Usability of BCMA not expl · Context of use should be a consideration.Van der Veen et al 2020.To identify possible risk factorsA prospective observational study.Direct observation of 5793 medication administrations on 1230 inpatientsSTROBE checklist for reporting data.Four Dutch hospitals of varying size.BCMA and CPOE implemented in all 4 hospitals using a variety• Workarounds as risk to saft • System design not discussed • Practical factors such as state	et al.occurrences,2008.causes and7)threats to sate	study	 Shadowing N=31. Semi-structured interviews N= 29. 13 specialists, including pharmacists, and nurse leaders interviewed. Additional analysis of BCMA override data. 	engineering in patient safety (SEIPS) model	hospitals for the Observed • Five hospitals interviewed.	Siemens medication administration check and McKesson, BCMA9 and display eMAR.	 lead to workarounds. Design issues explored, medication error as a result not examined Importance of collaboration between designer and user highlighted.
Veen et al 2020.possible risk factorsobservational study.medication administrations on 1230 inpatientschecklist for reporting data.hospitals of varying size.implemented in all 4 bospitals using a variety• System design not discusse • Practical factors such as state	et al.types and ex2006.of workarour31)strategies withe use of	ent ethnographic d study	 Direct observation n=15 acute care and n=13 long term care nurses. 79 hours of observation in total. Opportunistic interviews with observees'. BCMA override data 	activity	and large veteran's administration hospitals.	Unclear. BCMA in use of since 2000. CPOE and of PIS.	 Practical hardware design issues Usability of BCMA not explored Context of use should be a design consideration.
workarounds using BCMA technology.	/een et possible risk al 2020. factors 11) associated w workarounds using BCMA	observational study. th	medication administrations	checklist for	hospitals of	implemented in all 4 hospitals using a variety of software.	 System design not discussed. Practical factors such as staffing discussed and how they have safety consequences.

RESULTS

Study characteristics

Nine of the eleven papers included were primary studies. The exceptions were Novak's 2013 study (26), which reanalysed data from two previous studies (27,28) (both included in the selected studies) to examine a new research question and Van der Veen's 2020 study (11) on factors which contribute to the occurrence of workarounds, which reanalysed data from their 2018 study (29) to explore a different facet to the original research (also included in the selected papers).

Various study designs and methodologies were used to investigate BCMA implementation and use. All studies were gualitative or mixed methods, gathering data by observation of practice or a combination of observation, survey, focus groups, and interviews. Multiple papers also collected quantitative data, such as medication error reports (30), and BCMA override data (7,31). Theoretical frameworks were used in all studies except for Van der Veen's work (11,29). The majority of the frameworks originated in the human factors field, including SEIPS, the technology acceptance model and complexity theory. Full details of the frameworks used are listed in Table 1. Three studies used statistical methods to analyse their findings, Patterson and colleagues established statistical significance of a higher incidence of workarounds in long-term care when compared to acute care (93% vs. 23%, p<.001) (31). Van der Veen and colleagues utilised logistic regression analysis to assess the association between workarounds and medication error and identify factors which contribute to the occurrence of workarounds (11,29). Holden and colleagues used regression models to predict acceptance of new technologies, using general linear mixed models with repeated measures to examine user perception of BCMA both pre and post implementation (19). Further studies led by Rack (30) and Koppel (7) presented survey results and override data as percentages of agreement but did not present any further statistical analysis. The remaining studies used thematic analysis to establish emergent themes, with differing methods. Holden's 2013 study used descriptive coding (27), Novak's 2012 study used qualitative data analysis software to transcribe and analyse fieldnotes (28), whereas Novak's 2013 study utilised researchers independently assessing their fieldnotes for themes before discussing as a group and finalising theme inclusion (26). Staggers' study (32) differed from the others in terms of data collection and analysis: this team studied online BCMA training routinely undertaken by nurses. The researchers used heuristic evaluation methods to establish usability problems with the technology and rate how this affected users' situational awareness. A severity score was then assigned to the usability problem to establish the safety risk posed by the usability issue identified. Studies varied in terms of length, number of participants, use of comparison sites, pre/post analysis and settings as detailed in table 1.

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Research focus

The studies included in this review use human factors methods with a range of research focuses and diverse narratives on BCMA adoption, use and success. Holden (27,33), Novak (28), and Staggers (32) studied the design and usability of BCMA systems and the effects of pre-existing workflows at various stages of BCMA implementation and use. The safety risks introduced by poorly aligned BCMA design and clinical workflow were acknowledged as a distal outcome of poor design but were not the focus of these studies. Rather, this group of studies highlight how workarounds can identify design flaws. This is in line with Koppel's (7) and Rack's (30) studies on the causes and frequency of workarounds; they concluded that poor design could increase their prevalence and have long term consequences for safety whilst not explicitly studying design issues or safety outcomes, and instead focusing on workarounds. In parallel, Van der Veen (11,29) and Patterson (31) studied the patient safety risk presented by the use of workarounds in the clinical setting, focusing on the consequences of circumventing the safety features of BCMA, acknowledging that their root may be in poor design, but not further commenting on particular design failures. Holden (33) examined users' perspectives of BCMA use pre and post implementation, adding another dimension to understanding technology acceptance and suggesting that user perception and not just the study of workarounds can aid iterative design. A further perspective is presented in Novak's (26) study of an informatics team which implemented BCMA technology into clinical practice; as professionals with both clinical and informatics expertise, their experience is highly valuable to those planning to implement BCMA technology into the healthcare setting.

The differing research focus in the field of BCMA study is discussed in two of the papers (26,27). Holden (27) noted that BCMA research routinely focuses on the relationship between adverse events and workarounds, arguing that investigating the outcome alone does not enable identification of the causes of workarounds and neglects design issues that may be responsible. Novak (26) proposes that future research must do more to understand the perspective of the workers, designers and implementers, to better understand factors affecting successful BCMA use.

THEMES TABLE TABLE 2: HUMAN FACTORS RELATED THEMES FROM THE STUDIES

THEMES T TABLE 2: I		ORS RELATEI	O THEMES FRO	BMJ Open	ES	36/bmjopen-2020-044419 on 1 July 202 Safe
Author, date	Misaligned design & workflow	Adaptation & Workarounds	Usability & design	Factors which mediate BCMA use	User perception	Safety NON
Holden, et al. 2013. (27)	 BCMA limited ability to plan ahead. Narrowed field of vision of user. Focused on specific timepoints. Limited user access to vital patient information. Did not reflect the complexity of clinical work. Did not fulfil user need. 	Workarounds mask design flaws. The designer and organisation maybe unaware of these design flaws and/or workarounds.	 Poor BCMA usability. Poor fit between BCMA and existing technology. Paper documentation used to communicate information lost between BCMA and existing technology. 			Safety concerns regarding the use of paper <u>is</u> documentation identified. de from http://bmjop
Holden, et al. 2011. (19)	 BCMA Transformed existing workflow. Changed health outcomes. Poor designer understanding of original workflow led to poor acceptance of technology. 	 Healthcare workers adapt to new work systems with their own goal achieving strategies. Poor compliance with design use is frequently observed. 		• Studying user perception of BCMA can improve design and acceptance.	240	from http://bmjopen.bmj.com/ on April 28, 2024 by guest
Novak, et al. 2012.(28)	BCMA was misaligned to technology use practices.	• Workarounds frequently identified in study.	• Iterative process of design and evaluation advocated.	• Implementation mediators can help mitigate negative unintended consequences caused by BCMA implementation and limit the development of workarounds.	• Expectations should be set for nurses prior to implementation of BCMA so they understand its advantages and disadvantages.	y guest. Protected by copyright

Novak, et al 2013. (26)	Temporal design focused on					36/bmjopen-2020
	 timepoints. Difficulty planning ahead Design not reflective of the complexity of clinical work. Inflexible when a plan changes. Design based too rigidly around the 5 rights. Clinical judgement of nurses not considered. Poor design led to the use of paper handover documents for communication. 	Workarounds implemented to improve efficiency. Safety features of BCMA not aligned with user safety concerns, resulting in workarounds.	• Iterative process of design and evaluation advocated.	- 10	 Stigma of late doses, resulting in nurse's avoidance strategies. Compliance with BCMA used as a performance measure. Nurses show willingness to comply with BCMA but are still having the resort to workarounds to complete tasks. 	Rigid design reduce critign thinking in Gui potentially S increasing risk error. Simply S implementing BCMA does no improve modi safety. Safety feagur BCMA not gg with user safet
Rack, et al. 2012. (30)	 Design focused user on single timepoint. Difficulty accessing information on previous medication administration. Reduced ability to communicate concerns/errors with wider team. Vital patient information difficult to access, delaying administration. Five rights used as BCMA design basis too rigid. 	• Workarounds in response to poor design.	• BCMA Technology should be designed in such a way that using it appropriately is easier than working around the system.	 Regular Maintenance of hardware reduces frustration for users and improves compliance with use. Responsibility for the maintenance of hardware should be considered prior to implementation. 	 Nurses should not be given the impression that BCMA use is faster. Safety benefits should be emphasised. 	concerns concerns

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Staggers, et al. 2015. (32)	 Workflow twice as long with BCMA use. Poor fit with existing workflow and user need. 	• Workarounds discussed in relation to misaligned design and workflow.	 High volume of usability issues identified. Better design needed to improve 		User perception discussed in relation to misaligned design and workflow	Poor usabute Poor usabute design are at 10 risk. Safety feature BCMA
	 Temporal focus on time point can blinker users to wider issues. Design too inflexible for the complexity of clinical work. 5 Rights interpreted too rigidly during design process. 	• Workarounds developed in response to poor design.	 user situational awareness. User centred design advocated. Design should support patient journey through the hospital. 		WORKHOW	compromises workarounds • Reduced 21 awareness boo increased sate risk
Van de Veen, et al. 2018. (29)	BCMA did not fit well with existing workflow. Issues with hardware and software identified.	• Statistically significant association between workarounds and medication administration errors	• Poor human- machine interface result in healthcare workers working around the system, compromising safety.	• Post implementation evaluation recommended for BCMA to achieve it full benefits.		• Poor design resulting in workaroun produce a f risk. oom/ on April 28, 2024 by guest
Holden, et al. 2012. (33)	• May not be financially worthwhile for organisation.	Poor design results in a lack of acceptance and workarounds.	 Design and usability discussed in relation to workarounds. BCMA difficult for some to use. 		BCMA users' perceptions of new technologies should be studied in order to influence their acceptance.	st. Protected by copyright.

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				BMJ Open		36/bmjopen-2020-044419 on 1 Ju
					• Studies of acceptance can predict technology use.	044419 on 1 Ju
Koppel, et al. 2008. (7)		 SEIPS model used to identify causes of workarounds. Workarounds can increase medication error risk. Work arounds have multiple causes and cause subsequent workarounds. 	 Organisational and technology related causes were found to be associated with all 15 of the identify workarounds. 	• Study of workarounds can highlight design issues and find solutions.		Workaroulfids found to be 21 safety risk. 1. Downloaded from http://br
Patterson, et al. 2006. (31)	 Design did not reflect context of use. To prevent adverse events following BCMA implementation, existing workflow should be studied and designed accordingly. 	 Work arounds increase error risk by bypassing safety technology of BCMA. Workarounds may go undetected or be acknowledged and tolerated by organisations. Nurses expressed concern of how workarounds reflect on them as professionals. 	Redesign could reduce frequency of workarounds. Redesign could improve efficiency. User perception of inefficiency increased workarounds. Improved reliability of hardware would reduce workarounds.	evie	 Nurses who felt their goals were jeopardised by inefficient BCMA justified the use of workarounds. Disciplining non- compliance found to be ineffective if the nurse felt they were acting in the interest of the patient. 	• Workarounds are a safety riskon.bmj.com/ on April 28, 2024 by guest
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Van der Veen, 2020. (11)	 Workarounds more frequent on busy weekdays than weekends. More likely to occur with a higher patient to nurse ratio. Not associated with ability to scan barcode. Increased work pressure increased workarounds. 	• Increased staffing. • Redesign to make BCMA more efficient.	• As work pressure increases the frequency of workarounds also increases.	

THEMES

Each study employed unique approaches to better understand BCMA use and success; nevertheless, many themes were evident in multiple studies. The main themes identified were misaligned design and workflow, adaptation and workarounds, factors which mediate BCMA use, safety, users' perception, and design and usability. A summary of these themes is presented in Table 2.

Misaligned design and workflow

Many studies found that BCMA system design and clinical workflow were misaligned, limiting the user's ability to plan ahead and prioritise (19,26–32). This mismatch seemed to result from BCMA design underestimating the complexity of nurses work, and how frequently they have to adapt to individual, environmental, institutional and technological factors beyond their control (30).

During direct observation, nurses were seen to frequently adapt and reorganise their work to achieve their goals and optimise patient care, putting them at odds with the sometimes inflexible BCMA design (26,32). A frequent observation was that BCMA design focuses the user on single timepoints, assuming that nurses complete tasks at scheduled times, whereas in practice nurses' work involves prioritisation, making the importance of timeliness context dependent (19,26,26,30,32). BCMA design attempts to focus the user on the specific task of medication administration, but multiple studies found that nurses could not easily access additional information required to safely administer medication such as vital signs, past medical history, and information regarding previous or future doses (26,30,32). Holden found that this prescriptive design limited users' critical thinking and therefore posed a safety risk (33). Nurses were observed to use paper to record pertinent information because the BCMA design did not give them an overview of their tasks or patients and limited their ability to communicate with colleagues (27). Staggers' study of situational awareness found 99 usability issues with the BCMA system studied, of which 15 were rated catastrophic, arguing that the design did not match the way nurses think or work (32). Van der Veen and colleagues also found that the BCMA did not fit well with daily workflow of nurses who encountered both software and hardware blockades (11).

Adaptations & Workarounds

All studies which conducted observation in the clinical setting reported workarounds associated with BCMA technology. Although the consequences and causes of workarounds varied greatly, there was agreement that workarounds undermined the safety features of BCMA technology.

Patterson's BCMA compliance study found that workarounds reduced technology effectiveness and increased the risk of adverse events (31). Van der Veen's found a statistically significant relationship between workarounds and medication error: 6% of the workarounds resulted in the wrong dose being administered and 78% of the workarounds were medication omissions (29). Van der Veen and colleagues reanalysed this data to look for factors which made workarounds more likely, finding a statistically significant relationship between high patient to nurse ratios and workarounds, arguing that increased work pressures led to an increase in the prevalence of workarounds (11).

Holden found that BCMA triggered multiple types of problem-solving behaviours. He notes that the problem solving itself was a "double edged sword", preventing failures missed in the design process, thus concealing design flaws, preventing redesign (27). For example, the use of paper artefacts to record patient information is potentially dangerous because it is not available to the wider clinical team and the shared information may be out of date. The use of paper artefacts conceals the user need and introduces a safety risk, which could be alleviated by better design.

Using the SEIPS framework to examine technological, task, organisational, patient related or environmental causes of workarounds, Koppel found that workarounds were complex, resulting from numerous causes and themselves creating additional workarounds (7). Koppel and Holden suggest that workarounds may be unavoidable when introducing technologies that transform workflow. Koppel argues that the study of workaround can highlight design flaws in order to remedy them, whilst Holden suggests that workarounds can be pre-empted and controlled through design (7,33).

Koppel also posits that workarounds are made more prevalent and arguably more dangerous by poor design. Koppel found that workarounds were not only negative but sometimes perceived by users as necessary to deliver patient care, finding that consequences of workarounds could be positive, neutral or negative (7). Both Koppel and Patterson advocate human factors approaches to study the causes of workarounds instead of simply introducing policies to increase compliance with intended workflows (7,31).

Van der Veen's study (11) examining the factors that contribute to workarounds recommended mandatory nurse to patient ratios, as they found this to be a mediating factor to reduce dangerous workarounds.

Design and Usability

Design and usability issues were identified by most studies as a factor influencing successful BCMA use.

The studies reviewed linked poor design and implementation to increased medication errors and reduced situational awareness (7,32). Patterson's observational study found that many workarounds could be eliminated by redesign, and many of the processes could be made more efficient (31). Holden argues that usability should be a priority, noting that if the difficulty of use outweighs the benefit, from the user's perspective, workarounds and non-compliance will be more prevalent (27). Rack argues that the goal of design should be to work in such a way that it is easier to use it correctly than work around the system to achieve goals (30).

Many of the papers identified issues with poorly designed hardware and software. Staggers reported frustration and multiple login requests to access the BCMA and eMAR systems studied. Also, the systems could not accommodate patients moving to different areas in the hospital, due to design, which caused confusion regarding whether or not medications had been given. Staggers reasoned that better interoperability and patient centred design could alleviate many of these issues (32). Patterson, Koppel and Rack identified hardware issues such as barcode scanner tethers being too short, workstations on wheels (WOWs) being too bulky to enter treatment rooms and inadequate internet connectivity leading to delays in workflow (7,30,32). Van der Veen found that inadequate human computer interfaces result in frustration and workarounds (29).

The majority of papers advocated evaluation and re-evaluation during implementation and beyond to take full advantage of safety features and identify the causes of workarounds in order to redesign the system (26,27,29–32). Koppel and Novak advocate ensuring that the designers of the BCMA system understand the current medication administration workflow and environmental and technical factors that may result in poor acceptance and reduce utilisation of new technology. This process should include a pre-implementation assessment to understand user needs and ongoing evaluation, allowing for redesign as issues occur (7,26).

Factors which mediate BCMA use

Many studies identified factors which can ease BCMA implementation, reduce unintended consequences such as workarounds, and improve acceptance of new technologies. Factors identified include conducting research that establishes user needs and perceptions of technologies, engaging individuals who act as mediators for both users and designers, ensuring users are aware of system capabilities and limitations, and organisational commitment to ensuring hardware is maintained and appropriate for the environment, including sufficient staffing levels.

Holden's (19) study into user perception and acceptance examined expectations of use pre and post BCMA implementation. Three aspects of medication administration

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were studied: matching medication to MAR, checking patient ID, and documentation. After BCMA implementation, nurses reported decreased likelihood of error, increased likelihood of error detection, increased usefulness, accuracy and consistency for matching medication and identifying the patient. However, they also reported decreased time efficiency, and decreased usefulness with regards to documenting actions on the BCMA system. Holden suggests that whilst health information technologies such as BCMA have a transformative impact on workflow, these changes are measurable and can be mediated by design, if users' expectations and needs are explored prior to development and implementation.

Similarly, when examining how to reduce unintended consequences when switching to a new system such as BCMA, Novak (28) argued that users' expectations should be set prior to implementation for them to develop an understanding of system capability and limitations. Novak's study followed a group of mediators who acted as user advocates during BCMA implementation, maintaining timely communication with hospital management and system designers, resulting in a more iterative and evolving implementation process. This style of implementation helped to mitigate negative unintended consequences.

Rack (30) conducted a survey of 220 nurses using BCMA and held focus groups. Although 90% of survey respondents agreed that BCMA was safer, many recounted situations where compliance with the BCMA system was not possible, 63% reported instances of giving medication without scanning the patient, and 72% reported occasions when they did not scan the medication barcode, and 40% reported sometimes scanning medication post administration. Focus groups discussed scenarios where compliance with BCMA was problematic. 30 scenarios were identified where a workaround was necessary to administer medication. Rack emphasises the need to set user expectation prior to BCMA implementation, presenting BCMA as no more time efficient but safer. In addition, they note that technology will need maintenance and this needs to be delegated to avoid the frustration of failing or inappropriate equipment. Koppel also noted that users both overestimate the risk elimination ability of BCMA and underestimate the safety features. There is a need for ongoing education to encourage correct use, and for hospital management to thoroughly examine their technological, environmental and social contexts before choosing a BCMA technology (7).

User Perceptions

Two papers reported that user perception impacted on successful implementation and user compliance (32,33). The use of BCMA compliance as a performance measure was found to be unsuccessful and resulted in resistance, particularly where users felt they were acting in the best interests of their patients by employing

workarounds. However, users also reported feeling guilt and stigma if they were unable to complete an administration in line with the BCMA system workflow.

Both Novak (28) and Holden (33) identified a reported stigma regarding late doses and how nurses attempted to avoid this stigma via workarounds. In reanalysing these studies, Novak (28) identifies an issue with using BCMA compliance as a performance measure, finding that nurses withholding medication for a legitimate reason were not able to communicate this, resulting in the feeling that they had done something wrong. One hospital punished non-compliance and used it as a performance measure whilst the other provided continual coaching of staff with the emphasis on safety. Koppel (7) suggests that it is not enough to tell staff to comply; rather, a constant evaluation of BCMA use is necessary to improve safety. Holden's later study (33) of nurses' acceptance of BCMA found that nurses already dissatisfied with BCMA are unlikely to use it to its full capacity, only being compliant enough to achieve their goals. Patterson(31) also found that policies, sanctions and training were unlikely to improve compliance if users felt that BCMA use jeopardised their ability to provide adequate patient care and achieve their goals. The increased use of workarounds during times of high work pressure reported by Van der Veen suggests that users perceive BCMA as being inefficient, only fully complying with the technology when they have time to do so (11).

Safety

The main purpose of BCMA is to improve patient safety; the majority of studies included in this review did not focus on the safety benefits of BCMA but instead used human factors methods to establish the underlying causes of unintended consequences. Nonetheless, there is some evidence that BCMA has this intended effect; e.g., Koppel analysed BCMA alerts as well as focused observations; over 23,000 alerts apparently led to the user changing their action (7). However, these studies are unable to conclude that BCMA is safer, instead finding that BCMA has the potential to improve safety (19,26,27). The issue of improved safety with BCMA technology is complex, and simply having the technology does not make medication administration safer. Increased safety is context dependent, relying on numerous other factors. Rack et al. (30) found that the majority of nurses believed BCMA technology was safer but also reported numerous scenarios where they had to bypass the safety features to administer medication.

DISCUSSION

The aim of this literature review was to identify how human factors influenced the usability and adoption of BCMA use. Studies using a human factors approach revealed a mismatch between BCMA system design and the existing workflow, caused by poor system design, which led to poor user acceptance and the

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development workarounds which presented a safety risk to patients. A secondary objective was to describe how human factors related determinants for BCMA have been researched and reported by healthcare and human computer interaction disciplines. However, it became apparent that the studies included could not easily be divided into these two disciplines. Instead, the use of a human factors approach yielded a wide range of narratives, differing time points, outcomes of interest and measures of success. Despite the variety of research focuses, the themes identified were largely complementary and most studies acknowledged how their area of interest was connected to, and had consequences for, the overall themes. What does differ is the measures of success in terms of BCMA use. For those studying design, technologies which fit the existing workflow, address clinical demand and improve user situational awareness are considered successful (19,26,27). For those researching the safety consequences of workarounds, increased compliance with BCMA use, reduced workarounds and hence safer medication administration are markers of success (7,11,29–31). For users, increased efficiency was a priority (33), whilst implementers were concerned with user acceptance and appropriate use of the new BCMA system (28). Whilst the measures of success differ, they are all clearly related; the voice missing from this research is that of designers themselves: there is a consensus that system designers do not fully understand user needs and this may be the cause of many of the reported issues; how this is shared with those designing the systems is less clear.

The themes of this review are broadly in line with previous systematic and scoping literature reviews examining BCMA use (14,34,35); it differs by capturing diverse research focuses and outcomes of interest to represent multiple perspectives. Combined, these provide valuable insights into the successful use of BCMA from numerous actors within the process. The inclusion of human factors highlighted the many different research interests and measures of success regarding BCMA use. Some previous literature reviews focused on particular areas of BCMA use, such as safety or design (34,35). Others explored the connection between workarounds and safety, concluding that BCMA has the capacity to reduce medication errors if used correctly (14,36). Voshall (34) advocated improved compliance to realise the safety benefits of BCMA, whilst Hassink (35) highlighted how system design, workflow mismatch and implementation strategies influence the safety of BCMA but noted that the studies reviewed often did not elaborate on how BCMA was implemented or how the workflow mismatch was addressed. Debono's review (14) focuses on workarounds and why nurses use them to achieve their goals; they consider the wider context of healthcare delivery and conclude that the nurses' perspective must be understood to reduce workarounds and improve bedside care. By using human factors research to draw on many different voices within BCMA research, this review provides themes across a spectrum of activity for BCMA, from design to adoption.

By reviewing human factors studies which focus on system design, workflow mismatch, informatics and users, it becomes clearer how the identified themes relate to each other. The misalignment in system designed workflow and clinical workflow stems from designers not fully understanding the nature of work in the healthcare setting, as discussed by eight of the selected papers (19,26,28–32). The juxtaposition of complex tasks coupled with changing priorities seems to clash with the rigid, temporally focused BCMA design reported by several studies (26,27,30,32). The use of the five rights of medication administration was discussed by Novak and Rack (26,30), suggesting that its use as a guide for BCMA design results in an overly rigid system.

The "five rights" check list which is designed for use by nurses at the point of medication administration is in practice applied with more flexibility than is acknowledge by BCMA system design. In reality there are many occasions when a nurse may have to reframe or rationalise one or more of the "five rights", such as availability of stock, urgency of medication and patient access (27). There is an apparent assumption that a formulaic, stepwise BCMA system will lead to increased safety, but healthcare is complex, the ability to adapt to changing situations is essential, and inflexible systems may clash with the nature of work and result in resistance, workarounds and increased safety risks.

Nurses are frequently required to reorganise their work to achieve quality care, often in response to factors beyond their control such as policy, organisational pressure, available technology and demand (26,37). An important part of the nurse's role is to effectively manage these competing pressures, and to advocate for their patients' needs. This review found many examples of problem solving behaviours in nurses (19,26). Overly prescriptive design in technology challenges nurses' identity and role (14).

Policies enforcing compliance with BCMA technology and disciplining non-compliant users was not found to be effective (31). The BCMA systems studied frequently reduced perceived efficiency, failed to make essential information available, and reduced critical thinking and situational awareness (26,29,30,32). Poorly designed BCMA creates additional hurdles to patient care and bypassing the BCMA system could be perceived as justifiable if it is in the interests of the patient (32). However, the resulting workarounds circumvent the safety features of BCMA and expose the patient to increased risk of medication error. This conflict was evident in the literature reviewed: nurses agreed that BCMA use was safer but frequently encountered scenarios where they could not complete a task and use the BCMA technology correctly (30). Conversely, users can sometimes overestimate the risk reduction capability of BCMA, relying on the technology to identify an error rather than a combination of the technology and their own clinical judgment (30). Workarounds were witnessed in every observational study in the review, but the terminology used to describe them differed: from adaptive and problem solving behaviours, to deviations and errors (26,29). The use of different terminology surrounding workarounds implies either negative or positive attitudes towards them (14). In the studies presented, safety focused papers often examined workarounds as an adverse event risk, whilst design and usability focused papers often described them as unavoidable and even informative (27). Many of the papers were divided on the consequence of workarounds (9). While the association between workarounds and medication errors is concerning, most studies acknowledge that workarounds are unavoidable when introducing a transformative technology into an existing workflow, and it is poor design and implementation that make them problematic (7,29).

Studies included in this review agree that many of the problems with BCMA use are rooted in designers not fully understanding the complexity of clinical work. Measures to manage these design mismatches include careful and long-term implementation strategies, organisational and technological structures which encourage correct BCMA use and close monitoring of workarounds. However, many of these strategies seem to be compensating for less than adequate design; how to redesign systems to better match clinical need is not really addressed and the designer perspective is absent from the studies reviewed. However, the differing findings and perspectives act as a powerful message that there is a greater need for close working throughout design and deployment for BCMA to achieve its recognised potential in improving patient safety.

Implications for clinicians and policymakers

The literature identified many mediating factors and potential strategies for enhancing BCMA use for clinicians, policy makers and users. An understanding of users' perceptions of a new technology prior to implementation can be predictive of overall acceptance and can guide design (19). Employing staff who are trained to act as mediators to ease implementation and act as a bridge between users and designers was found to be helpful by Novak and colleagues (28). Ensuring that software and hardware are appropriate for the environment and properly maintained to reduce frustration and mistrust in technology, along with appropriate staffing levels, require an organisational commitment and cannot be achieved by an individual nurse (11,30). Most studies recommended pre implementation evaluation and constant re-evaluation during the implementation phase with human factors frameworks to identify the causes of poor compliance with technology and inform redesign of the BCMA system. Success is dependent on collaboration between designers, informatics experts, users and the organisation to prevent workarounds persisting and becoming risks to safety. It may be necessary to view BCMA (and

 other HIT) system vendors as long-term partners, establishing a good understanding of user needs, organisational capability and how usability issues will be addressed following implementation.

Recommendations for further research

Further research using a human factors approach is needed to better understand how new technologies can be safely implemented into healthcare settings. Interdisciplinary research has the potential to illuminate BCMA design opportunities and challenges, and improve both user experience and patient safety. Future research could examine the long-term effects of BCMA, not just at the point of implementation but as use evolves over years, to evaluate whether its safety benefits are sustainable as the environment and users change.

Limitations and strengths

Most studies included in this review were small in sample size and conducted in the United States. They relied on qualitative research methodologies such as observation, focus groups and surveys. Many of the studies triangulated their qualitative findings with quantitative data, such as BCMA compliance reports, to better understand what was being observed in practice and to make their findings more generalisable.

As this study particularly examined BCMA implementation with a human factors lens, many BCMA studies were excluded, resulting in only eleven papers being included in the final review. This has given a focused view of the available research including evidence from both healthcare and human computer interaction perspectives.

The search strategy of this review was independently repeated by a second reviewer to reduce the risk of bias, and a good level of agreement was achieved.

CONCLUSION

This review found that successful BCMA use is eased by a clear understanding of existing workflow and user needs; pre, during and post implementation evaluation of BCMA technology to identify workarounds and guide redesign; organisational commitment to understanding and resolving issues with BCMA acceptance; and collaboration between users and system designers. Human factors principles can be used to understand causes of poor BCMA use and acceptance in the complex healthcare setting, and can unify the voices and experiences of those using the technology, not just to compensate for poor design but also to share findings with system designers to improve system design and therefore patient safety.

AUTHOR CONTRIBUTIONS

Rachel Williams- protocol design, literature review development, literature search, analysis, manuscript writing.

Reham Aldakhil- Independent second literature search, review of themes and manuscript review.

Prof Ann Blandford- Protocol guidance, review and guidance on search strategy, identified themes and manuscript review and finalising.

Dr Yogini Jani- Protocol guidance, review and guidance on search strategy, identified themes and manuscript review and finalising.

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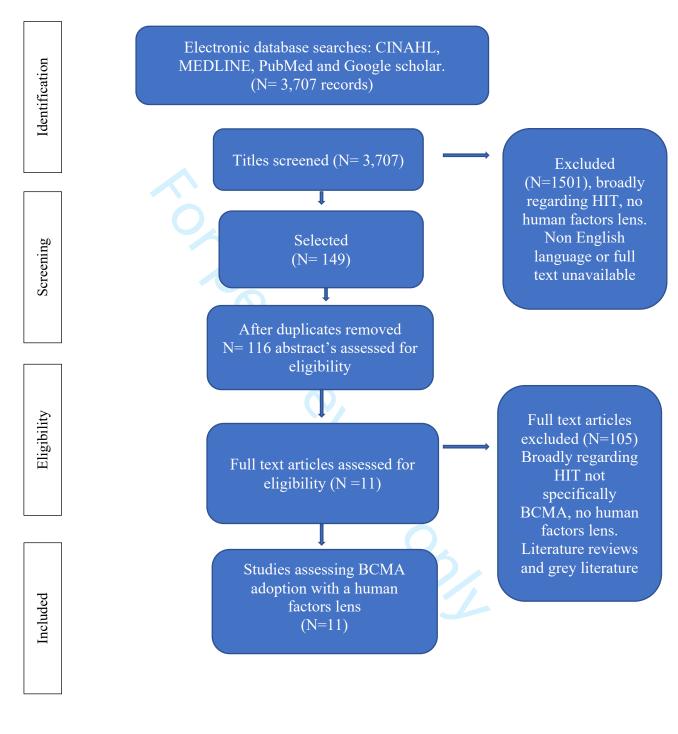
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PRISMA FLOW CHART- FIGURE 1



(25)

Reporting checklist for systematic review and metaanalysis.

Based on the PRISMA guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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	Reporting Item	Page Number
Title		
	<u>#1</u> Identify the report as a systematic review, meta-analysis, 1 or both.	
Abstract		
Structured summary	 #2 Provide a structured summary including, as applicable: 2 background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number 	
Introduction		
Rationale	#3Describe the rationale for the review in the context of what is already known.3, 4	
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1 2 4 5 6 7 8 9 10 11 12 13 14	Objectives	<u>#4</u>	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
	Methods			
	Protocol and registration	<u>#5</u>	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address) and, if available, provide registration information including the registration number.	Review protocol submitted with paper
15 16 17 18 19 20 21	Eligibility criteria	<u>#6</u>	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rational	4, 5
21 22 23 24 25 26 27 28 29 30 31 32 33 34	Information sources	<u>#7</u>	Describe all information sources in the search (e.g., databases with dates of coverage, contact with study authors to identify additional studies) and date last searched.	4, 5
	Search	<u>#8</u>	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Demonstrated in the PRISMA flowchart (Figure 1) and detailed in study protocol
35 36 27	Study selection	<u>#9</u>	State the process for selecting studies (i.e., for screening,	4,5.
37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59			for determining eligibility, for inclusion in the systematic review, and, if applicable, for inclusion in the meta- analysis).	PRISMA flow chart attached (Figure 1)
	Data collection process	<u>#10</u>	Describe the method of data extraction from reports (e.g., piloted forms, independently by two reviewers) and any processes for obtaining and confirming data from investigators.	5
	Data items	<u>#11</u>	List and define all variables for which data were sought (e.g., PICOS, funding sources), and any assumptions and simplifications made.	Included in the study protocol.
	Risk of bias in individual studies	<u>#12</u>	Describe methods used for assessing risk of bias in individual studies (including specification of whether this	Described in the study protocol.
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Page 3	35 of 35		BMJ Open	
1 2 3			was done at the study or outcome level, or both), and how this information is to be used in any data synthesis.	
4 5 6	Summary measures	<u>#13</u>	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
7 8 9 10 11 12	Planned methods of analyis	<u>#14</u>	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis.	N/A
13 14 15 16 17	Risk of bias across studies	<u>#15</u>	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
18 19 20 21 22	Additional analyses	<u>#16</u>	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
23 24 25	Results			
23 26 27 28 29 30	Study selection	<u>#17</u>	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a <u>flow diagram</u> .	PRISMA flow diagram attached (Figure 1)
31 32 33 34 35	Study characteristics	<u>#18</u>	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citation.	Study characteristics detailed in Table 1.
36 37 38 39	Risk of bias within studies	<u>#19</u>	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	N/A
40 41 42 43 44 45 46	Results of individual studies	<u>#20</u>	For all outcomes considered (benefits and harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
47 48 49 50 51	Synthesis of results	<u>#21</u>	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency.	Detailed in Themes table (Table 2).
52 53 54 55 56 57 58	Risk of bias across studies	<u>#22</u>	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
59 60		Fc	or peer review only - http://bmjopen.bmj.com/site/about/guidelines.x	html

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1 2 3 4 5	Additional analysis	<u>#23</u>	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
6 7	Discussion			
8 9 10 11 12 13 14	Summary of Evidence	<u>#24</u>	Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers	13
15 16 17 18 19	Limitations	<u>#25</u>	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	13
20 21 22 23 24 25	Conclusions	<u>#26</u>	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13, 14
25 26 27	Funding			
28 29 30 31 32	Funding	<u>#27</u>	Describe sources of funding or other support (e.g., supply of data) for the systematic review; role of funders for the systematic review.	3
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AN INTERDISCIPLINARY SYSTEMATIC REVIEW: DOES ALIGNMENT BETWEEN SYSTEM AND DESIGN SHAPE ADOPTION AND USE OF BARCODE MEDICATION ADMINISTRATION TECHNOLOGY?

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AN INTERDISCIPLINARY SYSTEMATIC REVIEW: DOES ALIGNMENT BETWEEN SYSTEM AND DESIGN SHAPE ADOPTION AND USE OF BARCODE MEDICATION ADMINISTRATION TECHNOLOGY?

Rachel Williams RN, BSc, MSc. Centre for Medicines Optimisation Research and Education University College London Hospitals NHS Foundation Trust, 235 Euston Road, London, NW1 2BU and UCL School of Pharmacy, 29-39 Brunswick Square, London, WC1N 1AX Reham Aldakhil Clinical and Informatics Research Unit Institution of Health Informatics University College London, 222 Euston Road, London NW1 2DA Professor Ann Blandford UCL Institute of Healthcare Engineering UCLIC, University College London 66 - 72 Gower Street London, WC1E 6EA United Kingdom Corresponding author- Dr Yogini Jani Centre for Medicines Optimisation Research and Education University College London Hospitals NHS Foundation Trust, 235 Euston Road, London, NW1 2BU and UCL School of Pharmacy, 29-39 Brunswick Square, London, WC1N 1AX y.jani@ucl.ac.uk

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8 9

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5,794 words

ABSTRACT

10 Background: Barcode medication administration (BCMA) is 11 increasingly utilised to improve safety in healthcare. 12 However, how human factors influence adoption and usability of 13 this technology is relatively unknown. 14 **Objective:** To describe how human factors related determinants 15 for BCMA have been researched and reported by healthcare and 16 human computer interaction disciplines. 17 Data sources: The Cumulative Index of Nursing, and Allied 18 19 Health literature (CINAHL), PubMed, OVID MEDLINE and Google 20 scholar. 21 Study eligibility criteria: Primary research published from 22 April-2000 to April-2020, search terms developed to identity 23 different disciplinary research perspectives that examined 24 BCMA use, used a human factors lens and were published in 25 English. 26 27 Synthesis Methods: Computerised systematic searches were 28 conducted in four databases. Eligible papers were 29 systematically analysed for themes. Themes were discussed with 30 a second reviewer and supervisors to ensure they were 31 representative of content. 32 Results: Of 3,707 papers screened, eleven were included. 33 Studies did not fit neatly into a clinical or HCI perspective 34 35 but instead uncovered a range of overlapping narratives, 36 demonstrating consensus on the key themes despite differing 37 research approaches. 38 Prevalent themes were misaligned design and workflow, 39 adaptation and workarounds, mediating factors, safety, users' 40 perceptions, and design and usability. Many of the studies 41 identified complementary themes, identifying a gap in 42 understanding between system designers and end users. 43 44 Inadequate design frequently led to workarounds, which 45 jeopardised safety. Reported mediating factors included 46 clarity of user needs, pre/post implementation evaluations, 47 analysis of existing workarounds and appropriate technology, 48 infrastructure and staffing. 49 Limitations: Most studies were relatively small, and 50 qualitative, making it difficult to generalise findings. 51 **Conclusion:** Evaluating interdisciplinary perspectives 52 53 including human factors approaches identified similar and 54 complementary enablers and barriers to successful technology 55 use. 56 Often, mediating factors were developed to compensate for 57 unsuitable design; a collaborative approach between system 58 designer and end users is necessary for BCMA to achieve its 59 true safety potential.

Keywords: Human factors, Human computer interaction, usability, workarounds, design, Barcode medication administration, patient safety.

ARTICLE SUMMARY

Strengths and limitations of this study

Strengths:

- The search strategy captured literature from both healthcare and human computer interaction perspectives, providing a rich understanding of the factors.
- A second reviewer repeated the initial search with a high level of agreement and reviewed the data extraction process and theme selection to ensure findings were representative.
- The PRISMA checklist was used to design the study protocol.

Limitations:

- Most studies included were relatively small in terms of number of participants and usually conducted in just one or two hospitals, primarily in the United States.
- Qualitative methodology was prevalent in the selected studies, making it difficult to generalise findings.

FUNDING STATEMENT

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COMPETING INTERESTS STATEMENT

There are no competing interests to declare.

DATA AVAILABILITY STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information.

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BACKGROUND

The prevalence and subsequent harm caused by medication errors has galvanised efforts to develop systems, policies and technologies to prevent medication errors (1-5). Medication administration errors are the most common adverse events in hospitals; it has been estimated that a patient will experience one medication error per 24 hours as an inpatient (6,7). Annually, an estimated 237 million 'medication errors' occur in the NHS in England; 72% do not cause harm but 66 million are clinically significant. Avoidable adverse drug reactions contribute to 1700 and cause an estimated 700 death per year, at a financial cost of £98.5 million (4).

Medication management and administration in the hospital setting encompass a complex and interlinked series of events and individuals, including pharmacists, doctors, nurses, stock managers and patients. There are many opportunities in this chain to intercept errors which may lead to adverse events, and it is hard to estimate how many potential errors are intercepted before they reach the patient (4). However, medication administration has been identified as the phase where interception of a medication error is least likely to occur, with only about 2% of errors being intercepted at the point of administration (7-10). To mitigate some of these risks, bar code medication administration (BCMA), usually in conjunction with an electronic medication administration record (eMAR), has been promoted to reduce the prevalence of medication administration errors (1,11,12).

Bates argues that the causes of frequent medication error are relatively simple: the bulk of the systems in place were not formally designed, and are not subject to the stringent regulation processes used in other high risk industries such as aviation (13). Furthermore, healthcare is complex: it is highly regimented and systematic whilst also being unpredictable, requiring clinicians to constantly learn alongside their practice, often adapting to conform to local policies; this presents many challenges for clinicians navigating safe practice (14). Health information technologies (HIT), such as BCMA, seek to ensure safety for both patient and clinician.

BCMA technology incorporates the "five rights of medicines administration" (right drug, right time, right patient, right dose, right route) into an automated system (15,16). BCMA automates and records each medication administration and prompts the user to ensure it meets the required safety standard, warning the user if any discrepancy between

prescription and administration detail is identified. For example, if the barcoded patient identification band does not match the selected electronic medication chart, an alert will notify the user of the mismatch, and prompt them to check they have the right medication for the right patient, potentially avoiding a "wrong patient" error (1,11). Whilst BCMA technology can reduce some medication errors, it can exacerbate others, or even cause new types of error to occur (11-13). The literature presents a complex picture of unintended consequences following BCMA implementation, indicating that the overall effect of a new health information technology, such as BCMA, is often difficult to predict (13,17).

From a human factors perspective, the belief that adopting health information technologies such as BCMA will lead to improved safety outcomes is termed 'magical thinking'; rather, successful adoption is complex, reliant on many mediating factors and context dependent (18,19). The introduction of any new work system will have a transformative effect on the established workflow; successful adoption is not guaranteed, but a positive outcome may result from the comparison and clarification of the established and proposed systems (19-22). However, unintended consequences such as workarounds may also occur.

Human factors models such as systems engineering in patient safety (SEIPS) have been instrumental in understanding the factors that influence successful implementation of BCMA and other HIT (23). Such models examine the wider context in which work takes place, acknowledging that adverse events are rarely caused by one individual, but from a series in interconnected events (24). A human factors lens can be used to examine multiple factors such as environment, organisation, technology and tasks, to gain understanding of why errors occur and how to prevent them (24).

This literature review identifies factors which enable and limit the use of BCMA, during the implementation phase and beyond, by using a human factors lens to capture primary research from both users and implementers of the technology. Human factors approaches can often expose the root causes of undesirable outcomes, and by using a search strategy that captures research from across the spectrum of those designing and using the technology, it may be possible to develop implementation strategies that enable effective BCMA implementation and long-term use.

METHOD

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Search strategy

Multiple key words were developed using terminology that would identify literature from healthcare, design, and informatics perspectives using a human factors lens. The preferred reporting items for systematic reviews and meta-analyses (PRISMA) was utilised as a guide for literature review protocol development (25). The Cumulative Index of Nursing, and Allied Health literature (CINAHL), PubMed, OVID MEDLINE and Google scholar were systematically searched for literature produced between April 2000-April 2020. Search terms were combined with Boolean operators and were adapted to match database terms.

Selection process

The selection process is displayed in figure 1. Full text, English language, peer reviewed papers of primary research were included; grey literature and literature reviews were excluded. The results from each database were compared and duplicates removed. Abstracts of the remaining papers were reviewed against the inclusion criteria and if the study included BCMA, usability and a human factors approach it was considered eligible and the full text was reviewed for inclusion. The paper did not have to explicitly state human factors in the title, as long as human factors principles were evident in the methodology. For example, workarounds are frequently studied in relation to BCMA; studies using human factors principle to understand the causes of workarounds were included, but studies examining workaround prevalence, in relation to error, without examining underlying causes were excluded.

PRISMA flow chart- Figure 1

Data Extraction process

A second reviewer (RA) repeated the search and study selection process, resulting in a high level of agreement (76%) for study eligibility through titles review. The level of agreement for final inclusion was very high, with both reviewers agreeing on 10 of the 11 studies following discussion all 11 were included in the review. Thematic data extraction was performed by RW, with the emergent themes developed iteratively through discussion with AB and YJ. RA reviewed a selection of the papers and associated thematic extraction and agreed that the identified themes were appropriate and representative of the study findings.

Patient and Public Involvement

No patient or public involvement was sought in the development and execution of the literature review. No personal or identifying private health information would be derived from the public sources being searched.

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TABLE 1: EXTRACTED CHARACTERISTICS OF SELECTED STUDIES

36/bmjopen-2020-044419 BCMA = Barcode medication administration, CPOE=Computerised physician order entry, STROBE=Strengehening reporting of observational studies in epidemiology, PIS= Pharmacy information system, eMAR= electronic medication administration record, PICU=paediatric intensive care unit, HIMSS= Health information and management systems society, EH electronic health record, TCU= Intensive care unit 2021.

Author , year	Aim	Study design	Research methods	Framework	Setting	Technology O	Research Focus
, year Holden et al. 2013. (26)	To Study of workflow alteration following BCMA implementati on.	 Comparison groups- Pre/post BCMA implementati on. 	 Observation of nursing practice (post- 47hrs, Pre- 89.5 hrs.) Interviews with 45 nurses post BCMA Implementation. Data collection Feb- Mar 2008. 	Cognitive systems engineering approach	 Paediatric hospital. 236 bed. United states. ICU, haematology/ oncology unit and a general medical/surgi cal unit. 	Software vendor: Centricity pharmacy (GE Healthcare). Integrated BCMA with CPOE, PIS and eMAR. Implemented Dec 2016.	 Notes BCMA research ofter focused on distal outcomes (adverse events). Often BCMA research does not explore underlying causes. Does not focus on impact safety as an outcome. Usability and design focu
Holden et al. 2011. (19)	To Study how BCMA may improve or worsen outcomes using a human factors lens.	• Comparison between BCMA and non-BCMA hospitals.	 Nurse survey conducted pre/post implementation. Additional data of 200 hrs of nurse practice observation, and 68 short interviews with BCMA users. Additional data collected during a previous study. 	The human factors model of health IT impact	•Two large paediatric hospitals. •United States.	Software vendor: Unclear. Integrated BCMA and CPOE with pharmacy checking of orders in place (PIS). BCMA accessible via eMAR. Implemented Dec 28, 2006. 20	 States that safety is not the outcome of interest. Focus on nursing workflow usability and design issue
Novak et al. 2012. (27)	To Identify strategies that mitigate the risks associated with BCMA implementati on.	•An ethnographic case study.	 50 hrs observation of mediator/nurse interaction during BCMA implementation. Additional data: Unstructured interviews, training, meeting minutes and emails. 	Technology use mediation (TUM) framework.	One US hospital with an Informatics support team (IST).	Software vendor:24 Unclear. CPOE and EHR in use prior to BCMA implementation. Protected by copyright	 Implementation process mainfluence safety outcomes, but not examined by this study. Highlight s that clinical staff cannot communicate design issues identified with designers.

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Novak et al. 2013. (28)	To study of collisions between nursing orientation (Practice frame) and the technology orientation (the system frame) and resulting adaptions.	• Mixed methods study.	 Study a) 120 hrs observation during implementation of BCMA, interviews with 27 nurses post implementation and notes from meetings and emails. Study b) 90hrs observation pre and 47 hrs post BCMA implementation. Interviews with 45 nurses postimplementation. 	Frames of reference- Author discussed finding in terms of system frame and Practice frame.	 Two large paediatric hospitals. United states. 	Software vendor: Unclear. BCMA and CPDE with pharmacy checking of orders in place (PIS). BCMA accessible via eMAR. Study 2007 ECMA rollou study B) 2006 BCCA rollout.	 Implementation and dest the focus not safety. Designs impact on work: and workarounds discusse Current separation in research between user concerns (patient safety and design concerns (Usability). A balance of user and design perspectives coul improve overall design.
Rack et al. 2012. (29)	To determine the existence, frequency, and potential causes of workarounds, and to determine whether workarounds were a factor in serious medication error, to determine if BCMA could have prevented the error.	Mixed method study.	 Survey (n=220 respondents). Focus groups with nurses. (6 conducted, 12 nurses in each). Review of medication errors and how they related to BCMA. Interviews with nurses responsible for medication errors. 	Complexity theory	 One 765 bed Hospital. United States. Three different BCMA systems implemented in three years. 	Software vendor: unclear. BCMA implemented in 2004, CPOE introduced in 2000 	 Need for design and clinical collaboration highlighted. Focus on how poor designed leads to nurse workaround Safety not the outcome interest.
Stagge rs et al. 2015. (30)	To understand how BCMA effects situational awareness in nurses and to identify the usability issues responsible.	Evaluation.	 Evaluators completed the BCMA wed based training for nurses in order to develop a list of usability problems. BCMA co-ordinators reviewed and refined usability issues. 	 Heuristic evaluation (Zhang). Severity rating (Nielsen). 	 One Veteran's hospital United states. Hospital included ICU, medical and surgical units. 	Software vendor: by VistA. Include get EHR, computerises patient record system (CPRS), Protect system (CPRS), Protect rated stage 7 not HIMSS. BCMA and ce MAR implemented in early 2000. by copyright.	 Focus on usability problems, design improved recommended. Poor design could impar patient safety but that not a primary outcome of study. Designers need to bett understand clinic task p to design.

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Van der Veen et al 2018. (31)	To study the association between workarounds and medication administrati on errors when using BCMA, and to determine frequency, type of workaround and type of error.	A prospective observationa l study.	Direct observation of 5793 medication administrations on 1230 inpatients.	No theoretical framework used.	Four Dutch hospitals of varying size.	BCMA and CPOE implemented in at 4 4 hospitals using on 1 July 2021. Downloaded	 Safety as outcome measure. Association between a error and workarounds studied. General Design issue identified as a possibl cause of workarounds bu specifically studied. Need for collaboration discussed. 			
Holden et al. 2012. (32)	To identify predictors of nurses' acceptance of BCMA.	A cross sectional survey	Survey (n=83). •August- Nov 2007.	Technology acceptance model (TAM)	 Paediatric hospital • Recently implemented BCMA. 236 bed United States. PICU, haematology/o ncology/ bone marrow transplant unit and a medical/surgi cal unit surveyed. 	Software vendor: Centricity pharmacy, GE healthcare). BCM CPOE, PIS and automated medication- dispensing cabinets. Implementation 2007	• Study of predictors of technology acceptance to influence design. Safety not an outcome of interest			
Koppel et al. 2008. (7)	To study the occurrences, causes and threats to safety of workarounds.	Mixed method study	 Analysis of BCMA data of 307,698 medication administrations. Observations N=62. Shadowing N=31. Semi-structured interviews N= 29. 13 specialists, including pharmacists, and nurse leaders interviewed. Data collection 2003-2006. 	System engineering in patient safety (SEIPS) model used.	 Two large hospitals for the Observed Five hospitals interviewed. United States. 	Software vendor:28 Siemens medication administration check and McKesson, BCMA apd display eMAR. Protected by copyright.	 Poor design implementation lead workarounds. Design issues explor medication error as a r not examined Importance of collaboration between designer and user highlighted. 			

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son et al. 2006. (33)	To identify the types and extent of workaround strategies with the use of BCMA.	A prospective ethnographic study	 Direct observation n=15 acute care and n=13 long term care nurses. 79 hours of observation in total. Opportunistic interviews with observees'. BCMA override data analysed. 	Standard activity protocol.	 Small, medium and large veteran's administratio n hospitals. United states. 	Software vendor: Unclear. BCMA in use since 2000. CPOE and PIS. Down BCMA and CPOE	 Safety risk of workarounds Practical hardware design issues Usability of BCMA not explored Context of use should be a design consideration.
Van der Veen et al 2020. (11)	To identify possible risk factors associated with workarounds using BCMA technology.	A prospective observationa l study.	Direct observation of 5793 medication administrations on 1230 inpatients	STROBE checklist for reporting data.	Four Dutch hospitals of varying size.	implemented in a D 4 hospitals usin a variety of	 Workarounds as risk to safety. System design not discussed. Practical factors such as staffing discussed and how they have safety consequences.
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RESULTS

Study characteristics

Nine of the eleven papers included were primary studies. The exceptions were Novak's 2013 study(28), which reanalysed data from two previous studies (26,27) (both included in the selected studies) to examine a new research question and Van der Veen's 2020 study (11) on factors which contribute to the occurrence of workarounds, which reanalysed data from their 2018 study (31) to explore a different facet to the original research (also included in the selected papers).

18 Various study designs and methodologies were used to 19 investigate BCMA implementation and use. All studies were 20 21 qualitative or mixed methods, gathering data by observation of 22 practice or a combination of observation, survey, focus 23 groups, and interviews. Multiple papers also collected 24 quantitative data, such as medication error reports (29), and 25 BCMA override data (7,33). Theoretical frameworks were used in 26 all studies except for Van der Veen's work (11,31). The 27 majority of the frameworks originated in the human factors 28 29 field, including SEIPS, the technology acceptance model and 30 complexity theory. Full details of the frameworks used are 31 listed in Table 1. Three studies used statistical methods to 32 analyse their findings, Patterson and colleagues established 33 statistical significance of a higher incidence of workarounds 34 in long-term care when compared to acute care (93% vs. 23%, 35 p<.001) (33). Van der Veen and colleagues utilised logistic 36 37 regression analysis to assess the association between 38 workarounds and medication error and identify factors which 39 contribute to the occurrence of workarounds (11,31). Holden 40 and colleagues used regression models to predict acceptance of 41 new technologies, using general linear mixed models with 42 repeated measures to examine user perception of BCMA both pre 43 and post implementation (19). Further studies led by Rack 44 (29) and Koppel (7) presented survey results and override data 45 46 as percentages of agreement but did not present any further 47 statistical analysis. The remaining studies used thematic 48 analysis to establish emergent themes, with differing methods. 49 Holden's 2013 study used descriptive coding (26), Novak's 2012 50 study used qualitative data analysis software to transcribe 51 and analyse fieldnotes (27), whereas Novak's 2013 study 52 utilised researchers independently assessing their fieldnotes 53 for themes before discussing as a group and finalising theme 54 55 inclusion (28). Staggers' study (30) differed from the others 56 in terms of data collection and analysis: this team studied 57 online BCMA training routinely undertaken by nurses. The 58 researchers used heuristic evaluation methods to establish 59 usability problems with the technology and rate how this 60

affected users' situational awareness. A severity score was then assigned to the usability problem to establish the safety risk posed by the usability issue identified. Studies varied in terms of length, number of participants, use of comparison sites, pre/post analysis and settings as detailed in table 1.

Research focus

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The studies included in this review use human factors methods with a range of research focuses and diverse narratives on BCMA adoption, use and success. Holden (26,32), Novak (27), and Staggers (30) studied the design and usability of BCMA systems and the effects of pre-existing workflows at various stages of BCMA implementation and use. The safety risks introduced by poorly aligned BCMA design and clinical workflow were acknowledged as a distal outcome of poor design but were not the focus of these studies. Rather, this group of studies highlight how workarounds can identify design flaws. This is in line with Koppel's (7) and Rack's (29) studies on the causes and frequency of workarounds; they concluded that poor design could increase their prevalence and have long term consequences for safety whilst not explicitly studying design issues or safety outcomes, and instead focusing on workarounds. In parallel, Van der Veen (11,31) and Patterson (33) studied the patient safety risk presented by the use of workarounds in the clinical setting, focusing on the consequences of circumventing the safety features of BCMA, acknowledging that their root may be in poor design, but not further commenting on particular design failures. Holden (32) examined users' perspectives of BCMA use pre and post implementation, adding another dimension to understanding technology acceptance and suggesting that user perception and not just the study of workarounds can aid iterative design. A further perspective is presented in Novak's (28) study of an informatics team which implemented BCMA technology into clinical practice; as professionals with both clinical and informatics expertise, their experience is highly valuable to those planning to implement BCMA technology into the healthcare setting.

48 The differing research focus in the field of BCMA study is 49 discussed in two of the papers (26,28). Holden (26) noted that 50 51 BCMA research routinely focuses on the relationship between 52 adverse events and workarounds, arguing that investigating the 53 outcome alone does not enable identification of the causes of 54 workarounds and neglects design issues that may be 55 responsible. Novak (28) proposes that future research must do 56 more to understand the perspective of the workers, designers 57 and implementers, to better understand factors affecting 58 successful BCMA use. 59

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TABLE 2: HUMAN FACTORS RELATED THEMES FROM THE STUDIES

BCMA = Barcode medication administration, SEIPS= System engineering in patient safety

design & workflow • BCMA limited ability to plan ahead. • Narrowed field of vision	Workarounds • Workarounds mask design flaws. • The	design Poor BCMA usability. Poor fit between BCMA 	mediate BCMA use		• Safet 2 concerns regardin the
• BCMA limited ability to plan ahead. • Narrowed field of vision	mask design flaws. • The	usability. • Poor fit			• Safet <u>N</u> concerns regardin D the
ability to plan ahead. • Narrowed field of vision	mask design flaws. • The	usability. • Poor fit			• Safet <u>N</u> concerns regardin D the
of user. • Focused on specific timepoints. • Limited user access to vital patient information. • Did not reflect the complexity of clinical work. • Did not fulfil user	designer and organisation maybe unaware of these design flaws and/or workarounds.	and existing technology. • Paper documentation used to communicate information lost between BCMA and existing technology.			use of paper documentation identified. dentified from http://bmjopen.bmj.g
need. • BCMA Transformed existing workflow. • Changed health outcomes. • Poor designer understanding of original workflow led to poor acceptance of technology.	 Healthcare workers adapt to new work systems with their own goal achieving strategies. Poor compliance with design use is frequently observed 		• Studying user perception of BCMA can improve design and acceptance.	Ч ⁰	led from http://bmjopen.bmj.com/ on April 28, 2024 by guest. Protected by copyright.
api • rcc• fn• Tew• ho• uowp	access to vital batient information. Did not reflect the complexity of clinical work. Did not culfil user need. BCMA Gransformed existing rorkflow. Changed health outcomes. Poor designer inderstanding of original rorkflow led to poor acceptance	<pre>workarounds. workarounds. atient aformation. Did not aeflect the complexity of clinical work. Did not culfil user need. BCMA ransformed existing rorkflow. Changed to new work systems with their own goal achieving foor designer inderstanding of original compliance with design use is</pre>	<pre>workarounds. information lost between BCMA and existing technology. Did not reflect the complexity of linical work. Did not fulfil user need. BCMA existing to new work rorkflow. Changed their own goal achieving Poor designer inderstanding orkflow led to workers adapt to new work systems with their own goal achieving Poor designer orkflow led to with design use is f technology.</pre>	<pre>workarounds. information lost between BCMA and existing technology. Did not reflect the complexity of linical work. Did not fulfil user need. BCMA BCMA BCMA BCMA Paransformed existing to new work rorkflow. Changed their own goal achieving Poor designer strategies. Meansformed with design poor acceptance of technology.</pre> . Studying user perception of BCMA can improve design and acceptance. * Studying user perception of BCMA can improve design and acceptance. * Poor use is frequently	<pre>workarounds. information lost between BCMA and existing technology.</pre> • Healthcare workers adapt to new work systems with Changed bealth wutcomes. Poor designer inderstanding of original compliance frequently • Healthcare workers adapt to new work systems with their own achieving foor designer inderstanding of technology. workers adapt to new work systems with their own strategies. • Studying user perception of BCMA can improve design and acceptance. • Studying user perception of BCMA can improve design and acceptance. • Poor compliance with design use is frequently

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Novak, et al. 2012. (27)	• BCMA was misaligned to technology use practices.	 Workarounds frequently identified in study. 	• Iterative process of design and evaluation advocated.	• Implementation mediators can help mitigate negative unintended consequences caused by BCMA implementation and limit the	• Expectations should be set for nurses prior to implementation of BCMA so they understand its advantages and disadvantages.	
Novak, et al 2013. (28)	 Temporal design focused on timepoints. Difficulty planning ahead Design not reflective of the complexity of clinical work. Inflexible when a plan changes. Design based too rigidly around the 5 rights. Clinical judgement of nurses not considered. Poor design led to the use of paper handover documents for communication. 	• Workarounds implemented to improve efficiency. • Safety features of BCMA not aligned with user safety concerns, resulting in workarounds.	• Iterative process of design and evaluation advocated.	development of workarounds.	 Stigma of late doses, resulting in nurse's avoidance strategies. Compliance with BCMA used as a performance measure. Nurses show willingness to comply with BCMA but are still having the resort to workarounds to complete tasks. 	 Rigid dan reduce critical thinking nurses, potential increasin risk of e Simply implement BCMA does improve medicine safety. Safety features BCMA not aligned user safe concerns

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Rack, et al. 2012. (29)	 Design focused user on single timepoint. Difficulty accessing information on previous medication administration. Reduced ability to communicate concerns/errors with wider team. Vital patient information difficult to access, delaying administration. Five rights used as BCMA design basis too rigid. 	• Workarounds in response to poor design.	• BCMA Technology should be designed in such a way that using it appropriately is easier than working around the system.	 Regular Maintenance of hardware reduces frustration for users and improves compliance with use. Responsibility for the maintenance of hardware should be considered prior to implementation. 	 Nurses should not be given the impression that BCMA use is faster. Safety benefits should be emphasised. 	- Poor
Staggers, et al. 2015. (30)	 Workflow twice as long with BCMA use. Poor fit with existing workflow and user need. Temporal focus on time point can blinker users to wider issues. Design too inflexible for the complexity of clinical work. 5 Rights interpreted too rigidly during design process. 	 Workarounds discussed in relation to misaligned design and workflow. Workarounds developed in response to poor design. 	 High volume of usability issues identified. Better design needed to improve user situational awareness. User centred design advocated. Design should support patient journey through the hospital. 		 User perception discussed in relation to misaligned design and workflow 	• Poor usability design at safety ri • Safety features BCMA compromit workarour • Reduced situation awareness to increa safety ri

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Van de Veen, et al. 2018. (31)	 BCMA did not fit well with existing workflow. Issues with hardware and software identified. 	• Statistically significant association between workarounds and medication administratio n errors	 Poor human- machine interface result in healthcare workers working around the system, compromising safety. 	 Post implementation evaluation recommended for BCMA to achieve it full benefits. 		Poor resulti workarc produce safety
Holden, et al. 2012. (32)	• May not be financially worthwhile for organisation.	• Poor design results in a lack of acceptance and workarounds.	 Design and usability discussed in relation to workarounds. BCMA difficult for some to use. 	revie	 BCMA users' perceptions of new technologies should be studied in order to influence their acceptance. Studies of acceptance can predict technology use. 	
Koppel, et al. 2008. (7)		 SEIPS model used to identify causes of workarounds. Workarounds can increase medication error risk. Work arounds have multiple causes and cause subsequent workarounds. 	• Organisational and technology related causes were found to be associated with all 15 of the identify workarounds.	 Study of workarounds can highlight design issues and find solutions. 	comology age.	• Worka have th potenti present safety

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Patterson, et al. 2006. (33)	 Design did not reflect context of use. To prevent adverse events following BCMA implementation, existing workflow should be studied and designed accordingly. 	 Work arounds increase error risk by bypassing safety technology of BCMA. Workarounds may go undetected or be acknowledged and tolerated by organisations 	 Redesign could reduce frequency of workarounds. Redesign could improve efficiency. User perception of inefficiency increased workarounds. Improved reliability of hardware would reduce 		 Nurses who felt their goals were jeopardised by inefficient BCMA justified the use of workarounds. Disciplining non-compliance found to be ineffective if the nurse felt they were acting in the interest of the 	86/bmjopen-2020-081 are a sat risk. • Workar&t 19 on 1 July 2021. Downloade
		 Nurses expressed concern of how workarounds reflect on them as professionals . 	workarounds.	r ro	patient.	d from http://bmjopen.l
Van der Veen, 2020. (11)		 Workarounds more frequent on busy weekdays than weekends. More likely to occur with a higher patient to nurse ratio. Not associated with ability to scan barcode. Increased work pressure increased workarounds. 		 Increased staffing. Redesign to make BCMA more efficient. 	• As work pressure increases the frequency of workarounds also increases.	on 1 July 2021. Downloaded from http://bmjopen.bmj.com/ on April 28, 2024 by guest. Protected by copyright

THEMES

in Table 2.

Each study employed unique approaches to better understand

misaligned design and workflow, adaptation and workarounds,

factors which mediate BCMA use, safety, users' perception, and

design and usability. A summary of these themes is presented

in multiple studies. The main themes identified were

BCMA use and success; nevertheless, many themes were evident

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Misaligned design and workflow Many studies found that BCMA system design and clinical workflow were misaligned, limiting the user's ability to plan ahead and prioritise (19,26-31,33). This mismatch seemed to result from BCMA design underestimating the complexity of

nurses work, and how frequently they have to adapt to individual, environmental, institutional and technological factors beyond their control (29).

During direct observation, nurses were seen to frequently adapt and reorganise their work to achieve their goals and optimise patient care, putting them at odds with the sometimes inflexible BCMA design (28,30). A frequent observation was that BCMA design focuses the user on single timepoints, assuming that nurses complete tasks at scheduled times, whereas in practice nurses' work involves prioritisation, making the importance of timeliness context dependent (19,28,28-30). BCMA design attempts to focus the user on the specific task of medication administration, but multiple studies found that nurses could not easily access additional information required to safely administer medication such as vital signs, past medical history, and information regarding previous or future doses (28-30). Holden found that this prescriptive design limited users' critical thinking and therefore posed a safety risk (32). Nurses were observed to use paper to record pertinent information because the BCMA design did not give them an overview of their tasks or patients and limited their ability to communicate with colleagues (26). Staggers' study of situational awareness found 99 usability issues with the BCMA system studied, of which 15 were rated catastrophic, arguing that the design did not match the way nurses think or work (30). Van der Veen and colleagues also found that the BCMA did not fit well with daily workflow of nurses who encountered both software and hardware blockades (11).

Adaptations & Workarounds

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All studies which conducted observation in the clinical setting reported workarounds associated with BCMA technology. Although the consequences and causes of workarounds varied greatly, there was agreement that workarounds undermined the safety features of BCMA technology.

Patterson's BCMA compliance study found that workarounds reduced technology effectiveness and increased the risk of adverse events (33). Van der Veen's found a statistically significant relationship between workarounds and medication error: 6% of the workarounds resulted in the wrong dose being administered and 78% of the workarounds were medication omissions (31). Van der Veen and colleagues reanalysed this data to look for factors which made workarounds more likely, finding a statistically significant relationship between high patient to nurse ratios and workarounds, arguing that increased work pressures led to an increase in the prevalence of workarounds (11).

Holden found that BCMA triggered multiple types of problemsolving behaviours. He notes that the problem solving itself was a "double edged sword", preventing failures missed in the design process, thus concealing design flaws, preventing redesign (26). For example, the use of paper artefacts to record patient information is potentially dangerous because it is not available to the wider clinical team and the shared information may be out of date. The use of paper artefacts conceals the user need and introduces a safety risk, which could be alleviated by better design.

Using the SEIPS framework to examine technological, task, organisational, patient related or environmental causes of workarounds, Koppel found that workarounds were complex, resulting from numerous causes and themselves creating additional workarounds (7). Koppel and Holden suggest that workarounds may be unavoidable when introducing technologies that transform workflow. Koppel argues that the study of workaround can highlight design flaws in order to remedy them, whilst Holden suggests that workarounds can be pre-empted and controlled through design (7,32).

Koppel also posits that workarounds are made more prevalent by poor design. Koppel found that workarounds were not only negative but sometimes perceived by users as necessary to deliver patient care, finding that consequences of workarounds could be positive, neutral or negative (7). Both Koppel and Patterson advocate human factors approaches to study the causes of workarounds instead of simply introducing policies to increase compliance with intended workflows (7,33).

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Van der Veen's study (11) examining the factors that contribute to workarounds recommended mandatory nurse to patient ratios, as they found this to be a mediating factor to reduce dangerous workarounds.

Design and Usability

Design and usability issues were identified by most studies as a factor influencing successful BCMA use.

The studies reviewed linked poor design and implementation to increased medication errors and reduced situational awareness (7,30). Patterson's observational study found that many workarounds could be eliminated by redesign, and many of the processes could be made more efficient (33). Holden argues that usability should be a priority, noting that if the difficulty of use outweighs the benefit, from the user's perspective, workarounds and non-compliance will be more prevalent (26). Rack argues that the goal of design should be to work in such a way that it is easier to use it correctly than work around the system to achieve goals (29).

Many of the papers identified issues with poorly designed hardware and software. Staggers reported frustration and multiple login requests to access the BCMA and eMAR systems studied. Also, the systems could not accommodate patients moving to different areas in the hospital, due to design, which caused confusion regarding whether or not medications had been given. Staggers reasoned that better interoperability and patient centred design could alleviate many of these issues (30). Patterson, Koppel and Rack identified hardware issues such as barcode scanner tethers being too short, workstations on wheels (WOWs) being too bulky to enter treatment rooms and inadequate internet connectivity leading to delays in workflow (7,29,30). Van der Veen found that inadequate human computer interfaces result in frustration and workarounds (31).

The majority of papers advocated evaluation and re-evaluation during implementation and beyond to take full advantage of safety features and identify the causes of workarounds in order to redesign the system (26,28-31,33). Koppel and Novak advocate ensuring that the designers of the BCMA system understand the current medication administration workflow and environmental and technical factors that may result in poor acceptance and reduce utilisation of new technology. This process should include a pre-implementation assessment to understand user needs and ongoing evaluation, allowing for redesign as issues occur (7,28).

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Factors which mediate BCMA use

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Many studies identified factors which can ease BCMA implementation, reduce unintended consequences such as workarounds, and improve acceptance of new technologies. Factors identified include conducting research that establishes user needs and perceptions of technologies, engaging individuals who act as mediators for both users and designers, ensuring users are aware of system capabilities and limitations, and organisational commitment to ensuring hardware is maintained and appropriate for the environment, including sufficient staffing levels.

Holden's (19) study into user perception and acceptance examined expectations of use pre and post BCMA implementation. Three aspects of medication administration were studied: matching medication to MAR, checking patient ID, and documentation. After BCMA implementation, nurses reported decreased likelihood of error, increased likelihood of error detection, increased usefulness, accuracy and consistency for matching medication and identifying the patient. However, they also reported decreased time efficiency, and decreased usefulness with regards to documenting actions on the BCMA system. Holden suggests that whilst health information technologies such as BCMA have a transformative impact on workflow, these changes are measurable and can be mediated by design, if users' expectations and needs are explored prior to development and implementation.

Similarly, when examining how to reduce unintended consequences when switching to a new system such as BCMA, Novak (27) argued that users' expectations should be set prior to implementation for them to develop an understanding of system capability and limitations. Novak's study followed a group of mediators who acted as user advocates during BCMA implementation, maintaining timely communication with hospital management and system designers, resulting in a more iterative and evolving implementation process. This style of implementation helped to mitigate negative unintended consequences.

Rack (29) conducted a survey of 220 nurses using BCMA and held focus groups. Although 90% of survey respondents agreed that BCMA was safer, many recounted situations where compliance with the BCMA system was not possible, 63% reported instances of giving medication without scanning the patient, and 72% reported occasions when they did not scan the medication barcode, and 40% reported sometimes scanning medication post administration. Focus groups discussed scenarios where compliance with BCMA was problematic. 30 scenarios were identified where a workaround was necessary to administer

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medication. Rack emphasises the need to set user expectation prior to BCMA implementation, presenting BCMA as no more time efficient but safer. In addition, they note that technology will need maintenance and this needs to be delegated to avoid the frustration of failing or inappropriate equipment. Koppel also noted that users both overestimate the risk elimination ability of BCMA and underestimate the safety features. There is a need for ongoing education to encourage correct use, and for hospital management to thoroughly examine their technological, environmental and social contexts before choosing a BCMA technology (7).

User Perceptions

Two papers reported that user perception impacted on successful implementation and user compliance (30,32). The use of BCMA compliance as a performance measure was found to be unsuccessful and resulted in resistance, particularly where users felt they were acting in the best interests of their patients by employing workarounds. However, users also reported feeling guilt and stigma if they were unable to complete an administration in line with the BCMA system workflow.

Both Novak (27) and Holden (32) identified a reported stigma regarding late doses and how nurses attempted to avoid this stigma via workarounds. In reanalysing these studies, Novak (27) identifies an issue with using BCMA compliance as a performance measure, finding that nurses withholding medication for a legitimate reason were not able to communicate this, resulting in the feeling that they had done something wrong. One hospital punished non-compliance and used it as a performance measure whilst the other provided continual coaching of staff with the emphasis on safety. Koppel (7) suggests that it is not enough to tell staff to comply; rather, a constant evaluation of BCMA use is necessary to improve safety. Holden's later study (32) of nurses' acceptance of BCMA found that nurses already dissatisfied with BCMA are unlikely to use it to its full capacity, only being compliant enough to achieve their goals. Patterson(33) also found that policies, sanctions and training were unlikely to improve compliance if users felt that BCMA use jeopardised their ability to provide adequate patient care and achieve their goals. The increased use of workarounds during times of high work pressure reported by Van der Veen suggests that users perceive BCMA as being inefficient, only fully complying with the technology when they have time to do so (11).

Safety

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The main purpose of BCMA is to improve patient safety; the majority of studies included in this review did not focus on the safety benefits of BCMA but instead used human factors methods to establish the underlying causes of unintended consequences. Nonetheless, there is some evidence that BCMA has this intended effect; e.g., Koppel analysed 307,698 BCMA alerts as well as focused observations; over 23,000 alerts apparently led to the user changing their action (7). However, these studies are unable to conclude that BCMA is safer, instead finding that BCMA has the potential to improve safety (19,26,28). The issue of improved safety with BCMA technology is complex, and simply having the technology does not make medication administration safer. Increased safety is context dependent, relying on numerous other factors. Rack et al. (29) found that the majority of nurses believed BCMA technology was safer but also reported numerous scenarios where they had to bypass the safety features to administer medication.

DISCUSSION

The aim of this literature review was to identify how human factors influenced the usability and adoption of BCMA use. Studies using a human factors approach revealed a mismatch between BCMA system design and the existing workflow, caused by poor system design, which led to poor user acceptance and the development workarounds which presented a safety risk to patients. A secondary objective was to describe how human factors related determinants for BCMA have been researched and reported by healthcare and human computer interaction disciplines. However, it became apparent that the studies included could not easily be divided into these two disciplines. Instead, the use of a human factors approach yielded a wide range of narratives, differing time points, outcomes of interest and measures of success. Despite the variety of research focuses, the themes identified were largely complementary and most studies acknowledged how their area of interest was connected to, and had consequences for, the overall themes. What does differ is the measures of success in terms of BCMA use. For those studying design, technologies which fit the existing workflow, address clinical demand and improve user situational awareness are considered successful (19,26,28). For those researching the safety consequences of workarounds, increased compliance with BCMA use, reduced workarounds and hence safer medication administration are markers of success (7,11,29,31,33). For users, increased efficiency was a priority (32), whilst implementers were concerned with user acceptance and appropriate use of the new BCMA system (27). Whilst the measures of success differ, they are all clearly related; the

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voice missing from this research is that of designers themselves: there is a consensus that system designers do not fully understand user needs and this may be the cause of many of the reported issues; how this is shared with those designing the systems is less clear.

The themes of this review are broadly in line with previous systematic and scoping literature reviews examining BCMA use (14,34,35); it differs by capturing diverse research focuses and outcomes of interest to represent multiple perspectives. Combined, these provide valuable insights into the successful use of BCMA from numerous actors within the process. The inclusion of human factors highlighted the many different research interests and measures of success regarding BCMA use. Some previous literature reviews focused on particular areas of BCMA use, such as safety or design (34,35). Others explored the connection between workarounds and safety, concluding that BCMA has the capacity to reduce medication errors if used correctly (14,36). Voshall (34) advocated improved compliance to realise the safety benefits of BCMA, whilst Hassink (35) highlighted how system design, workflow mismatch and implementation strategies influence the safety of BCMA but noted that the studies reviewed often did not elaborate on how BCMA was implemented or how the workflow mismatch was addressed. Debono's review (14) focuses on workarounds and why nurses use them to achieve their goals; they consider the wider context of healthcare delivery and conclude that the nurses' perspective must be understood to reduce workarounds and improve bedside care. By using human factors research to draw on many different voices within BCMA research, this review provides themes across a spectrum of activity for BCMA, from design to adoption.

By reviewing human factors studies which focus on system design, workflow mismatch, informatics and users, it becomes clearer how the identified themes relate to each other. The misalignment in system designed workflow and clinical workflow stems from designers not fully understanding the nature of work in the healthcare setting, as discussed by eight of the selected papers (19,26,28-32). The juxtaposition of complex tasks coupled with changing priorities seems to clash with the rigid, temporally focused BCMA design reported by several studies (26,28-30). The use of the five rights of medication administration was discussed by Novak and Rack (28,29), suggesting that its use as a guide for BCMA design results in an overly rigid system.

56 The "five rights" check list which is designed for use by 57 nurses at the point of medication administration is in 58 practice applied with more flexibility than is acknowledge by 59 BCMA system design. In reality there are many occasions when a 60

nurse may have to reframe or rationalise one or more of the "five rights", such as availability of stock, urgency of medication and patient access (26). There is an apparent assumption that a formulaic, stepwise BCMA system will lead to increased safety, but healthcare is complex, the ability to adapt to changing situations is essential, and inflexible systems may clash with the nature of work and result in resistance, workarounds and increased safety risks.

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Nurses are frequently required to reorganise their work to achieve quality care, often in response to factors beyond their control such as policy, organisational pressure, available technology and demand (28,37). An important part of the nurse's role is to effectively manage these competing pressures, and to advocate for their patients' needs. This review found many examples of problem solving behaviours in nurses (19,28). Overly prescriptive design in technology challenges nurses' identity and role (14).

Policies enforcing compliance with BCMA technology and disciplining non-compliant users was not found to be effective (33). The BCMA systems studied frequently reduced perceived efficiency, failed to make essential information available, and reduced critical thinking and situational awareness (26,29,30,32). Poorly designed BCMA creates additional hurdles to patient care and bypassing the BCMA system could be perceived as justifiable if it is in the interests of the patient (30). However, the resulting workarounds circumvent the safety features of BCMA and expose the patient to increased risk of medication error. This conflict was evident in the literature reviewed: nurses agreed that BCMA use was safer but frequently encountered scenarios where they could not complete a task and use the BCMA technology correctly (29). Conversely, users can sometimes overestimate the risk reduction capability of BCMA, relying on the technology to identify an error rather than a combination of the technology and their own clinical judgment (29).

Workarounds were witnessed in every observational study in the review, but the terminology used to describe them differed: from adaptive and problem solving behaviours, to deviations and errors (28,31). The use of different terminology surrounding workarounds implies either negative or positive attitudes towards them (14). In the studies presented, safety focused papers often examined workarounds as an adverse event risk, whilst design and usability focused papers often described them as unavoidable and even informative (26). Many of the papers were divided on the consequence of workarounds (9). While the association between workarounds and medication errors is concerning, most studies acknowledge that workarounds are unavoidable when introducing a transformative

technology into an existing workflow, and it is poor design and implementation that make them problematic (7,31).

Studies included in this review agree that many of the problems with BCMA use are rooted in designers not fully understanding the complexity of clinical work. Measures to manage these design mismatches include careful and long-term implementation strategies, organisational and technological structures which encourage correct BCMA use and close monitoring of workarounds. However, many of these strategies seem to be compensating for less than adequate design; how to redesign systems to better match clinical need is not really addressed and the designer perspective is absent from the studies reviewed. However, the differing findings and perspectives act as a powerful message that there is a greater need for close working throughout design and deployment for BCMA to achieve its recognised potential in improving patient safety.

Implications for clinicians and policymakers

The literature identified many mediating factors and potential strategies for enhancing BCMA use for clinicians, policy makers and users. An understanding of users' perceptions of a new technology prior to implementation can be predictive of overall acceptance and can guide design (19). Employing staff who are trained to act as mediators to ease implementation and act as a bridge between users and designers was found to be helpful by Novak and colleagues (27). Ensuring that software and hardware are appropriate for the environment and properly maintained to reduce frustration and mistrust in technology, along with appropriate staffing levels, require an organisational commitment and cannot be achieved by an individual nurse (11,29). Most studies recommended pre implementation evaluation and constant re-evaluation during the implementation phase with human factors frameworks to identify the causes of poor compliance with technology and inform redesign of the BCMA system. Success is dependent on collaboration between designers, informatics experts, users and the organisation to prevent workarounds persisting and becoming risks to safety. It may be necessary to view BCMA (and other HIT) system vendors as long-term partners, establishing a good understanding of user needs, organisational capability and how usability issues will be addressed following implementation.

Recommendations for further research

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As noted above, the designers of BCMA systems are rarely visible in the discourse around their implementation and use. Studies of workarounds tend not to question the details of specific BCMA design, but to focus more on the complexity of the broader system. Further research is needed to better understand how new technologies can be designed and safely implemented into complex healthcare settings. In particular, very little prior research has explored the interdependencies between technology design and use within complex systems (a rare exception being the work of (38)). More specifically, little work in Human-Computer Interaction, which addresses design for usability, utility and safety, has focused on how to design technology to support complex tasks. This review has made it clear that BCMA technology is a component within a complex system of medication administration. Interdisciplinary research is needed to better understand how technology to support safer medication administration can be designed to accommodate the complexities of use while also supporting staff in managing that complexity. In parallel, it is important to improve both user experience and patient safety. Future research should also examine the long-term effects of BCMA, not just at the point of implementation but as use evolves over years, to evaluate whether its safety benefits are sustainable as the environment and users change.

Limitations and strengths

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Most studies included in this review were small in sample size and conducted in the United States. They relied on qualitative research methodologies such as observation, focus groups and surveys. Many of the studies triangulated their qualitative findings with quantitative data, such as BCMA compliance reports, to better understand what was being observed in practice and to make their findings more generalisable.

As this study particularly examined BCMA implementation with a human factors lens, many BCMA studies were excluded, resulting in only eleven papers being included in the final review. This has given a focused view of the available research including evidence from both healthcare and human computer interaction perspectives.

The search strategy of this review was independently repeated by a second reviewer to reduce the risk of bias, and a good level of agreement was achieved.

CONCLUSION

This review found that successful BCMA use is eased by a clear understanding of existing workflow and user needs; pre, during

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59 60 and post implementation evaluation of BCMA technology to identify workarounds and guide redesign; organisational commitment to understanding and resolving issues with BCMA acceptance; and collaboration between users and system designers. Human factors principles can be used to understand causes of poor BCMA use and acceptance in the complex healthcare setting, and can unify the voices and experiences of those using the technology. This should not just enable people to compensate for poor design but also guide system designers to improve system design and therefore patient safety.

AUTHOR CONTRIBUTIONS

Rachel Williams- protocol design, literature review development, literature search, analysis, manuscript writing. Reham Aldakhil- Independent second literature search, review of themes and manuscript review.

Prof Ann Blandford- Protocol guidance, review and guidance on search strategy, identified themes and manuscript review and finalising.

Dr Yogini Jani- Protocol guidance, review and guidance on search strategy, identified themes and manuscript review and finalising.

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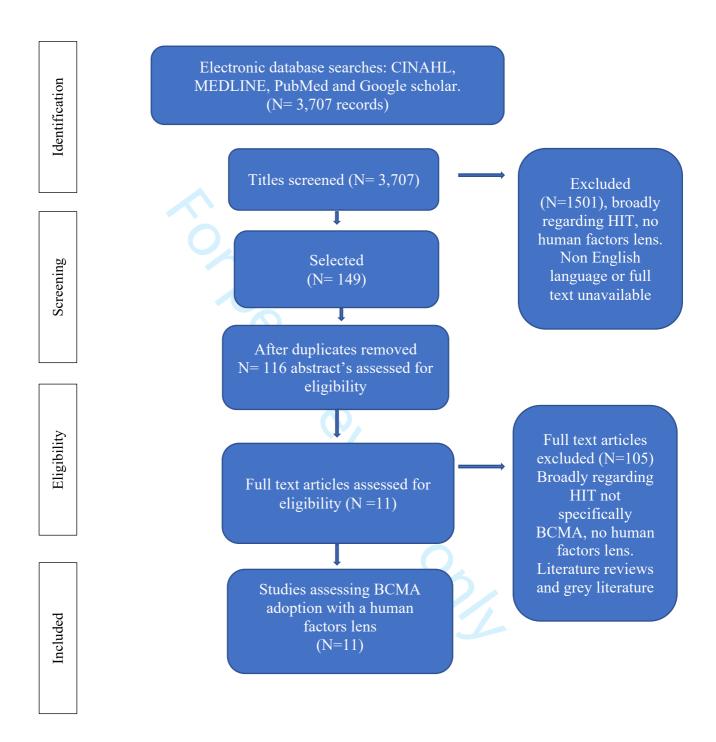
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FIGURE 1- PRISMA FLOW CHART



(25)

PRISMA= Transparent reporting of systematic reviews and meta-analyses, CINAHL= Cumulative Index of Nursing, and Allied Health literature, BCMA= Barcode medication administration, HIT= Health information technology.

Reporting checklist for systematic review and metaanalysis.

Based on the PRISMA guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMAreporting guidelines, and cite them as:

Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement

30 31			Reporting Item		Page Number
32 33 34	Title		Ċ,		
35 36 37 38 39 40	Abstract	<u>#1</u>	Identify the report as a systematic review, meta-analysis, or both.	1	
41 42 43 44 45 46 47 48 49 50	Structured summary	<u>#2</u>	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number	2	
51 52 53 54 55 56 57 58 59 60	Introduction Rationale	<u>#3</u> Fo	Describe the rationale for the review in the context of what is already known.	3, 4 khtml	
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1 2 3 4 5	Objectives	<u>#4</u>	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
6 7	Methods			
8 9 10 11 12 13 14	Protocol and registration	<u>#5</u>	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address) and, if available, provide registration information including the registration number.	Review protocol submitted with paper
15 16 17 18 19 20 21	Eligibility criteria	<u>#6</u>	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rational	4, 5
22 23 24 25 26 27 28	Information sources	<u>#7</u>	Describe all information sources in the search (e.g., databases with dates of coverage, contact with study authors to identify additional studies) and date last searched.	4, 5
29 30 31 32 33 34	Search	<u>#8</u>	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Demonstrated in the PRISMA flowchart (Figure 1) and detailed in study protocol
35 36	Study selection	<u>#9</u>	State the process for selecting studies (i.e., for screening,	4,5.
37 38 39 40 41			for determining eligibility, for inclusion in the systematic review, and, if applicable, for inclusion in the meta- analysis).	PRISMA flow chart attached (Figure 1)
42 43 44 45 46 47 48	Data collection process	<u>#10</u>	Describe the method of data extraction from reports (e.g., piloted forms, independently by two reviewers) and any processes for obtaining and confirming data from investigators.	5
49 50 51 52 53	Data items	<u>#11</u>	List and define all variables for which data were sought (e.g., PICOS, funding sources), and any assumptions and simplifications made.	Included in the study protocol.
54 55 56 57 58 59	Risk of bias in individual studies	<u>#12</u>	Describe methods used for assessing risk of bias in individual studies (including specification of whether this	Described in the study protocol.
60		FC	or peer review only - http://bmjopen.bmj.com/site/about/guidelines.x	ntml

Page 3	9 of 39		BMJ Open	
1 2 3			was done at the study or outcome level, or both), and how this information is to be used in any data synthesis.	
4 5 6	Summary measures	<u>#13</u>	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
7 8 9 10 11 12	Planned methods of analyis	<u>#14</u>	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis.	N/A
13 14 15 16 17	Risk of bias across studies	<u>#15</u>	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
18 19 20 21 22	Additional analyses	<u>#16</u>	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
23 24 25	Results			
23 26 27 28 29 30	Study selection	<u>#17</u>	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a <u>flow diagram</u> .	PRISMA flow diagram attached (Figure 1)
31 32 33 34 35	Study characteristics	<u>#18</u>	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citation.	Study characteristics detailed in Table 1.
36 37 38 39	Risk of bias within studies	<u>#19</u>	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	N/A
40 41 42 43 44 45 46	Results of individual studies	<u>#20</u>	For all outcomes considered (benefits and harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
47 48 49 50 51	Synthesis of results	<u>#21</u>	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency.	Detailed in Themes table (Table 2).
52 53 54 55 56 57 58	Risk of bias across studies	<u>#22</u>	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
59 60		Fc	or peer review only - http://bmjopen.bmj.com/site/about/guidelines.x	html

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1 2 3 4 5	Additional analysis	<u>#23</u>	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
6 7	Discussion			
8 9 10 11 12 13 14	Summary of Evidence	<u>#24</u>	Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers	13
15 16 17 18 19	Limitations	<u>#25</u>	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	13
20 21 22 23 24 25	Conclusions	<u>#26</u>	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13, 14
25 26 27	Funding			
28 29 30 31 32	Funding	<u>#27</u>	Describe sources of funding or other support (e.g., supply of data) for the systematic review; role of funders for the systematic review.	3
 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 		can be ration	klist is distributed under the terms of the Creative Commons completed online using https://www.goodreports.org/, a too with Penelope.ai	ol made by the <u>EQUATOR</u>

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AN INTERDISCIPLINARY SYSTEMATIC REVIEW: DOES ALIGNMENT BETWEEN SYSTEM AND DESIGN SHAPE ADOPTION AND USE OF BARCODE MEDICATION ADMINISTRATION TECHNOLOGY?

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Primary Subject Heading :	Qualitative research
Secondary Subject Heading:	Health informatics
Keywords:	QUALITATIVE RESEARCH, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health informatics < BIOTECHNOLOGY & BIOINFORMATICS

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AN INTERDISCIPLINARY SYSTEMATIC REVIEW: DOES ALIGNMENT BETWEEN SYSTEM AND DESIGN SHAPE ADOPTION AND USE OF BARCODE MEDICATION ADMINISTRATION TECHNOLOGY?

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Word count (Excluding title page, abstract, references, figures and tables)

5,811 words

ABSTRACT

Background:

In order to reduce safety risks associated with medication administrations, technologies such as barcode medication administration (BCMA) are increasingly utilised. Examining how human factors influence adoption and usability of this technology can potentially highlight areas for improvement in design and implementation.

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Objective: To describe how human factors related determinants for BCMA have been researched and reported by healthcare and human computer interaction disciplines. **Data sources**: The Cumulative Index of Nursing, and Allied Health literature (CINAHL), PubMed, OVID MEDLINE and Google scholar.

Study eligibility criteria: Primary research published from April-2000 to April-2020, search terms developed to identity different disciplinary research perspectives that examined BCMA use, used a human factors lens and were published in English.

Synthesis Methods: Computerised systematic searches were conducted in four databases. Eligible papers were systematically analysed for themes. Themes were discussed with a second reviewer and supervisors to ensure they were representative of content. **Results**: Of 3,707 papers screened, eleven were included. Studies did not fit neatly into a clinical or HCI perspective but instead uncovered a range of overlapping narratives, demonstrating consensus on the key themes despite differing research approaches. Prevalent themes were misaligned design and workflow, adaptation and workarounds, mediating factors, safety, users' perceptions, and design and usability. Inadequate design frequently led to workarounds, which jeopardised safety. Reported mediating factors included clarity of user needs, pre/post implementation evaluations, analysis of existing workarounds and appropriate technology, infrastructure and staffing.

generalise findings.

Conclusion: Evaluating interdisciplinary perspectives including human factors approaches identified similar and complementary enablers and barriers to successful technology use. Often, mediating factors were developed to compensate for unsuitable design; a collaborative approach between system designer and end users is necessary for BCMA to achieve its true safety potential.

Keywords: Human factors, Human computer interaction, usability, workarounds, design, Barcode medication administration, patient safety.

ARTICLE SUMMARY

Strengths and limitations of this study

Strengths:

- The search strategy captured literature from both healthcare and human computer interaction perspectives, providing a rich understanding of the factors.
- A second reviewer repeated the initial search with a high level of agreement and reviewed the data extraction process and theme selection to ensure findings were representative.
- The PRISMA checklist was used to design the study protocol.

Limitations:

- Most studies included were relatively small in terms of number of participants and usually conducted in just one or two hospitals, primarily in the United States.
 - Qualitative methodology was prevalent in the selected studies, making it difficult to generalise findings.

FUNDING STATEMENT

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COMPETING INTERESTS STATEMENT

There are no competing interests to declare.

DATA AVAILABILITY STATEMENT

All data relevant to the study are included in the article or uploaded as supplementary information.

BACKGROUND

The prevalence and subsequent harm caused by medication errors has galvanised efforts to develop systems, policies and technologies to prevent medication errors (1–5). Medication administration errors are the most common adverse events in hospitals; it has been estimated that a patient will experience one medication error per 24 hours as an inpatient (6,7). Annually, an estimated 237 million 'medication errors' occur in the NHS in England; 72% do not cause harm but 66 million are clinically significant. Avoidable adverse drug reactions

contribute to 1700 and cause an estimated 700 death per year, at a financial cost of £98.5 million (4).

Medication management and administration in the hospital setting encompass a complex and interlinked series of events and individuals, including pharmacists, doctors, nurses, stock managers and patients. There are many opportunities in this chain to intercept errors which may lead to adverse events, and it is hard to estimate how many potential errors are intercepted before they reach the patient (4). However, medication administration has been identified as the phase where intercepted at the point of administration (7–10). To mitigate some of these risks, bar code medication administration (BCMA), usually in conjunction with an electronic medication administration record (eMAR), has been promoted to reduce the prevalence of medication administration errors (1,11,12).

Bates argues that the causes of frequent medication error are relatively simple: the bulk of the systems in place were not formally designed, and are not subject to the stringent regulation processes used in other high risk industries such as aviation (13). Furthermore, healthcare is complex: it is highly regimented and systematic whilst also being unpredictable, requiring clinicians to constantly learn alongside their practice, often adapting to conform to local policies; this presents many challenges for clinicians navigating safe practice (14). Health information technologies (HIT), such as BCMA, seek to ensure safety for both patient and clinician.

BCMA technology incorporates the "five rights of medicines administration" (right drug, right time, right patient, right dose, right route) into an automated system (15,16). BCMA automates and records each medication administration and prompts the user to ensure it meets the required safety standard, warning the user if any discrepancy between prescription and administration detail is identified. For example, if the barcoded patient identification band does not match the selected electronic medication chart, an alert will notify the user of the mismatch, and prompt them to check they have the right medication for the right patient, potentially avoiding a "wrong patient" error (1,11). Whilst BCMA technology can reduce some medication rates (17), it can exacerbate others, or even cause new types of error to occur (11–13). The literature presents a complex picture of unintended consequences following

BCMA implementation, indicating that the overall effect of a new health information technology, such as BCMA, is often difficult to predict (13,18).

From a human factors perspective, the belief that adopting health information technologies such as BCMA will lead to improved safety outcomes is termed 'magical thinking'; rather, successful adoption is complex, reliant on many mediating factors and context dependent (19,20). The introduction of any new work system will have a transformative effect on the established workflow; successful adoption is not guaranteed, but a positive outcome may result from the comparison and clarification of the established and proposed systems (20–23). However, unintended consequences such as workarounds may also occur.

Human factors models such as systems engineering in patient safety (SEIPS) have been instrumental in understanding the factors that influence successful implementation of BCMA and other HIT (24). Such models examine the wider context in which work takes place, acknowledging that adverse events are rarely caused by one individual, but from a series in interconnected events (25). A human factors lens can be used to examine multiple factors such as environment, organisation, technology and tasks, to gain understanding of why errors occur and how to prevent them (25).

This literature review identifies factors which enable and limit the use of BCMA, during the implementation phase and beyond, by using a human factors lens to capture primary research from both users and implementers of the technology. Human factors approaches can often expose the root causes of undesirable outcomes, and by using a search strategy that captures research from across the spectrum of those designing and using the technology, it may be possible to develop implementation strategies that enable effective BCMA implementation and long-term use.

METHOD

Search strategy

Multiple key words were developed using terminology that would identify literature from healthcare, design, and informatics perspectives using a human factors lens. The preferred reporting items for systematic reviews and meta-analyses (PRISMA) was utilised as a guide for literature review protocol development (26). The Cumulative Index of Nursing, and Allied Health literature (CINAHL), PubMed, OVID MEDLINE and Google scholar were systematically searched for literature produced between April 2000-April 2020. Search terms were combined with Boolean operators and were adapted to match database terms. A document detailing the search strategy is available as a supplementary file (Search Strategy).

Selection process

The selection process is displayed in figure 1. Full text, English language, peer reviewed papers of primary research were included; grey literature and literature reviews were excluded. The results from each database were compared and duplicates removed. Abstracts of the remaining papers were reviewed against the inclusion criteria and if the study included BCMA, usability and a human factors approach it was considered eligible and the full text was reviewed for inclusion. The paper did not have to explicitly state human factors in the title, as long as human factors principles were evident in the methodology. For example, workarounds are frequently studied in relation to BCMA; studies using human factors principle to understand the causes of workarounds were included, but studies examining workaround prevalence, in relation to error, without examining underlying causes were excluded.

PRISMA flow chart- Figure 1

Data Extraction process

A second reviewer (RA) repeated the search and study selection process, resulting in a high level of agreement (76%) for study eligibility through titles review. The level of agreement for final inclusion was very high, with both reviewers agreeing on 10 of the 11 studies following discussion all 11 were included in the review. Thematic data extraction was performed by RW, with the emergent themes developed iteratively through discussion with AB and YJ. RA reviewed a selection of the papers and associated thematic extraction and agreed that the identified themes were appropriate and representative of the study findings.

Patient and Public Involvement

BMJ Open

No patient or public involvement was sought in the development and execution of the literature review. No personal or identifying private health information would be derived from the public sources being searched.

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TABLE 1: EXTRACTED CHARACTERISTICS OF SELECTED STUDIES

BCMA = Barcode medication administration, CPOE=Computerised physician order entry, STROBE=Strengthening reporting of observational studies in epidemiology, PIS= Pharmacy information system, eMAR= electronic medication administration record, PICU=paediatric intensive care unit, HIMSS= Health information and fanagement systems society, EHR= electronic health record, ICU= Intensive care unit

al. 2013. wor (27) alte	o Study of orkflow teration	• Comparison groups- Pre/post	•Observation of nursing	Cognitive		Technology Do ad	
al. 2013. wor (27) alte	orkflow	1	C C	Cognitive		Ō	
(27) alte		groups- Pre/post		Cognitive	• Paediatric hospital.	Software vendor:	•Notes BCMA research often focused on
	teration		practice (post- 47hrs, Pre- 89.5	systems	• 236 bed.	Centricity pharmacy (GB	distal outcomes (adverse events).
fo11		BCMA	hrs.)	engineering	• United states.	Healthcare).	• Often BCMA research does not explore
1011	ollowing BCMA	implementation.	•Interviews with 45 nurses post	approach	• ICU, haematology/	Integrated BCMA with 😽	underlying causes.
imp	nplementation.		BCMA Implementation.		oncology unit and a	CPOE, PIS and eMAR.	•Does not focus on impact on safety as an
			•Data collection Feb-Mar 2008.		general	Implemented Dec 2016.	outcome.
					medical/surgical	n.br	•Usability and design focus.
					unit.	mj.o	
Holden et To	o Study how	 Comparison 	•Nurse survey conducted	The human	•Two large	Software vendor: Uncleage.	•States that safety is not the outcome of
al. 2011. BC	CMA may	between BCMA	pre/post implementation.	factors model of	paediatric hospitals.	Integrated BCMA and 9	interest.
(20) imp	nprove or	and non-BCMA	•Additional data of 200 hrs of	health IT impact	•United States.	CPOE with pharmacy	•Focus on nursing workflow, usability an
woi	orsen outcomes	hospitals.	nurse practice observation, and			checking of orders in place	design issues.
usir	sing a human		68 short interviews with			(PIS). BCMA accessible	
fact	ctors lens.		BCMA users.			via eMAR.	
			•Additional data collected			Implemented Dec 2006.	
			during a previous study.			y guest.	

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	Novak et To Identify •An ethnographic •50 hrs observation of Technology use One US hospital Software vendor: Uncleage •Implementation process may information										
					1	2020-0					
Novak et al. 2012. (28)	To Identify strategies that mitigate the risks associated with BCMA implementation.	•An ethnographic case study.	 •50 hrs observation of mediator/nurse interaction during BCMA implementation. •Additional data: Unstructured interviews, training, meeting minutes and emails. 	Technology use mediation (TUM) framework.	One US hospital with an Informatics support team (IST).	Software vendor: Unclear CPOE and EHR in use prior to BCMA on implementation. Software vendor: Unclear Software vendor: Unclear	 Implementation process may influsively outcomes, but not examined study. Highlight s that clinical staff can communicate design issues identified designers. 				
Neuclast	To study of	- Missed weather de	- Studies) 120 has sharmation	Emmer of	- True la nue	Ownlo	- Inclusion and design the f				
Novak et al. 2013.	To study of collisions between	• Mixed methods study.	• Study a) 120 hrs observation during implementation of	Frames of reference-	• Two large paediatric hospitals.	BCMA and CPOE with \mathbf{Q}	• Implementation and design the for safety.				
(29)	nursing		BCMA, interviews with 27	Author	• United states.	pharmacy checking of	 Designs impact on workflow and workarounds discussed. 				
	orientation (Practice frame)		nurses post implementation and notes from meetings and	discussed finding in terms		orders in place (PIS). BCMA accessible via	Current separation in the research				
	and the		emails.	of system frame		eMAR. Study a) 2007	between user concerns (patient safe				
	technology		• Study b) 90hrs observation	and Practice		BCMA rollout, study B)	and design concerns (Usability).				
	orientation (the		pre and 47 hrs post BCMA	frame.		Ō	• A balance of user and design				
	system frame) and		implementation.			2006 BCMA rollout.	perspectives could improve overall				
	resulting		• Interviews with 45 nurses								
	adaptions.		postimplementation.			, , , , , , , , , , , , , , , , , , ,					
Rack et	To determine the	Mixed method	• Survey (n=220 respondents).	Complexity	• One 765 bed	Software vendor: unclear	Need for design and clinical				
al. 2012.	existence,	study.	• Focus groups with nurses. (6	theory	Hospital.	BCMA implemented in $\frac{6}{2}$.	collaboration highlighted.				
(30)	frequency, and		conducted, 12 nurses in each).		• United States.	2004, CPOE introduced	• Focus on how poor design leads t				
	potential causes of		Review of medication errors		• Three different	2008	workarounds.				
	workarounds, and		and how they related to		BCMA systems	2008 2024 by guest	• Safety not the outcome of interest				
	to determine		BCMA.		implemented in	υ γί					
	whether		• Interviews with nurses		three years.	ues					
	workarounds were		responsible for medication			· · · · · · · · · · · · · · · · · · ·					
	a factor in serious		errors.			rote					
	medication error,					ecte					
	to determine if					Protected by copyright.					
	BCMA could					y c					

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Staggers	have prevented the error. To understand	Evaluation.	• Evaluators completed the	• Heuristic	• One Veteran's	Software vendor: VistAloaded Include EHR, computerised patient record system (CPRS), rated stage 7 HIMSS.	• Focus on usability problems, design
(31)	how BCMA effects situational awareness in nurses and to identify the usability issues responsible.	Evaluation.	 BCMA wed based training for nurses in order to develop a list of usability problems. BCMA co-ordinators reviewed and refined usability issues. 	 valuation (Zhang). Severity rating (Nielsen). 	 One veteral s hospital United states. Hospital included ICU, medical and surgical units. 	BCMA and eMAR	• Designers need to better understand
Van der Veen et al 2018. (32)	To study the association between workarounds and medication administration errors when using BCMA, and to determine frequency, type of workaround and type of error.	A prospective observational study.	Direct observation of 5793 medication administrations on 1230 inpatients.	No theoretical framework used.	Four Dutch hospitals of varying size.	BCMA and CPOE implemented in all 4 hospitals using a variety software. April 28, 2024 by guest. P	 Safety as outcome measure. Association between med error and workarounds studied. General Design issues identified as a possible cause of workarounds but not specifically studied. Need for collaboration not discussed.
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Holden et al. 2012. (33)	To identify predictors of nurses' acceptance of BCMA.	A cross sectional survey	Survey (n=83). •August- Nov 2007.	Technology acceptance model (TAM)	 Paediatric hospital Recently implemented BCMA. 236 bed United States. PICU, haematology/oncolo gy/ bone marrow transplant unit and a medical/surgical unit surveyed. 	Software vendor: 44 Centricity pharmacy, GE healthcare). BCMA, 00 CPOE, PIS and automated medication-dispensing 20 cabinets. Implementatio 2007 . Downloaded from	• Study of predictors of technology acceptance to influence design. Safety not an outcome of interest
Koppel et al. 2008. (7)	To study the occurrences, causes and threats to safety of workarounds.	Mixed method study	 Analysis of BCMA data of 307,698 medication administrations. Observations N=62. Shadowing N=31. Semi-structured interviews N= 29. 13 specialists, including pharmacists, and nurse leaders interviewed. Data collection 2003-2006. 	System engineering in patient safety (SEIPS) model used.	 Two large hospitals for the Observed Five hospitals interviewed. United States. 	Software vendor: Siemen medication administration check and McKesson, BCMA and display eMAR BCMA and display eMAR	 Poor design and implementation lead t workarounds. Design issues explored, medication error as a result not examined Importance of collaboration between designer and user highlighted.
Patterson et al. 2006. (34)	To identify the types and extent of workaround strategies with the use of BCMA.	A prospective ethnographic study	 Direct observation n=15 acute care and n=13 long term care nurses. 79 hours of observation in total. Opportunistic interviews with observees'. BCMA override data analysed. 	Standard activity protocol.	 Small, medium and large veteran's administration hospitals. United states. 	Software vendor: Unclear BCMA in use since 2004 CPOE and PIS.	 Safety risk of workarounds Practical hardware design issues Usability of BCMA not explored Context of use should be a design consideration.
			•BCMA override data analysed.			ed by copyright	

				ВМЈ Ор	en	BCMA and CPOE implemented in all 4		
						en-2020-		
Van der Veen et al 2020. (11)	To identify possible risk factors associated with workarounds using BCMA technology.	A prospective observational study.	Direct observation of 5793 medication administrations on 1230 inpatients	STROBE checklist for reporting data.	Four Dutch hospitals of varying size.	hospitals using a variety software.	• Practical factors such as staffing	
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RESULTS

Study characteristics

Nine of the eleven papers included were primary studies. The exceptions were Novak's 2013 study(29), which reanalysed data from two previous studies (27,28) (both included in the selected studies) to examine a new research question and Van der Veen's 2020 study (11) on factors which contribute to the occurrence of workarounds, which reanalysed data from their 2018 study (32) to explore a different facet to the original research (also included in the selected papers).

Various study designs and methodologies were used to investigate BCMA implementation and use. All studies were qualitative or mixed methods, gathering data by observation of practice or a combination of observation, survey, focus groups, and interviews. Multiple papers also collected quantitative data, such as medication error reports (30), and BCMA override data (7,34). Theoretical frameworks were used in all studies except for Van der Veen's work (11,32). The majority of the frameworks originated in the human factors field, including SEIPS, the technology acceptance model and complexity theory. Full details of the frameworks used are listed in Table 1. Three studies used statistical methods to analyse their findings, Patterson and colleagues established statistical significance of a higher incidence of workarounds in long-term care when compared to acute care (93% vs. 23%, p<.001) (34). Van der Veen and colleagues utilised logistic regression analysis to assess the association between workarounds and medication error and identify factors which contribute to the occurrence of workarounds (11,32). Holden and colleagues used regression models to predict acceptance of new technologies, using general linear mixed models with repeated measures to examine user perception of BCMA both pre and post implementation (20). Further studies led by Rack (30) and Koppel (7) presented survey results and override data as percentages of agreement but did not present any further statistical analysis. The remaining studies used thematic analysis to establish emergent themes, with differing methods. Holden's 2013 study used descriptive coding (27), Novak's 2012 study used qualitative data analysis software to transcribe and analyse fieldnotes (28), whereas Novak's 2013 study utilised researchers independently assessing their fieldnotes for themes before discussing as a group and finalising theme inclusion (29). Staggers' study (31) differed from the others in terms of data collection and analysis: this team studied online BCMA training routinely undertaken by

nurses. The researchers used heuristic evaluation methods to establish usability problems with the technology and rate how this affected users' situational awareness. A severity score was then assigned to the usability problem to establish the safety risk posed by the usability issue identified. Studies varied in terms of length, number of participants, use of comparison sites, pre/post analysis and settings as detailed in table 1.

Research focus

The studies included in this review use human factors methods with a range of research focuses and diverse narratives on BCMA adoption, use and success. Holden (27,33), Novak (28), and Staggers (31) studied the design and usability of BCMA systems and the effects of pre-existing workflows at various stages of BCMA implementation and use. The safety risks introduced by poorly aligned BCMA design and clinical workflow were acknowledged as a distal outcome of poor design but were not the focus of these studies. Rather, this group of studies highlight how workarounds can identify design flaws. This is in line with Koppel's (7) and Rack's (30) studies on the causes and frequency of workarounds; they concluded that poor design could increase their prevalence and have long term consequences for safety whilst not explicitly studying design issues or safety outcomes, and instead focusing on workarounds. In parallel, Van der Veen (11,32) and Patterson (34) studied the patient safety risk presented by the use of workarounds in the clinical setting, focusing on the consequences of circumventing the safety features of BCMA, acknowledging that their root may be in poor design, but not further commenting on particular design failures. Holden (33) examined users' perspectives of BCMA use pre and post implementation, adding another dimension to understanding technology acceptance and suggesting that user perception and not just the study of workarounds can aid iterative design. A further perspective is presented in Novak's (29) study of an informatics team which implemented BCMA technology into clinical practice; as professionals with both clinical and informatics expertise, their experience is highly valuable to those planning to implement BCMA technology into the healthcare setting.

The differing research focus in the field of BCMA study is discussed in two of the papers (27,29). Holden (27) noted that BCMA research routinely focuses on the relationship between adverse events and workarounds, arguing that investigating the outcome alone does not enable identification of the causes of workarounds and neglects design issues that may be responsible. Novak (29) proposes that future research must do more to understand the

1 2	
3	perspective of the workers, designers and implementers, to better understand factors affecting
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6	successful BCMA use.
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TABLE 2: HUMAN FACTORS RELATED THEMES FROM THE STUDIES

BCMA = Barcode medication administration, SEIPS= System engineering in patient safety

	HUMAN FACTO					36/bmjopen-2020-044419 on 1 July 802
Author, date	Misaligned design &	Adaptation &	Usability & design	Factors which mediate	User perception	Safet
	workflow	Workarounds		BCMA use		021
Holden, et al.	BCMA limited	Workarounds	Poor BCMA			• Safety concerns
2013. (27)	ability to plan ahead.	mask design flaws.	usability.			regarding the use of
	 Narrowed field of 	The designer and	• Poor fit between			paper docun
	vision of user.	organisation maybe	BCMA and existing			identified.
	 Focused on specific 	unaware of these	technology.			fro
	timepoints.	design flaws and/or	• Paper			B B
	• Limited user access	workarounds.	documentation used			ittp://
	to vital patient		to communicate			//br
	information.		information lost			njo
	• Did not reflect the		between BCMA and			Den
	complexity of clinical		existing technology.			.br
	work.					ji.co
	• Did not fulfil user					Ŭ, Ŭ
	need.					9
Holden, et al.	BCMA Transformed	Healthcare		• Studying user		Apr
2011. (20)	existing workflow.	workers adapt to		perception of BCMA		
	Changed health	new work systems		can improve design and		8, 2
	outcomes.	with their own goal		acceptance.		022
	 Poor designer 	achieving strategies.				4 by
	understanding of	Poor compliance				nɓ ,
	original workflow led	with design use is				lest.
	to poor acceptance of	frequently observed.				identified. identified. Protected

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Novak, et al. 2012. (28)	• BCMA was misaligned to technology use practices.	• Workarounds frequently identified in study.	• Iterative process of design and evaluation advocated.	• Implementation mediators can help mitigate negative unintended consequences caused by BCMA implementation and limit the development of workarounds.	• Expectations should be set for nurses prior to implementation of BCMA so they understand its advantages and disadvantages.	96/bmjopen-2020-044419 on 1 July 2021. Downloage erigid desiage
Novak, et al 2013. (29)	 Temporal design focused on timepoints. Difficulty planning ahead Design not reflective of the complexity of clinical work. Inflexible when a plan changes. Design based too rigidly around the 5 rights. Clinical judgement of nurses not considered. Poor design led to the use of paper handover documents for communication. 	 Workarounds implemented to improve efficiency. Safety features of BCMA not aligned with user safety concerns, resulting in workarounds. 	• Iterative process of design and evaluation advocated.	r evie	 Stigma of late doses, resulting in nurse's avoidance strategies. Compliance with BCMA used as a performance measure. Nurses show willingness to comply with BCMA but are still having the resort to workarounds to complete tasks. 	Rigid design reduce critical thinking in more potentially importantially importantially implementing BCMA does improve media safety. BCMA not all with user sale concerns 28, 2024 by guess

				BMJ Open		/bmjopen-20
Rack, et al. 2012. (30)	 Design focused user on single timepoint. Difficulty accessing information on previous medication administration. Reduced ability to communicate concerns/errors with wider team. Vital patient information difficult to access, delaying administration. Five rights used as 	• Workarounds in response to poor design.	• BCMA Technology should be designed in such a way that using it appropriately is easier than working around the system.	 Regular Maintenance of hardware reduces frustration for users and improves compliance with use. Responsibility for the maintenance of hardware should be considered prior to implementation. 	 Nurses should not be given the impression that BCMA use is faster. Safety benefits should be emphasised. 	36/bmjopen-2020-044419 on 1 July 2021. Downloaded from http://bmjopen.b
Staggers, et al. 2015. (31)	 Five rights used as BCMA design basis too rigid. Workflow twice as long with BCMA use. Poor fit with existing workflow and user need. 	Workarounds discussed in relation to misaligned design and workflow. Workarounds	 High volume of usability issues identified. Better design needed to improve 	- 16	• User perception discussed in relation to misaligned design and workflow	Poor usability and design are a safety risk. Safety features of BCMA compton
	 Temporal focus on time point can blinker users to wider issues. Design too inflexible for the complexity of clinical work. 5 Rights interpreted too rigidly during design process. 	developed in response to poor design.	user situational awareness. User centred design advocated. • Design should support patient journey through the hospital.			by workaroughts. • Reduced situation awareness least increased safety r guest. Protected by copyright.

				BMJ Open		• Poor desig
Van de Veen, et al. 2018. (32)	 BCMA did not fit well with existing workflow. Issues with hardware and software identified. 	• Statistically significant association between workarounds and medication administration errors	• Poor human- machine interface result in healthcare workers working around the system, compromising safety.	• Post implementation evaluation recommended for BCMA to achieve it full benefits.		resulting in $\frac{1}{6}$ workaround g produce a safet
Holden, et al. 2012. (33)	• May not be financially worthwhile for organisation.	• Poor design results in a lack of acceptance and workarounds.	 Design and usability discussed in relation to workarounds. BCMA difficult for some to use. 		 BCMA users' perceptions of new technologies should be studied in order to influence their acceptance. Studies of acceptance can predict technology use. 	July 2021. Downloaded from http://bmjopen.bmj.com/ on April 28, 2004
Koppel, et al. 2008. (7)		 SEIPS model used to identify causes of workarounds. Workarounds can increase medication error risk. Work arounds have multiple causes and cause 	• Organisational and technology related causes were found to be associated with all 15 of the identify workarounds.	• Study of workarounds can highlight design issues and find solutions.		Workarount the potential by present a safety protected by copyright.

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				BMJ Open		36/bmjopen-2020-
		subsequent workarounds.				044419 on 1 July 202
Patterson, et al. 2006. (34)	 Design did not reflect context of use. To prevent adverse events following BCMA implementation, existing workflow should be studied and designed accordingly. 	 Work arounds increase error risk by bypassing safety technology of BCMA. Workarounds may go undetected or be acknowledged and tolerated by organisations. Nurses expressed concern of how workarounds reflect on them as professionals. 	 Redesign could reduce frequency of workarounds. Redesign could improve efficiency. User perception of inefficiency increased workarounds. Improved reliability of hardware would reduce workarounds. 	rev;	 Nurses who felt their goals were jeopardised by inefficient BCMA justified the use of workarounds. Disciplining non- compliance found to be ineffective if the nurse felt they were acting in the interest of the patient. 	36/bmjopen-2020-044419 on 1 July 2021 are a • Workaround Source of the safety risk. Safety risk of the safe
					0	April 28, 2024 by guest. Protected by copyright.

Page 23 of 48			BMJ Open		36/bmjopen-20
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Van der Veen, 2020. (11)	 Workarounds more frequent on busy weekdays than weekends. More likely to occur with a higher patient to nurse ratio. Not associated with ability to scan barcode. Increased work pressure increased 	 Increased staffing. Redesign to make BCMA more efficient. 	• As work pressure increases the frequency of workarounds also increases.	020-044419 on 1 July 2021. Downloaded from h
18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42		workarounds.	Te Vie	3 W OJ	36/bmjopen-2020-044419 on 1 July 2021. Downloaded from http://bmjopen.bmj.com/ on April 28, 2024 by guest. Protected by copyright.

THEMES

Each study employed unique approaches to better understand BCMA use and success; nevertheless, many themes were evident in multiple studies. The main themes identified were misaligned design and workflow, adaptation and workarounds, factors which mediate BCMA use, safety, users' perception, and design and usability. A summary of these themes is presented in Table 2.

Misaligned design and workflow

Many studies found that BCMA system design and clinical workflow were misaligned, limiting the user's ability to plan ahead and prioritise (20,27–32,34). This mismatch seemed to result from BCMA design underestimating the complexity of nurses work, and how frequently they have to adapt to individual, environmental, institutional and technological factors beyond their control (30).

During direct observation, nurses were seen to frequently adapt and reorganise their work to achieve their goals and optimise patient care, putting them at odds with the sometimes inflexible BCMA design (29,31). A frequent observation was that BCMA design focuses the user on single timepoints, assuming that nurses complete tasks at scheduled times, whereas in practice nurses' work involves prioritisation, making the importance of timeliness context dependent (20,29,29–31). BCMA design attempts to focus the user on the specific task of medication administration, but multiple studies found that nurses could not easily access additional information required to safely administer medication such as vital signs, past medical history, and information regarding previous or future doses (29–31). Holden found that this prescriptive design limited users' critical thinking and therefore posed a safety risk (33). Nurses were observed to use paper to record pertinent information because the BCMA design did not give them an overview of their tasks or patients and limited their ability to communicate with colleagues (27). Staggers' study of situational awareness found 99 usability issues with the BCMA system studied, of which 15 were rated catastrophic, arguing that the design did not match the way nurses think or work (31). Van der Veen and colleagues also found that the BCMA did not fit well with daily workflow of nurses who encountered both software and hardware blockades (11).

Adaptations & Workarounds

All studies which conducted observation in the clinical setting reported workarounds associated with BCMA technology. Although the consequences and causes of workarounds varied greatly, there was agreement that workarounds undermined the safety features of BCMA technology.

Patterson's BCMA compliance study found that workarounds reduced technology effectiveness and increased the risk of adverse events (34). Van der Veen's found a statistically significant relationship between workarounds and medication error: 6% of the workarounds resulted in the wrong dose being administered and 78% of the workarounds were medication omissions (32). Van der Veen and colleagues reanalysed this data to look for factors which made workarounds more likely, finding a statistically significant relationship between high patient to nurse ratios and workarounds, arguing that increased work pressures led to an increase in the prevalence of workarounds (11).

Holden found that BCMA triggered multiple types of problem-solving behaviours. He notes that the problem solving itself was a "double edged sword", preventing failures missed in the design process, thus concealing design flaws, preventing redesign (27). For example, the use of paper artefacts to record patient information is potentially dangerous because it is not available to the wider clinical team and the shared information may be out of date. The use of paper artefacts conceals the user need and introduces a safety risk, which could be alleviated by better design.

Using the SEIPS framework to examine technological, task, organisational, patient related or environmental causes of workarounds, Koppel found that workarounds were complex, resulting from numerous causes and themselves creating additional workarounds (7). Koppel and Holden suggest that workarounds may be unavoidable when introducing technologies that transform workflow. Koppel argues that the study of workaround can highlight design flaws in order to remedy them, whilst Holden suggests that workarounds can be pre-empted and controlled through design (7,33).

Koppel also posits that workarounds are made more prevalent by poor design. Koppel found that workarounds were not only negative but sometimes perceived by users as necessary to

deliver patient care, finding that consequences of workarounds could be positive, neutral or negative (7). Both Koppel and Patterson advocate human factors approaches to study the causes of workarounds instead of simply introducing policies to increase compliance with intended workflows (7,34).

Van der Veen's study (11) examining the factors that contribute to workarounds recommended mandatory nurse to patient ratios, as they found this to be a mediating factor to reduce dangerous workarounds.

Design and Usability

 Design and usability issues were identified by most studies as a factor influencing successful BCMA use.

The studies reviewed linked poor design and implementation to increased medication errors and reduced situational awareness (7,31). Patterson's observational study found that many workarounds could be eliminated by redesign, and many of the processes could be made more efficient (34). Holden argues that usability should be a priority, noting that if the difficulty of use outweighs the benefit, from the user's perspective, workarounds and non-compliance will be more prevalent (27). Rack argues that the goal of design should be to work in such a way that it is easier to use it correctly than work around the system to achieve goals (30).

Many of the papers identified issues with poorly designed hardware and software. Staggers reported frustration and multiple login requests to access the BCMA and eMAR systems studied. Also, the systems could not accommodate patients moving to different areas in the hospital, due to design, which caused confusion regarding whether or not medications had been given. Staggers reasoned that better interoperability and patient centred design could alleviate many of these issues (31). Patterson, Koppel and Rack identified hardware issues such as barcode scanner tethers being too short, workstations on wheels (WOWs) being too bulky to enter treatment rooms and inadequate internet connectivity leading to delays in workflow (7,30,31). Van der Veen found that inadequate human computer interfaces result in frustration and workarounds (32).

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The majority of papers advocated evaluation and re-evaluation during implementation and beyond to take full advantage of safety features and identify the causes of workarounds in order to redesign the system (27,29–32,34). Koppel and Novak advocate ensuring that the designers of the BCMA system understand the current medication administration workflow and environmental and technical factors that may result in poor acceptance and reduce utilisation of new technology. This process should include a pre-implementation assessment to understand user needs and ongoing evaluation, allowing for redesign as issues occur (7,29).

Factors which mediate BCMA use

Many studies identified factors which can ease BCMA implementation, reduce unintended consequences such as workarounds, and improve acceptance of new technologies. Factors identified include conducting research that establishes user needs and perceptions of technologies, engaging individuals who act as mediators for both users and designers, ensuring users are aware of system capabilities and limitations, and organisational commitment to ensuring hardware is maintained and appropriate for the environment, including sufficient staffing levels.

Holden's (20) study into user perception and acceptance examined expectations of use pre and post BCMA implementation. Three aspects of medication administration were studied: matching medication to MAR, checking patient ID, and documentation. After BCMA implementation, nurses reported decreased likelihood of error, increased likelihood of error detection, increased usefulness, accuracy and consistency for matching medication and identifying the patient. However, they also reported decreased time efficiency, and decreased usefulness with regards to documenting actions on the BCMA system. Holden suggests that whilst health information technologies such as BCMA have a transformative impact on workflow, these changes are measurable and can be mediated by design, if users' expectations and needs are explored prior to development and implementation.

Similarly, when examining how to reduce unintended consequences when switching to a new system such as BCMA, Novak (28) argued that users' expectations should be set prior to implementation for them to develop an understanding of system capability and limitations. Novak's study followed a group of mediators who acted as user advocates during BCMA

implementation, maintaining timely communication with hospital management and system designers, resulting in a more iterative and evolving implementation process. This style of implementation helped to mitigate negative unintended consequences.

Rack (30) conducted a survey of 220 nurses using BCMA and held focus groups. Although 90% of survey respondents agreed that BCMA was safer, many recounted situations where compliance with the BCMA system was not possible, 63% reported instances of giving medication without scanning the patient, and 72% reported occasions when they did not scan the medication barcode, and 40% reported sometimes scanning medication post administration. Focus groups discussed scenarios where compliance with BCMA was problematic. 30 scenarios were identified where a workaround was necessary to administer medication, presenting BCMA as no more time efficient but safer. In addition, they note that technology will need maintenance and this needs to be delegated to avoid the frustration of failing or inappropriate equipment. Koppel also noted that users both overestimate the risk elimination ability of BCMA and underestimate the safety features. There is a need for ongoing education to encourage correct use, and for hospital management to thoroughly examine their technological, environmental and social contexts before choosing a BCMA technology (7).

User Perceptions

Two papers reported that user perception impacted on successful implementation and user compliance (31,33). The use of BCMA compliance as a performance measure was found to be unsuccessful and resulted in resistance, particularly where users felt they were acting in the best interests of their patients by employing workarounds. However, users also reported feeling guilt and stigma if they were unable to complete an administration in line with the BCMA system workflow.

Both Novak (28) and Holden (33) identified a reported stigma regarding late doses and how nurses attempted to avoid this stigma via workarounds. In reanalysing these studies, Novak (28) identifies an issue with using BCMA compliance as a performance measure, finding that nurses withholding medication for a legitimate reason were not able to communicate this,

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resulting in the feeling that they had done something wrong. One hospital punished noncompliance and used it as a performance measure whilst the other provided continual coaching of staff with the emphasis on safety. Koppel (7) suggests that it is not enough to tell staff to comply; rather, a constant evaluation of BCMA use is necessary to improve safety. Holden's later study (33) of nurses' acceptance of BCMA found that nurses already dissatisfied with BCMA are unlikely to use it to its full capacity, only being compliant enough to achieve their goals. Patterson(34) also found that policies, sanctions and training were unlikely to improve compliance if users felt that BCMA use jeopardised their ability to provide adequate patient care and achieve their goals. The increased use of workarounds during times of high work pressure reported by Van der Veen suggests that users perceive BCMA as being inefficient, only fully complying with the technology when they have time to do so (11).

Safety

The main purpose of BCMA is to improve patient safety; the majority of studies included in this review did not focus on the safety benefits of BCMA but instead used human factors methods to establish the underlying causes of unintended consequences. Nonetheless, there is some evidence that BCMA has this intended effect; e.g., Koppel analysed 307,698 BCMA alerts as well as focused observations; over 23,000 alerts apparently led to the user changing their action (7). However, these studies are unable to conclude that BCMA is safer, instead finding that BCMA has the potential to improve safety (20,27,29). The issue of improved safety with BCMA technology is complex, and simply having the technology does not make medication administration safer. Increased safety is context dependent, relying on numerous other factors. Rack et al. (30) found that the majority of nurses believed BCMA technology was safer but also reported numerous scenarios where they had to bypass the safety features to administer medication.

DISCUSSION

The aim of this literature review was to identify how human factors influenced the usability and adoption of BCMA use. Studies using a human factors approach revealed a mismatch between BCMA system design and the existing workflow, caused by poor system design, which led to poor user acceptance and the development workarounds which presented a

safety risk to patients. A secondary objective was to describe how human factors related determinants for BCMA have been researched and reported by healthcare and human computer interaction disciplines. However, it became apparent that the studies included could not easily be divided into these two disciplines. Instead, the use of a human factors approach yielded a wide range of narratives, differing time points, outcomes of interest and measures of success. Despite the variety of research focuses, the themes identified were largely complementary and most studies acknowledged how their area of interest was connected to, and had consequences for, the overall themes. What does differ is the measures of success in terms of BCMA use. For those studying design, technologies which fit the existing workflow, address clinical demand and improve user situational awareness are considered successful (20,27,29). For those researching the safety consequences of workarounds, increased compliance with BCMA use, reduced workarounds and hence safer medication administration are markers of success (7,11,30,32,34). For users, increased efficiency was a priority (33), whilst implementers were concerned with user acceptance and appropriate use of the new BCMA system (28). Whilst the measures of success differ, they are all clearly related; the voice missing from this research is that of designers themselves: there is a consensus that system designers do not fully understand user needs and this may be the cause of many of the reported issues; how this is shared with those designing the systems is less clear.

The themes of this review are broadly in line with previous systematic and scoping literature reviews examining BCMA use (14,35,36); it differs by capturing diverse research focuses and outcomes of interest to represent multiple perspectives. Combined, these provide valuable insights into the successful use of BCMA from numerous actors within the process. The inclusion of human factors highlighted the many different research interests and measures of success regarding BCMA use. Some previous literature reviews focused on particular areas of BCMA use, such as safety or design (35,36). Others explored the connection between workarounds and safety, concluding that BCMA has the capacity to reduce medication errors if used correctly(14,37). Voshall (35) advocated improved compliance to realise the safety benefits of BCMA, whilst Hassink (36) highlighted how system design, workflow mismatch and implementation strategies influence the safety of BCMA but noted that the studies reviewed often did not elaborate on how BCMA was implemented or how the workflow mismatch was addressed. Debono's review (14) focuses on workarounds and why nurses use them to achieve their goals; they consider the wider context of healthcare delivery and conclude

that the nurses' perspective must be understood to reduce workarounds and improve bedside care. More recent studies show that medication related factors, such as the time of the medication round and route of administration, and other factors, such as the bar code integrity, may also influence the likelihood of workarounds (11,38). By using human factors research to draw on many different voices within BCMA research, this review provides themes across a spectrum of activity for BCMA, from design to adoption.

By reviewing human factors studies which focus on system design, workflow mismatch, informatics and users, it becomes clearer how the identified themes relate to each other. The misalignment in system designed workflow and clinical workflow stems from designers not fully understanding the nature of work in the healthcare setting, as discussed by eight of the selected papers (19,26,28–32). The juxtaposition of complex tasks coupled with changing priorities seems to clash with the rigid, temporally focused BCMA design reported by several studies (27,29–31). The use of the five rights of medication administration was discussed by Novak and Rack (29,30), suggesting that its use as a guide for BCMA design results in an overly rigid system.

The "five rights" check list which is designed for use by nurses at the point of medication administration is in practice applied with more flexibility than is acknowledge by BCMA system design. In reality there are many occasions when a nurse may have to reframe or rationalise one or more of the "five rights", such as availability of stock, urgency of medication and patient access (27). There is an apparent assumption that a formulaic, stepwise BCMA system will lead to increased safety, but healthcare is complex, the ability to adapt to changing situations is essential, and inflexible systems may clash with the nature of work (39) and result in resistance, workarounds and increased safety risks.

Nurses are frequently required to reorganise their work to achieve quality care, often in response to factors beyond their control such as policy, organisational pressure, available technology and demand (29,40). An important part of the nurse's role is to effectively manage these competing pressures, and to advocate for their patients' needs. This review found many examples of problem solving behaviours in nurses (20,29). Overly prescriptive design in technology challenges nurses' identity and role (14).

Policies enforcing compliance with BCMA technology and disciplining non-compliant users was not found to be effective (34). The BCMA systems studied frequently reduced perceived

efficiency, failed to make essential information available, and reduced critical thinking and situational awareness (26,29,30,32). Poorly designed BCMA creates additional hurdles to patient care and bypassing the BCMA system could be perceived as justifiable if it is in the interests of the patient (31). However, the resulting workarounds circumvent the safety features of BCMA and expose the patient to increased risk of medication error. This conflict was evident in the literature reviewed: nurses agreed that BCMA use was safer but frequently encountered scenarios where they could not complete a task and use the BCMA technology correctly (30). Conversely, users can sometimes overestimate the risk reduction capability of BCMA, relying on the technology to identify an error rather than a combination of the technology and their own clinical judgment (30).

Workarounds were witnessed in every observational study in the review, but the terminology used to describe them differed: from adaptive and problem solving behaviours, to deviations and errors (29,32). The use of different terminology surrounding workarounds implies either negative or positive attitudes towards them (14). In the studies presented, safety focused papers often examined workarounds as an adverse event risk, whilst design and usability focused papers often described them as unavoidable and even informative (27). Many of the papers were divided on the consequence of workarounds (9). While the association between workarounds and medication errors is concerning, most studies acknowledge that workarounds are unavoidable when introducing a transformative technology into an existing workflow, and it is poor design and implementation that make them problematic (7,32).

Studies included in this review agree that many of the problems with BCMA use are rooted in designers not fully understanding the complexity of clinical work. Measures to manage these design mismatches include careful and long-term implementation strategies, organisational and technological structures which encourage correct BCMA use and close monitoring of workarounds. However, many of these strategies seem to be compensating for less than adequate design; how to redesign systems to better match clinical need is not really addressed and the designer perspective is absent from the studies reviewed. However, the differing findings and perspectives act as a powerful message that there is a greater need for close working throughout design and deployment for BCMA to achieve its recognised potential in improving patient safety.

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Implications for clinicians and policymakers

The literature identified many mediating factors and potential strategies for enhancing BCMA use for clinicians, policy makers and users. An understanding of users' perceptions of a new technology prior to implementation can be predictive of overall acceptance and can guide design (20). Employing staff who are trained to act as mediators to ease implementation and act as a bridge between users and designers was found to be helpful by Novak and colleagues (28). Ensuring that software and hardware are appropriate for the environment and properly maintained to reduce frustration and mistrust in technology, along with appropriate staffing levels, require an organisational commitment and cannot be achieved by an individual nurse (11,30). Most studies recommended pre implementation evaluation and constant re-evaluation during the implementation phase with human factors frameworks to identify the causes of poor compliance with technology and inform redesign of the BCMA system. Success is dependent on collaboration between designers, informatics experts, users and the organisation to prevent workarounds persisting and becoming risks to safety. It may be necessary to view BCMA (and other HIT) system vendors as long-term partners, establishing a good understanding of user needs, organisational capability and how usability issues will be addressed following implementation.

Recommendations for further research

As noted above, the designers of BCMA systems are rarely visible in the discourse around their implementation and use. Studies of workarounds tend not to question the details of specific BCMA design, but to focus more on the complexity of the broader system. Further research is needed to better understand how new technologies can be designed and safely implemented into complex healthcare settings. This review, along with others (14,35,36), has made it clear that BCMA technology is a component within a complex system of medication administration. Further interdisciplinary research is needed to better understand how technology to support safer medication administration can be designed to accommodate the complexities of use while also supporting staff in managing that complexity. In parallel, it is important to improve both user experience and patient safety. Future research should also examine the long-term effects of BCMA, not just at the point of implementation but as use evolves over years, to evaluate whether its safety benefits are sustainable as the environment and users change.

Limitations and strengths

Most studies included in this review were small in sample size and conducted in the United States. They relied on qualitative research methodologies such as observation, focus groups and surveys. Many of the studies triangulated their qualitative findings with quantitative data, such as BCMA compliance reports, to better understand what was being observed in practice and to make their findings more generalisable.

As this study particularly examined BCMA implementation with a human factors lens, many BCMA studies were excluded, resulting in only eleven papers being included in the final review. This has given a focused view of the available research including evidence from both healthcare and human computer interaction perspectives.

The search strategy of this review was independently repeated by a second reviewer to reduce the risk of bias, and a good level of agreement was achieved.

CONCLUSION

This review found that successful BCMA use is eased by a clear understanding of existing workflow and user needs; pre, during and post implementation evaluation of BCMA technology to identify workarounds and guide redesign; organisational commitment to understanding and resolving issues with BCMA acceptance; and collaboration between users and system designers. Human factors principles can be used to understand causes of poor BCMA use and acceptance in the complex healthcare setting, and can unify the voices and experiences of those using the technology. This should not just enable people to compensate for poor design but also guide system designers to improve system design and therefore patient safety.

AUTHOR CONTRIBUTIONS

Rachel Williams- protocol design, literature review development, literature search, analysis, manuscript writing.

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Reham Aldakhil- Independent second literature search, review of themes and manuscript review.

Prof Ann Blandford- Protocol guidance, review and guidance on search strategy, identified themes and manuscript review and finalising.

Dr Yogini Jani- Protocol guidance, review and guidance on search strategy, identified themes and manuscript review and finalising.

Ethics Statement

Due to the characteristics of this study design, ethical approval was not required.

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FIGURE 1- PRISMA FLOW CHART

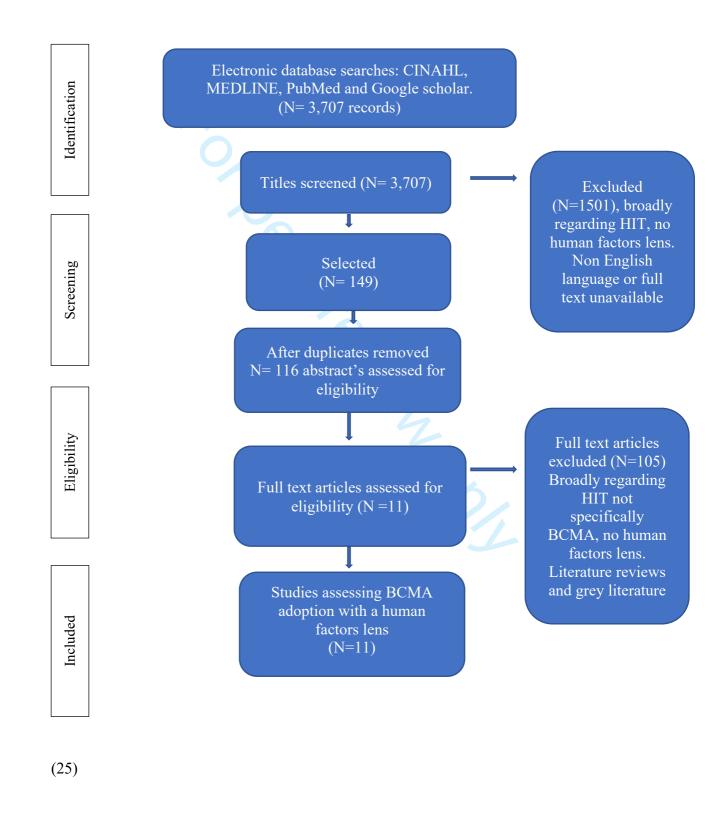
Detailing selection process of studies reviewed. PRISMA= Transparent reporting of systematic reviews and meta-analyses, CINAHL= Cumulative Index of Nursing, and Allied

Health literature, BCMA= Barcode medication administration, HIT= Health information technology.

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FIGURE 1- PRISMA FLOW CHART

Detailing selection process. *PRISMA*= *Transparent reporting of systematic reviews and meta-analyses, CINAHL*= *Cumulative Index of Nursing, and Allied Health literature, BCMA*= *Barcode medication administration, HIT*= *Health information technology.*



Eligibility criteria

Inclusion

- 1. Studies referring to both BCMA and human factors.
- 2. Studies referring to usability and/or systems design and enabling and inhibiting factors to adoption of BCMA.
- 3. Studies after April 2000.
- 4. Primary studies which have been peer reviewed.

Exclusion

- 1. Studies not linking human factors to BCMA.
- 2. Studies researching BCMA and medication errors without human factors.
- **3.** Literature published before April 2000.

Information sources

CINAHL, PubMed, Medline, google scholar.

Search strategy and information sources

Initial google scholar search of systematic reviews to refine key words using search terms: medication administration, BCMA, human factors, systematic reviews, resulted in limited reviews conducted using human factors to examine BCMA. Therefore, keywords were expanded to include the following.

Keywords:

- 1. Human factors, systems design, usability, usability testing, human computer interaction, HCI, unintended consequences, workarounds.
- BCMA, EHRS, electronic health record system, barcode medication administration, eMAR, electronic medication administration record, EPMA, electronic prescribing and medication administration, EPA, electronic prescribing and administration.
- 3. Medication administration, medicines administration, drug administration.

Search database

Google scholar search to be conducting using keywords above and manually reviewing the findings, chaining citation lists from appropriate papers.

CINAHL and PubMed searches also to be conducted in the following format:

	CINAHL	PubMED	Medline	Google scholar
1.	Human factors OR	"Human factors"	Human factors	Human factors OR
	usability OR	OR "usability" OR	OR usability OR	usability OR
	usability testing	"usability testing"	usability testing	usability testing OR
	OR human	OR "human	OR human	human computer
	computer	computer	computer	interaction OR HCI
	interaction OR HCI	interaction" OR	interaction OR	OR unintended
	OR unintended	"HCI" OR	HCI OR	consequences OR
	consequences OR	"unintended	unintended	workarounds OR
	workarounds OR	consequences"	consequences OR	system design
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		"workarounds"	system design	
		OR "system	, 0	
		design"		
2.	BCMA OR EHRS OR	"BCMA" OR	BCMA OR EHRS	BCMA, EHRS,
	electronic health	"EHRS" OR	OR electronic	electronic health
	records OR barcode	"electronic health	health records	records, barcode
	medication	records" OR	OR barcode	medication
	administration OR	"barcode	medication	administration,
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Screenshot of CINAHL search

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Reporting checklist for systematic review and metaanalysis.

Based on the PRISMA guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMAreporting guidelines, and cite them as:

Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement

	Reporting Item	Page Number
Title		
	<u>#1</u> Identify the report as a systematic review, meta-analysis, or both.	1
Abstract Structured summary	#2 Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number	2
Introduction		
Rationale	#3 Describe the rationale for the review in the context of what is already known.	3, 4
	For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xh	tml

1 2 3 4 5	Objectives	<u>#4</u>	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
6 7	Methods			
8 9 10 11 12 13 14	Protocol and registration	<u>#5</u>	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address) and, if available, provide registration information including the registration number.	Review protocol submitted with paper
15 16 17 18 19 20 21	Eligibility criteria	<u>#6</u>	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rational	4, 5
22 23 24 25 26 27 28	Information sources	<u>#7</u>	Describe all information sources in the search (e.g., databases with dates of coverage, contact with study authors to identify additional studies) and date last searched.	4, 5
29 30 31 32 33 34	Search	<u>#8</u>	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Demonstrated in the PRISMA flowchart (Figure 1) and detailed in study protocol
35 36 37	Study selection	<u>#9</u>	State the process for selecting studies (i.e., for screening,	4,5.
38 39 40 41			for determining eligibility, for inclusion in the systematic review, and, if applicable, for inclusion in the meta- analysis).	PRISMA flow chart attached (Figure 1)
42 43 44 45 46 47 48	Data collection process	<u>#10</u>	Describe the method of data extraction from reports (e.g., piloted forms, independently by two reviewers) and any processes for obtaining and confirming data from investigators.	5
49 50 51 52 53 54 55 56 57 58	Data items	<u>#11</u>	List and define all variables for which data were sought (e.g., PICOS, funding sources), and any assumptions and simplifications made.	Included in the study protocol.
	Risk of bias in individual studies	<u>#12</u>	Describe methods used for assessing risk of bias in individual studies (including specification of whether this	Described in the study protocol.
59 60		Fo	r peer review only - http://bmjopen.bmj.com/site/about/guidelines.xł	ntml

			was done at the study or outcome level, or both), and how this information is to be used in any data synthesis.	
	Summary measures	<u>#13</u>	State the principal summary measures (e.g., risk ratio, difference in means).	N/A
0 1 2	Planned methods of analyis	<u>#14</u>	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis.	N/A
2 3 4 5 6 7	Risk of bias across studies	<u>#15</u>	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
8 9 0 1 2 3	Additional analyses	<u>#16</u>	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
4	Results			
5 6 7 8 9 0	Study selection	<u>#17</u>	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a <u>flow diagram</u> .	PRISMA flow diagram attached (Figure 1)
1 2 3 4 5	Study characteristics	<u>#18</u>	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citation.	Study characteristics detailed in Table 1.
6 7 8 9	Risk of bias within studies	<u>#19</u>	Present data on risk of bias of each study and, if available, any outcome-level assessment (see Item 12).	N/A
0 1 2 3 4 5 6 7	Results of individual studies	<u>#20</u>	For all outcomes considered (benefits and harms), present, for each study: (a) simple summary data for each intervention group and (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
8 9 0 1	Synthesis of results	<u>#21</u>	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency.	Detailed in Themes table (Table 2).
2 3 4 5 6 7 8 9	Risk of bias across studies	<u>#22</u>	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
8 9 0		Fo	r peer review only - http://bmjopen.bmj.com/site/about/guidelines.xl	ntml

Additional analysis	<u>#23</u>	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
Discussion			
Summary of Evidence	<u>#24</u>	Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers	13
Limitations	<u>#25</u>	Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).	13
Conclusions	<u>#26</u>	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	13, 14
Funding			
Funding	<u>#27</u>	Describe sources of funding or other support (e.g., supply of data) for the systematic review; role of funders for the systematic review.	3
BY. This checklist	can be ration	completed online using <u>https://www.goodreports.org/</u> , a too with <u>Penelope.ai</u>	I made by the EQUATOR
	analysis Discussion Summary of Evidence Limitations Conclusions Funding Funding None The PRISMA BY. This checklist	analysis Discussion Summary of #24 Evidence Limitations #25 Conclusions #26 Funding #27 None The PRISMA cheef BY. This checklist can be Network in collaboration	analysis sensitivity or subgroup analyses, meta-regression [see Item 16]). Discussion Summarize the main findings, including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., health care providers, users, and policy makers Limitations #25 Discuss limitations at study and outcome level (e.g., risk of bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias). Conclusions #26 Provide a general interpretation of the results in the context of other evidence, and implications for future research. Funding #27 Describe sources of funding or other support (e.g., supply of data) for the systematic review; role of funders for the systematic review. None The PRISMA checklist is distributed under the terms of the Creative Commons BY. This checklist can be completed online using https://www.goodreports.org/ , a too Network in collaboration with <u>Penelope.ai</u>