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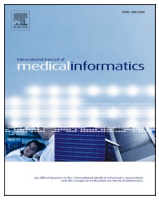

Review article

Human factors and safety analysis methods used in the design and redesign of electronic medication management systems: A systematic review

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ABSTRACT

Introduction: Poorly designed electronic medication management systems (EMMS) or computerized physician order entry (CPOE) systems in hospital settings can result in usability issues and in turn, patient safety risks. As a safety science, human factors and safety analysis methods have potential to support the safe and usable design of EMMS.

Objective: To identify and describe human factors and safety analysis methods that have been used in the design or redesign of EMMS used in hospital settings.

Materials and methods: A systematic review, following PRISMA guidelines, was conducted by searching online databases and relevant journals from January 2011 to May 2022. Studies were included if they described the practical application of human factors and safety analysis methods to support the design or redesign of a clinician-facing EMMS, or its components. Methods used were extracted and mapped to human centered design (HCD) activities: understanding context of use; specifying user requirements; producing design solutions; and evaluating the design.

Results: Twenty-one papers met the inclusion criteria. Overall, 21 human factors and safety analysis methods were used in the design or redesign of EMMS with prototyping, usability testing, participant surveys/questionnaires and interviews the most frequent. Human factors and safety analysis methods were most frequently used to evaluate the design of a system (n = 67; 56.3%). Nineteen of 21 (90%) methods used aimed to identify usability issues and/or support iterative design; only one paper utilized a safety-oriented method and one, a mental workload assessment method.

Discussion and conclusion: While the review identified 21 methods, EMMS design primarily utilized a subset of available methods, and rarely a method focused on safety. Given the high-risk nature of medication management in complex hospital environments, and the potential for harm due to poorly designed EMMS, there is significant potential to apply more safety-oriented human factors and safety analysis methods to support EMMS design.

1. Background

The implementation of electronic medication management systems (EMMS) or computerized physician order entry (CPOE) systems in hospital settings has become widespread [1]. EMMS support the prescribing, review and administration of medications [2]. Although these systems have delivered benefits, including increased legibility of medication orders and reduced medication errors, they have also presented new error types resulting from system design (e.g., selection and editing errors) [1–3].

Usability is a measure of how well a specific user in a specific context can use a product to achieve a defined goal safely, effectively, efficiently and satisfactorily [4]. The link between poor system usability and adverse patient outcomes is recognised in the literature. Poor EMMS usability can result in inefficient care provision as tasks take longer to complete, decreased user satisfaction, and incorrect system use (e.g., workarounds) which may lead to patient harm [4–8]. For example, a review of patient safety event reports from 595 health care facilities revealed that 1508 (55.9%) described a medication error that was associated with health information technology (HIT) use and 97.3% of

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these involved usability issues including data entry, workflow support, and alerting [9].

Human centred design (HCD) is a development approach that aims to make systems usable through the application of human factors, and usability knowledge and techniques [4]. While optimising system usability through HCD may require some upfront investment, studies demonstrate that this can avoid potentially significant additional costs in later phases due to the need for further design changes and significant training requirements [4,10,11]. There is a growing view that system usability and patient safety can be improved through the application of structured human factors and safety analysis methods to support HIT design decisions, as practised in many other safety critical sectors such as aviation and transportation [7,8,10].

Human factors (or ergonomics) is a science based discipline which explores the interaction between humans and systems by understanding factors that facilitate the completion of work [12]. The discipline involves the application of theory, principles, data, and methods to optimise human wellbeing and overall system performance[13]. The primary tenets which underpin the practice of human factors to support design include fitting the design to the person, not the person to the design, and designing systems to make it difficult to do the wrong thing [12].

As a safety science, the application of human factors methods, approaches and principles can support patient safety including the safe design of HIT [9]. More specifically, human factors can assist with understanding factors that affect human performance through physical and cognitive ergonomics and how humans interact with system (macroergonomics), and the identification of hazards and errors through safety analysis techniques [7,12].

Researchers within the human factors industry are calling for further active involvement of human factors experts in the design and implementation of HIT, and evaluation of the impact of human factors methods and principles on patient safety [10]. With medication prescription being the most common healthcare intervention in both acute and primary care settings [2], and the potential for hazards in EMMS to lead to clinical risk scenarios [1,5,6], EMMS design decisions are likely to benefit from the structured application of human factors methods [8]. However, when attempting to select and apply appropriate human factors methods (including combinations of methods) to support EMMS design decisions, limited information is available [14]. While some studies describe the theoretical and practical application of human factors and safety analysis methods to support the design and implementation of HIT systems broadly, these demonstrate variable application of these methods, are not always specific to EMMS, are primarily focused on post-implementation evaluation and do not provide adequate guidance on the practical systematic integration of human methods by HIT designers specifically during design and development [7,10,15]. No previous systematic reviews have been conducted to collate available evidence on human factors and safety analysis methods that have been practically applied to inform the design or redesign of hospital EMMS prior to implementation, including how they have been applied and any learnings from their application.

2. Objective

This systematic review aimed to identify and describe human factors and safety analysis methods that have been used in the design or redesign of electronic medication management systems (EMMS) used in hospital settings. In particular, the review aimed to map the identified methods to HCD activities, describe how the methods have been applied and their outputs, and collate lessons learned from the application of these methods.

3. Material and methods

Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [16] guidelines were used to design and report on this review.

3.1. Search strategy

With the assistance of an academic librarian, databases including Medline (Ovid), Embase (Ovid) and PsycINFO (Ovid) were searched from 1 January 2011 to May 2022 using keywords and subject headings. This timeframe was chosen due to the relatively recent adoption of human factors in healthcare. Search terms associated with two concepts were combined with 'and': 1) human factors or similar methods (for example, ergonomics and safety analysis methods) and 2) electronic medication management systems. In addition, medical informatics and human factors journals, listed in Appendix 1, were individually searched for relevant papers.

3.2. Eligibility criteria

Studies were included if they described the practical application of one or more human factors (or similar) methods to support the design or redesign of a clinician-facing EMMS, or its components in hospital settings. Studies were excluded if they were not English, did not involve the design or redesign of an EMMS, did not use a human factors method, described the theoretical application of a method only (i.e. did not describe results from application of the method), were focused on a system used outside of hospital settings, or focused on post-implementation only. Included papers were primary studies (of any design) and case studies. Reviews, news articles, conference abstracts, commentaries and books were excluded.

3.3. Study selection

All search results were imported into Endnote X9 referencing software and papers before 2011 were deleted. Remaining papers were exported into Covidence, and duplicates removed. Three researchers conducted title and abstract screening in Covidence. The first 500 were screened independently by two researchers (SA, MB) to refine the inclusion and exclusion criteria, and ensure consistency in inclusion/exclusion. Remaining papers were divided between three researchers (SA, KA, MB) so that each paper's title and abstract were screened once. The three researchers then convened to collectively rescreen the titles and abstracts of papers shortlisted through initial screening and agree on papers which should proceed to full text screening. Independent full text screening was undertaken by two researchers and discrepancies discussed to achieve consensus.

3.4. Quality assessment

The quality of included studies was assessed independently by two reviewers (SA, KA) using the Mixed Methods Appraisal Tool (MMAT) version 2018[17]. This validated quality assessment tool was selected as it allows assessment of qualitative, quantitative, and mixed methods studies [17]. The 2018 version was developed based on findings from a literature review, interviews with MMAT users and an e-Delphi study with experts [17]. Use of the MMAT involved rating studies against 7 criteria relevant to the study type by ticking 'yes', 'no' or 'can't tell' to inform the quality of included studies rather than calculating an overall score. Following their independent reviews, the two reviewers then came together to discuss any disagreements in quality assessment until a consensus was reached.

3.5. Data extraction and analysis process

Two researchers independently extracted data from the 21 included studies using two tables (Appendices 2 and 3) and discrepancies in data extraction were discussed until consensus was achieved. As there was some variability in the nomenclature used to describe human factors and

safety analysis methods in studies, two human factors researchers (SA, MB) developed a consistent naming approach for the methods, informed by classifications in recognized human factors textbooks [18,19] and their practice. This appears in Appendix 4.

Using the first table (Appendix 2), data was extracted about the country, setting, study objectives, aim of the system or tool developed and the study method. More granular information about the specific human factors methods used including individuals applying the methods, further detail on how the methods were applied, and the outcomes or outputs of each application was extracted and documented in the second table (Appendix 3). Methods were mapped to the four activities of HCD as outlined in the International Standard on human centered design for interactive systems [4]: understanding and specifying the context of use; specifying the user requirements; producing design solutions; and evaluating the design (Fig. 1). As HCD is an iterative development approach that aims to make systems usable through the application of human factors, and usability knowledge and techniques [4], it is useful to understand which specific human factors methods have been used to support each HCD activity. HCD activities 1 and 2 were combined as methods used typically aimed to understand the context of use and specify user requirements as an integrated process. Any reflections on the methods, as reported in studies, were collated and grouped into strengths and weaknesses.

4. Results

4.1. Study characteristics

The online database search and journal searching returned 11,020 papers, 21 of which met the inclusion criteria and were included for data extraction (Fig. 2). Appendix 2 summarizes study characteristics. Of the 21 studies, thirteen were conducted in the United States (USA) [20–32], and one in the Netherlands [33], Australia [34], Canada [35], Belgium [36], Argentina [37], Spain [11], Iran [38] and Germany [39]. Fifteen of 21 studies applied human factors methods to design or redesign clinical decision support (e.g., alerts and order sets), three focused on the computerized provider order entry system more broadly and the remainder on other EMMS components such as the medication allergy interface, nursing e-chart, or electronic Medication Administration Record (eMAR). All the studies described the development of new designs, except two [25,37] which involved redesigning existing interfaces.

4.2. Quality assessment

Using the MMAT, 18 of 21 studies met 5 or more of the 7 criteria within the tool (Appendix 5). Nineteen studies addressed a clear research question and collected data that were appropriate for the research question. Three of 13 mixed methods studies did not meet criteria around the effective integration of different study components to answer the research question, two did not adequately interpret the integrated outputs of quantitative and qualitative components, one did not adequately address divergences and inconsistencies between quantitative and qualitative results, and four did not adhere to the quality criteria of each tradition of the methods involved.

4.3. Human factors and safety analysis methods used and how they were applied

As seen in Table 1, 21 human factors methods were used to design or redesign EMMS (or its components). Of the 21 studies, 16 used methods to aid with iterative design and usability only. Three studies used methods with a safety focus by either proactively identifying and assessing risks and vulnerabilities which included patient safety issues [26] or assessing the severity of identified usability problems [11,33]. Only one study used a safety analysis method to support design [26] (Table 1). One study used a method to assess mental workload [29] (Table 1).

As seen in Table 2, methods were most frequently used to support Activity 4 of the HCD process: evaluating the design. Methods used across all four HCD activities included: functional analysis, group discussions/workshops, heuristic checklists/evaluation, interviews, representational analysis, and task analysis (Table 2). Observations, literature and data interpretation, process charting, requirements analysis, and user analysis were used only for understanding the context of use and specifying requirements (Activities 1 and 2). Design standards, human factors principles, storyboarding and user stories were only used in Activity 3: produce design solutions while cognitive walkthrough, participant surveys/questionnaires, usability testing and mental workload assessment were used only for design evaluation (Activity 4).

With respect to HCD Activities 1 and 2, task analysis and requirements analysis were the most frequently used methods followed by group discussions/workshops and interviews (Table 2). Of the 9 studies that addressed HCD Activities 1 and 2, two studies [25,37] involved redesign of existing interfaces and used methods (e.g. observations, heuristic evaluation) for the purpose of evaluating existing interfaces, and identifying required changes as part of HCD Activities 1 and 2. Five of 9 studies which utilized methods to understand the context of use and specify requirements (HCD Activities 1 and 2) combined methods involving direct consultation with users (e.g. interviews and group discussions/workshops) and analysis type methods (e.g. process charting,

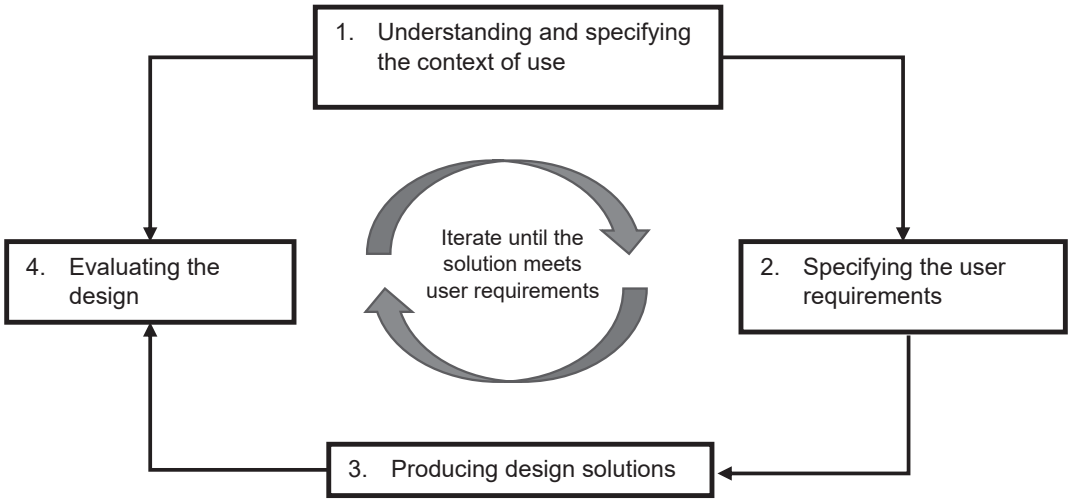

Fig. 1. Human-centered design process consisting of four activities, adapted from the International Standard on human centered design for interactive systems [4].

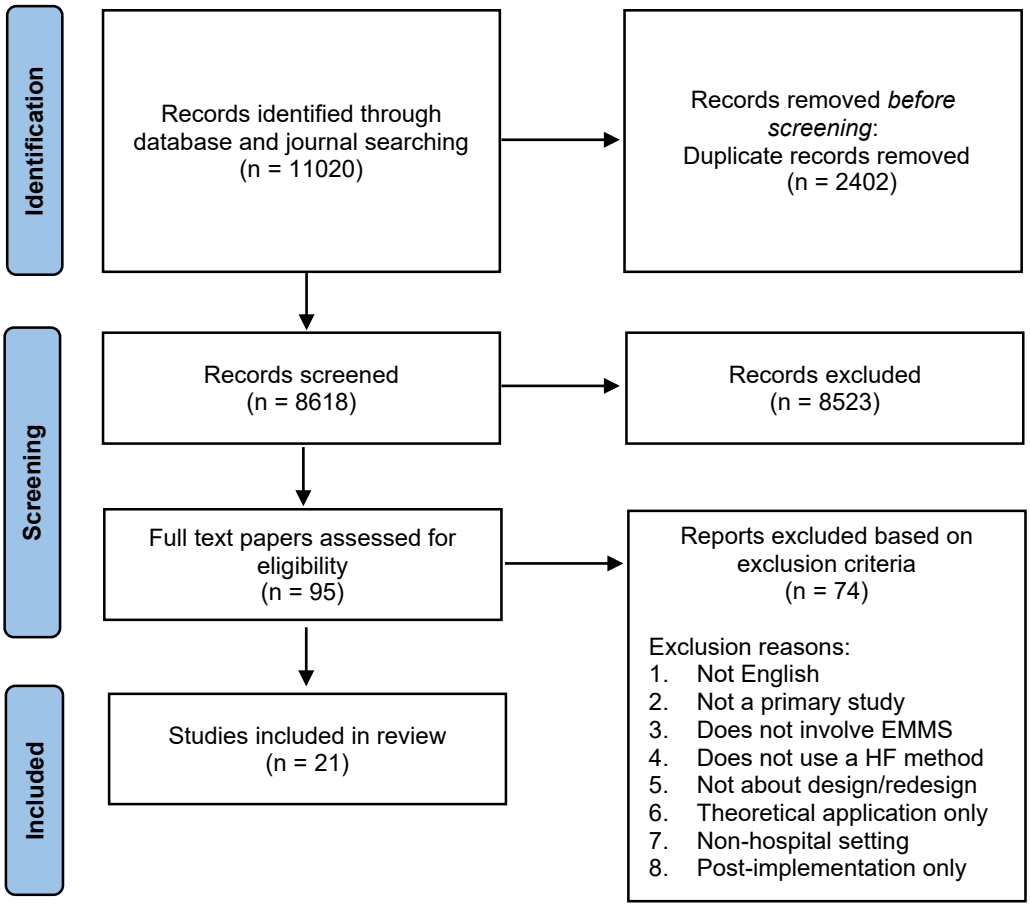

Fig. 2. Study selection process.

Table 1
Human factors and safety analysis methods used within Human-Centred Design Activities.

Method	Focus: Usability/ design, safety or other	1. Understanding and specifying the context of use 2. Specifying the user requirements	3. Produce design solutions to meet these requirements	4. Evaluating the design
Cognitive walkthrough	Usability/ design	N	N	Y
Design standards	Usability/ design	N	Y	N
Functional analysis	Usability/ design	Y	Y	Y
Group discussions/ workshops	Usability/ design	Y	Y	Y
Heuristic checklist/ evaluation	Usability/ design	Y	Y	Y
Human Factors principles	Usability/ design	N	Y	N
Interviews	Usability/ design	Y	Y	Y
Literature and data interpretation	Usability/ design	Y	N	N
Mental workload assessment	Other: Workload	N	N	Y
Observations	Usability/ design	Y	N	N
Participant surveys/ questionnaires	Usability/ design	N	N	Y
Proactive risk assessment	Safety	Y	N	Y
Process charting	Usability/ design	Y	N	N
Prototyping	Usability/ design	N	Y	Y
Representational analysis	Usability/ design	Y	Y	Y
Requirements analysis	Usability/ design	Y	N	N
Storyboarding	Usability/ design	N	Y	N
Task analysis	Usability/ design	Y	Y	Y
Usability testing	Usability/ design	N	N	Y
User analysis	Usability/ design	Y	N	Y
User stories	Usability/ design	N	Y	N

Y = the method has been used to support the Human Centred Design activity; N = the method has not been used to support the Human Centred Design activity.

Table 2
Frequency of method use within Human Centered Activities, as reported in 21 studies.

HCD Activities	Method	Frequency of use
1. Understanding and specifying the context of use Specifying user requirements	Requirements analysis	6
	Interviews	5
	Group discussions/ workshops	4
	Task analysis	4
	Process charting	3
	Literature and data interpretation	2
	Observations	1
	Heuristic checklist/ evaluation	1
	User analysis	1
	Representational analysis	1
	Functional analysis	1
	Total	29
2. Produce design solutions to meet these requirements	Prototyping	9
	Heuristic checklist/ evaluation	3
	Group discussions/ workshops	3
	User stories	1
	Storyboarding	1
	Interviews	1
	Human Factors principles	1
	Task analysis	1
	Representational analysis	1
	Functional analysis	1
	Design standards	1
	Total	23
3. Evaluating the design	Prototyping	17
	Usability testing	15
	Participant surveys/ questionnaires	12
	Interviews	10
	Heuristic checklist/ evaluation	4
	Cognitive walkthrough	2
	Group discussions/ workshops	2
	Task analysis	1
	Representational analysis	1
	Functional analysis	1
	Proactive risk assessment	1
	Mental workload assessment	1
	Total	67

task analysis) [20,21,25,31,37].

With respect to HCD Activity 3 (producing design solutions) which was addressed by 9 studies, prototyping was the most frequently used method to support design and iterative evaluation (Table 2). When producing design solutions (HCD Activity 3), prototyping was often supported by use of a complementary method such as a heuristic checklist [20,21], user stories [21], or group discussions/workshops [21,23,37].

For HCD Activity 4 which relates to design evaluation, prototyping was the most frequently used method followed by usability testing, participant surveys/questionnaires and interviews (Table 2). Overall, 20 studies addressed HCD Activity 4. When used, usability testing (with think-aloud protocol) was frequently combined with interviews and/or participant surveys/questionnaires (e.g., System Usability Scale). Heuristic evaluation was used in four studies [11,22,25,35] to evaluate the design of interfaces and identify usability violations. Principles used to support heuristic evaluation included Nielsen's usability heuristics [35], Nielsen's principles customized by Zhang [22] and clinical knowledge heuristics [22]. In one study, usability testing was used to supplement heuristic evaluation [11] and in another study, Task analysis, User analysis, Representational analysis and Functional analysis (TURF) was combined with heuristic evaluation[25].

4.4. Individuals applying the methods and method outputs or outcomes

Where information was provided on personnel who applied the human factors methods (Appendix 3), interviews, heuristic evaluation, TURF evaluation, group discussions/workshops, prototyping and proactive risk assessment were generally applied by a multidisciplinary team including representative clinical users, usability/human factors/ human computer interaction experts, designers and experts in technology and informatics. Usability testing was usually conducted by a facilitator and observer, however minimal information was provided in studies on the expertise and backgrounds of these individuals (Appendix 3).

When understanding context of use and specifying requirements (HCD Activities 1 and 2), the outputs of methods included artefacts describing user tasks and processes, use case scenarios or user stories, requirements, and required changes to existing interfaces (in the case of redesign) (Appendix 3).

The primary output of HCD Activity 3 (produce design solutions) was a prototype (Appendix 4). Methods used to evaluate designs (HCD Activity 4) often resulted in the identification of design enhancements and usability problems or heuristic violations, and quantitative data (e.g. usability measures, such as time to complete tasks) (Appendix 3).

4.5. Strengths and weaknesses of the methods

Across the studies, reflections or learnings were reported in over half the studies for 11 of the 21 methods identified. In general, authors reported on the effectiveness of the method in contributing to usable designs, and also described some method limitations (Tables 3a and b).

5. Discussion

This paper systematically reviewed studies that applied human factors and safety analysis methods to design or redesign EMMS in practice, and summarized learnings from their application. Only twenty-one studies were identified across a 11-year period suggesting that evidence around the practical application of human factors and safety analysis methods in the EMMS context is not widely available in the literature.

While 21 methods were identified through this review, EMMS design or redesign efforts primarily utilized a subset of methods. These included prototyping, usability testing, participant surveys/questionnaires and interviews. This finding is generally consistent with other literature related to usability evaluations of electronic health records across the development and implementation cycle [15]. Methods were also most frequently used to support Activity 4 of the HCD process (evaluating the design), likely because many of the studies included in the review aimed to identify and address usability problems within prototypes as part of an iterative development approach.

Most methods used in the studies, such as interviews, observations, and usability testing, could be classified as general design methods, used by other design disciplines (e.g., user experience designers), and not unique to the human factors discipline. While this overlap is not surprising as human factors and other design methods share a common goal of achieving human-centered design, this finding highlights the limited application of methods unique to human factors, such as human error identification; situation awareness, mental workload and team assessment; and human factors integration methods [19] to support EMMS design.

Human factors as a safety-oriented science primarily aims to identify human-system risks and safety critical elements related to human-system interactions [7,10,12]. A range of human factors and safety analysis methods and techniques exist, underpinned by systems safety

Table 3a
Summary of authors' reflections or learnings on strengths of human factors methods (where reported).

Method	Strengths
Requirements analysis	• Can result in time and financial efficiencies, and a safer and more usable system [31]
Group discussions/ workshops	• Helped draw out perspectives from those involved in the clinical process [20] • Led to identification of user needs and preferences and increased adoption [31,37]
Interviews	• Allowed identification of design features considered important by users [28] • Contributed to high satisfaction scores [28] • Had an effect on user willingness to accept the solution and reduced the risk of alert fatigue [31]
Task Analysis, User Analysis, Representational Analysis and Functional Analysis (TURF Framework)	• Effective, comprehensive method for enabling measurable improvement in interface design, identifying problematic areas and developing alternatives [25] • Can be used for initial design and enhancing existing designs [25] • Significantly improved the amount of steps to perform tasks [25]
Heuristic evaluation	• Clinicians identified issues not identified by the engineers [35] • Resulted in the identification of usability problems and so no new usability problems in subsequent usability testing were found [11] • Provided an additional crosscheck of the TURF evaluation and served as a baseline for comparing improvements in the redesigned interface [25] • Thorough method to achieve usability which improved with each round of evaluation [11] • Completed by engineers and users [35] • Possible to perform on paper prototypes [11] • Each evaluation took 2 h [35] • Time spent on evaluation was 4 h [11] • Quick, inexpensive and economically attractive [11,35] • Low skill requirement [11]
Proactive Risk Assessment (PRA)	• Interdisciplinary involvement of key stakeholders in the PRA was extremely valuable for developing user-friendly health IT [26] • Compensated for problems associated with traditional PRAs such as the FMEA including improved efficiency of the process [26] • Considered effective by the PRA team and feedback from the evaluation of the method was positive [26] • Provided a structured means of identifying vulnerabilities in design and workflows [26] • Addressed a well-defined process with a limited scope [26] • Participating staff provided input while human factors engineering researchers developed and facilitated the method which contributed to the process' efficiency [26] • Considered an efficient process overall compared to other PRA methods (e.g. FMEA)[26]
Usability testing	• Allowed the identification of task complexities and designing the solution to addressing them [11] • Resulted in rich and meaningful discussions [36] and proved to be highly informative [34] • Led to the identification of usability problems and design changes [11,20,33,36] • Led to the development of a functional and usable solution [11,20,28,33,34,36] • Complemented heuristic evaluation as each method found usability problems overlooked by the other [11] • Interdisciplinary collaboration was useful for preparing, observing testing and translating results into requirements [36] • Led to acceptance of the solution [32] • Resulted in a learning effect (i.e. users did not repeat the same errors in the subsequent scenarios) [32]
Participant surveys/ questionnaires	• EHRUS aims to help interface developers identify areas of concern, e.g. risks to care quality, that would not be captured by the SUS [23]

thinking, which can aid with hazard analysis and risk assessment [18,40]. While several studies within this review utilized methods to identify heuristic and usability violations which could impact safety due to the inherent link between usability and safety, only three specifically focused on safety by proactively identifying and assessing risks and vulnerabilities, including patient safety issues [26] or assessing the severity of identified usability problems [11,33]. And only one study used a safety analysis method to support design [26].

The limited use of human factors and safety analysis methods to identify, assess and address hazards and safety critical issues also emerged as a result from a previous review which summarized evaluations of electronic health records [41], highlighting that there is significant potential to apply more safety-oriented human factors and safety analysis methods in both HIT design and evaluation. For example, human error identification methods such as Systematic Human Error Reduction and Prediction Approach (SHERPA) and predictive risk assessment methods such as the Systems Theoretic Accident Model and Process (STAMP) are frequently used in other sectors, like aviation and transportation, but no studies were found using these approaches in this review. Given the complexity and high-risk nature of medication management, and the potential for major harm due to poorly designed EMMS, the systematic application of safety-focused human factors and safety analysis methods to support EMMS design efforts is likely to be highly beneficial.

It should also be noted that only one study used a mental workload assessment (NASA Task Load Index) to evaluate the design's impact on cognitive load [29]. Due to the increased risk of human error in situations of cognitive or physical overload, particularly in stressful and complex environments such as hospitals, there may be a role for workload assessments in optimizing HIT design.

Some studies provided reflections on the strengths and weaknesses of the methods applied and these may be useful for design teams considering the application of these methods to the EMMS context. The multidisciplinary nature of teams applying methods which aided with incorporating multiple perspectives into the design process was called out as a key strength of some methods e.g., proactive risk assessment [26]. Furthermore, some studies highlighted the value of involving end users in the design process in enhancing usability, satisfaction and adoption which is consistent with human-centered design principles in

Table 3b
Summary of authors' reflections or learnings on weaknesses of human factors methods (where reported).

Method	Weaknesses
Group discussions/ workshops	• Preferences and feedback of participants may not reflect those of clinicians working in other settings [31]
Interviews	• Preferences and feedback of participants may not reflect those of clinicians working in other settings [31]
Task Analysis, User Analysis, Representational Analysis and Functional Analysis (TURF Framework)	• Leverages theoretical estimation of improvement; further data collection and user testing is required to validate findings [25]
Heuristic evaluation	• Usability studies with a larger sample of representative end users are required to identify specific areas of improvement and quantitative measures [35]
Proactive Risk Assessment (PRA)	• Challenges with identifying and clearly defining a process that met original ground rules established around the scope and delivery of the PRA [26] • More interface and workflow vulnerabilities may have been identified if additional meetings were held [26] • Although application of the method demonstrated benefits, it is unknown if another method may have proven to be equality or more effective [26] • Due to resources requirements for PRAs (e.g., time, expertise, commitment), it may not be possible to apply this method to larger implementations. For organisation wide implementations, method application should be reserved for prioritised high-risk processes [26]
Usability testing	• Involved a small number of users [27,28,36,39] Requires investment of several weeks of testing, analysis and redesign [34] • Participants recruited were volunteers who may have been more interested and experienced in health informatics than randomly selected participants; this may have influenced results [28,33,36] • Researchers' presence and observations may have impacted behaviours [27,30,36,39] • Scenarios were simulated which may have impacted how users completed tasks [27,28,33] • The testing environment may not have fully mimicked a real clinical environment [23,34,39] which involves other system components and workplace interruptions [39] • Should be followed by testing in realistic clinical simulations [39] or real life settings [11,39] and other forms of testing to assess efficiency, effectiveness and satisfaction [34] • Should be complemented with expert-based approaches e.g., walkthroughs [39]
Participant surveys/ questionnaires	• Small sample sizes limiting the application of inferential statistics from survey results [27]

the ISO standard [4]. End user contributions included the identification of issues and potential design enhancements that were not identified by other team members such as IT or human factors personnel [11,35]; and prioritization of user preferences and requirements [28,37].

While it is possible to achieve saturation point with a small number of user participants, some studies cited weaknesses associated with involving small numbers of user participants such as findings from group discussions/workshops, interviews, heuristic evaluation, and usability testing not reflecting the views of all users [27,28,31,35,36,39]. In addition, the limited ability to apply inferential statistics to participant survey/questionnaire results involving a small number of respondents was highlighted [27]. As the delivery of digital health projects often occurs within resourcing and time constraints, it is likely that factors influencing the choice of HF methods applied, including the number of user participants engaged, may involve balancing the perceived usefulness of the method for obtaining sufficient information for design iteration with project resource and time limitations. Another weakness related to simulation-based approaches such as usability testing is that they may not adequately mimic the real clinical environment [23,24,39]. Given that usability testing was one of the main methods used to support EMMS design, the design and evaluation of EMMS may benefit from the application of methods and environments that better mimic the complex and interruptive nature of clinical environments.

This review showed that representative users or subject matter experts tended to apply the method themselves (e.g., heuristic and TURF evaluation, and workflow analysis) [11,35,38] or participate in the method (e.g., usability testing, workshops, and proactive risk assessment). It was interesting to note that one study considered heuristic evaluation to have a 'low skill requirement' [11] which may explain why user representatives (e.g., nurses and physicians) were considered sufficiently skilled to apply the method. This is inconsistent with the view held by most human factors practitioners that human factors expertise is required to undertake a heuristic evaluation, as usability violation detection is heavily reliant on the expertise of assessors [18]. Across the studies, the role of human factors (or similar) personnel tended to involve planning approaches for applying the method, facilitation, and addressing usability or heuristic issues through design enhancements [11,26,36]. Within the literature, there are knowledge gaps with respect to who is best placed to apply human factors and safety analysis methods, resource and skill requirements, and the feasibility of human factors method application by HIT designers who may be non-human factors practitioners. It has been argued that lack of understanding about the work and context of HIT designers has made it difficult to formulate recommendations about how such roles could integrate human factors and safety analysis approaches during the HIT development cycle [10]. Further research is required to understand the designers' work context and the potential of these roles in systematically applying human factors and safety analysis methods.

This review identifies human factors and safety analysis methods that have been used in the design or redesign of EMMS and provides useful detail around how they have been applied. However, several limitations should be considered when interpreting the results of this review. The review included only published studies which may have introduced publication bias. It is possible that human factors methods (or similar) are being used to support EMMS design without corresponding publications in academic literature. While some information around who applied the methods and learnings from method applications could be gathered from the studies, not all studies reported this information. Learnings and reflections identified through this review should not be interpreted as a comprehensive guide to method application in the design and redesign of EMMS. The variation in the naming of methods and mapping to HCD activities required the researchers to exercise their judgement in interpreting the information provided to enable comparison across studies. Whilst the research team, which included human factors researchers, attempted to create consistent naming approaches using recognized human factors literature and their

expert opinion to enable comparison across the studies, the naming of methods used in this review may not reflect the views of all human factors practitioners.

Whilst the practice of human factors in HIT has evolved in its maturity over the past 15 years, this review highlights opportunities to further advance and optimize the use of human factors methods to support safe and usable design. This could be done by the translation of learnings from other sectors which are more advanced in the use of safety-focused human factors methods, and creating educational opportunities or upskilling pathways for designers of HIT systems including clinicians, health informaticians and human factors professionals. The requirement for consistent integration of safety-focused human factors methods to support the design, evaluation and iteration of HIT systems could be incorporated within relevant policies, regulations and standards for system development. However, future research is required to determine how safety-focused human factors methods can be applied within the digital health context to ensure that they deliver value, effectively support design and redesign, and can be feasibly integrated within the delivery of complex digital health projects which are often constrained by resources, time and budgets.

6. Conclusion

This review summarized available evidence on human factors and safety analysis methods that have been applied to inform the design or redesign of hospital EMMS. Although several methods were used, the most frequently reported methods included prototyping, usability testing, participant surveys/questionnaires and interviews. Very few studies applied safety-orientated methods, despite their potential value in identifying safety issues and risks in other domain areas. Most method applications involved a multidisciplinary team and the value of including end users in the design process was highlighted by several studies. Whilst some information could be gathered around the strengths and weaknesses of methods, further research is required to determine the optimal ways of applying a broader range of human factors and safety analysis methods to support the design and redesign of EMMS. To contribute to this evidence base, it is recommended that system designers and human factors practitioners consider the application of more safety-oriented methods to support the identification of design issues that may impact the safety of EMMS.

Summary Table.

What was already known on the topic	• Poorly design EMMS can result in harm • Human factors methods can assist with supporting patient safety and health IT design • There is variable application of human factors methods in the health IT space. These applications tend to be non-EMMS specific, and are primarily focused on post-implementation evaluation rather than design
What this study added to our knowledge	• The most frequently used human factors methods to support EMMS design are prototyping, usability testing, participant surveys/questionnaires and interviews • There is limited use of safety-oriented methods to support the design of EMMS, and further research is required to understand how these methods can be applied

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Author contributions

SA and MB conceived the study design. SA, MB and KA conducted title/abstract and full-text screening. SA and KA performed the data extraction. SA wrote the manuscript and all the authors contributed to reviewing the manuscript.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix 1 – Additional information on the search strategy

Search terms associated with each concept

Concept	Examples of search terms used
Concept 1: Human factors or similar methods	ergonomic* or human engineer* or human factors engineer* or usability or human factors or user-centred or human-centred or human-centered or medication safety or safety analysis or heuristic or formative or summative or technology-induced error or medical error or user error or safe use* or patient safety or hazard* analysis or safety management
Concept 2: Electronic prescribing system / Electronic medication management system (EMMS)	Electronic Medication Management System* or emm* or electronic* prescrib* or electronic prescription* or eprescipt* or eprescrib* or cpo or computeri? provider order entry or EMMS or electronic health record* or electronic medical record or medical order entry or physician order entry or medical records system*

Journals individually searched

Medical informatics and human factors journals were individually searched for relevant papers using appropriate search terms for these journals. The journals included:

- International Journal of Medical Informatics
- JMIR Medical Informatics
- Journal of the American Medical Informatics Association

- Human Factors
- Applied Ergonomics, and Ergonomics

Appendix 2 – Study characteristics including setting, objectives and methods

Author and year of publication	Country	Setting	Study objective/s	Aim of the system or tool developed	Study Method
Abdel Rahman et al., 2016	USA	Paediatric hospital	Develop and test a CDS tool	- Support the appropriate dosing and therapeutic drug monitoring of busulfan by bone marrow transplantation clinical staff	- Engagement with users and requirements analysis Backend development Front end design of a prototype guided by a heuristic checklist Integration with the electronic health record Usability evaluation via structured cognitive walkthroughs, usability testing and participant satisfaction survey
Abdel Rahman et al., 2020	USA	Paediatric hospital	Develop a CDS tool	- Support antihemophilic factor dose individualisation	- Engagement with users and requirements analysis Backend development Front end design of a prototype guided by a heuristic checklist and user stories Integration with the electronic health record Usability evaluation via structured cognitive walkthroughs, usability testing and participant satisfaction survey
Afrash et al., 2022	Iran	Teaching hospital	Design and implement an information system that involves a CPOE system, a patient management system, a prescription verification system, and a nurse administration system	- Improve the care of cancer patients who are candidates for chemotherapy	- Analysis of the chemotherapy workflow Protocol and order set development Design and implementation of a guideline-based workflow software system
Akhloufi et al., 2019	Netherlands	Tertiary university medical center	Determine if changes to a CDS system are required	- Support empirical antibiotic treatment to increase appropriate antibiotic use	- Usability testing with end users Assessment of identified usability problems using a classification scheme
Baysari et al., 2021	Australia	Teaching hospital	Conduct formative usability testing of a CDS tool to identify well-designed aspects and modifications required before pilot testing the tool in practice	- Support identification of at-risk patients who may benefit from deprescribing and support the deprescribing process	- Formative usability testing (two rounds) Semi-structured interviews
Chan et al., 2011	Canada	Academic hospital	Conduct a heuristic evaluation to evaluate the usability of standardised medication order sets within a CPOE system prior to implementation	- Standardise groupings of medication orders for treating specific conditions to reduce ordering time and decrease care variation	- Heuristic evaluation
Devine et al., 2014	USA	University of Washington	Evaluate an early prototype of a commercial CPOE system with pharmacogenomics CDS alerts, identify user interface improvements and understand when pharmacogenomic knowledge embedded in the electronic health record is useful to prescribers	- Promote uptake of pharmacogenomics information during prescribing	- Heuristic evaluation Participant satisfaction survey
Garvin et al., 2019	USA	Tertiary hospital medical center	Use interactive user-centred design methods to develop an order set and CDS tool	- Improve clinical decision making and workflow around cirrhosis identification and management	- Requirements analysis Design workshop to develop design storyboards Development of prototype Scenario-based formative evaluation and participant satisfaction survey Iteration and refinement of prototype
Genes et al., 2016	USA	Medicine School	Conduct an iterative usability and redesign process of a CDS tool	- Improve abdominal pain management for at-risk older patients in emergency departments	- Development of CDS interventions (e.g. alerts) Three rounds of usability testing Further user feedback via participant satisfaction survey and other methods
Harrington et al., 2011	USA	Unknown	Use the TURF analysis framework to improve the design of a medication	- Present medication allergy information	- Evaluation of medication allergy interface design using:

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Author and year of publication	Country	Setting	Study objective/s	Aim of the system or tool developed	Study Method
			allergy interface		the NIST test procedure *Maintain an Active Medication Allergy* to guide heuristic evaluation the TURF framework Development of prototype Review of prototype using heuristic evaluation and TURF framework
Hundt et al., 2012	USA	Quaternary hospital	Develop, conduct, and evaluate a PRA of the design and implementation of CPOE in an ICU	- Support order entry in intensive care and transition of care within the hospital	- PRA of the design and implementation of the CPOE over three phases to identify vulnerabilities: a planning phase, a team phase, and an evaluation phase.
Kernebeck et al., 2022	Germany	Children's and adolescents' hospital	Evaluate user acceptance of a medication module and involve them in the development process	- Support medication management in pediatric palliative care	- User feedback on an interface gathered through: concurrent think-aloud while using typical tasks semi-structured qualitative interviews
Larsen et al., 2022	USA	Simulated setting	Evaluate the application of a UCD process in the development of a medication recommender	- Provide evidence-based medication recommendations for type 2 diabetes mellitus	- Prototype app development Eight rounds of iterative user testing followed by interviews, with participants assigned to two groups: Mock EHR and Prototype app Cognitive load assessed using the NASA TLX Participant satisfaction surveys
Marien et al., 2019	Belgium	Regional eHealth network	Develop and conduct usability testing of a medication reconciliation application	- Support the medication reconciliation process to improve continuity of care	- Three phased iterative evaluation and refinement of prototypes. Several methods used during each phase including group discussions, questionnaires, scenario-based testing, interviews and a participant satisfaction survey.
Melton et al., 2016	USA	Tertiary hospital	Develop and evaluate a CDS system	- Pharmacogenomic-guided warfarin dosing	- Evaluation of two prototypes (a development iteration and evaluation iteration) through scenario-based testing and debrief interviews Participant satisfaction survey
Nanji et al., 2021	USA	Tertiary hospital	Describe the development and analysis of user feedback for a CDS application	- Provide patient specific dosing information and alerts to warn of medication errors in the operating room	- Needs identified Alert algorithm developed Technical requirements determined Iterative user-centered design to gather user requirements and feedback on the usability of the interface
Nanji et al., 2022	USA	Tertiary hospital	Evaluate the usability of a novel medication CDS software compared to the current medication administration and documentation process	- Provide patience-specific medication related perioperative decision support	- 2 parallel arm randomized controlled superiority trial conducted in a simulation setting to compare the usability of the new CDS and the standard current medication workflow electronic anesthesia information management system Evaluation was conducted through usability testing with think-aloud and a participant satisfaction survey
Nguyen et al., 2019	USA	Large medical center, major academic healthcare system	To develop and evaluate a prototype of a pharmacogenomic CDS tool user interface for thiopurine medications with user-centered design methods	- Help physicians incorporate pharmacogenomic results into prescribing decisions for thiopurine medications	- Phase I: qualitative interviews to assess the information needs of physicians and develop interface design requirements Phase 2: developed a prototype and evaluated the design through usability testing and participant satisfaction survey
Schachner et al., 2016	Argentina	Hospital healthcare network	Describe the participatory redesign of the nursing e-chart user interface	- Improve the quality of nursing records	- Information gathering to identify required changes to the current interface and requirements Development of a new prototype through participatory design sessions Usability testing and participant

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Author and year of publication	Country	Setting	Study objective/s	Aim of the system or tool developed	Study Method
					satisfaction surveys to inform iterative improvements to the prototype
Siegel et al., 2021	USA	Two tertiary pediatric hospitals	Design a CDS alert and evaluate prescribing behaviors after implementation	- Reduce carbohydrate-containing medication orders in hospitalized patients on ketogenic diet	- Alert developed Formative usability testing with think-aloud conducted and iterative improvements made Summative testing conducted, debrief interview and participant satisfaction survey Post-implementation evaluation
Vincente Oliveros et al., 2017	Spain	Teaching hospital	Evaluate the usability of an eMAR application during its development	- Support medication tasks performed by nurses	- Usability evaluation of the interface through heuristic evaluation and usability testing

App = application; CDS = clinical decision support; CPOE = computerized provider order entry; HER = electronic health record; eMAR = electronic Medication Administration Record; ICU = Intensive Care Unit; NASA TLX = National Aeronautics and Space Administration Task Load Index; PRA = Proactive Risk Assessment; TURF = Task Analysis, User Analysis, Representation Analysis and Functional Analysis; UCD = user-centered design; USA = United States of America.

Appendix 3 – Table containing further detail about the specific human factors and safety analysis methods used mapped to the human-centred design approach to design and development

HCD Activity	Studies which used HF and safety analysis methods relevant to the corresponding HCD Activity	HF and safety analysis methods used	Further detail	Individuals applying the HF and safety analysis method/s	Outcomes or outputs
1. **Understanding and specifying the context of use** **Specifying the user requirements**	AbdelRahman et al., 2016	- Task analysis Process charting Requirements analysis Group discussions/ workshops	- Existing processes analysed and sequence of tasks and information flows documented. Users engaged to understand user needs, tasks, information flows and other requirements as part of requirements analysis.	Nil information provided	- Process charts Task flow diagrams Task decomposition tables Use case scenarios Requirements
	AbdelRahman et al., 2020	- Task analysis Process charting Requirements analysis Group discussions/ workshops	- Existing processes analysed and sequence of tasks and information flows documented. Users engaged to understand user needs, tasks, challenges, workflows, information flows and other requirements as part of requirements analysis.	Nil information provided	- Process charts Task flow diagrams Task decomposition tables Use case scenarios/user stories Requirements
	Afrash et al., 2022	- Process charting Requirements analysis	- The current chemotherapy workflow was analysed and documented using a flowchart Needs assessment was conducted to inform the design of the software	Clinical team: Oncologists Clinical pharmacists Nurses	- Workflow flowchart Requirements
	Nguyen et al., 2019	- Interviews	- Semi-structured, qualitative interviews with users to develop interface design requirements.	Interviewers: Pharmacist researcher HCI expert HF expert	- Identification of required design features for the CDS and requirements
	Schachner et al., 2016	- Literature and data interpretation Observations Interviews Task analysis Requirements analysis Group discussions/ workshops	- Information gathered through review of the literature, the current nursing record assessment (including content evaluation, nurse-system interaction, usability defects and navigation); contextual interviews with users and observations; analysis of tasks, workflows and requirements; and focus groups.	Nil information provided	- Required changes to the current nurse e-chart and requirements
	Harrington et al., 2011	- Heuristic checklist/ evaluation Task analysis User analysis Representational	- Evaluation of the existing interface via heuristic evaluation and the TURF framework to identify required changes and requirements for a prototype.	Heuristic and TURF evaluators: Students in a graduate level interface design course: physician nurse	- Heuristic violations and TURF analysis results to inform required changes to the current interface and requirements

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HCD Activity	Studies which used HF and safety analysis methods relevant to the corresponding HCD Activity	HF and safety analysis methods used	Further detail	Individuals applying the HF and safety analysis method/s	Outcomes or outputs
		analysis Functional analysis Interviews	Interviews with medical experts were also conducted to support TURF analysis.	social worker students with technology backgrounds	
	Garvin et al., 2019	- Requirements analysis	- Requirements for prototype developed based on analysis of patient care.	Nil information provided	- Requirements
	Nanji et al., 2021	- Requirements analysis Interviews Group discussions/ workshops	- Group and individual design feedback sessions with front-line clinicians and subject matter experts to gather information about user requirements for the alert content.	Nil information provided	- Requirements
	Larsen et al., 2022	- Literature and data interpretation Interviews	- Review of guidelines and interviews with users to understand patient facts the app would need to incorporate, users' context of use, and workflows to inform development of a prototype.	Nil information provided	- App content Workflows
2. **Produce design solutions to meet these requirements**	AbdelRahman et al., 2016	- Prototyping Heuristic checklist/ evaluation	- Information gathered through requirements analysis used to develop wireframe prototype. A 296-item heuristic checklist used to guide front-end design of prototype.	Nil information provided	- Prototype Heuristic violations
	AbdelRahman et al., 2020	- User stories Group discussions/ workshops Prototyping Heuristic checklist/ evaluation	- User stories based on clinical scenarios used during development to prioritise feature development and bug fixes. Information gathered through requirements analysis used to develop a wireframe prototype. A 296-item heuristic checklist used to guide front-end design of prototype.	Nil information provided	- Prototype Heuristic violations
	Garvin et al., 2019	- Group discussions/ workshops Storyboarding Prototyping	- Workshop convened with clinical and non-clinical representatives to develop design storyboards based on clinical scenarios. Storyboard simulations used to develop a wireframe prototype.	Design workshop participants: Clinicians User experience designers Information technologists Health services researchers Prototype developers: User experience designer Informatics scientists Human factors experts Clinicians Software engineer	- Design concept Storyboard design Prototype
	Nguyen et al., 2019	- Interviews HF principles Prototyping	- Data from semi-structured, interviews with users and HF principles used to develop electronic prototype.	Prototype developers: Pharmacist researcher HCI expert	- Prototype
	Schachner et al., 2016	- Group discussions/ workshops Prototyping	- Participatory design sessions with users held to develop interface prototype.	Design session participants: Informaticians Usability experts	- Prototype
	Harrington et al., 2011	- Prototyping Heuristic checklist/ evaluation Task analysis Representational analysis Functional analysis Design standards	- Prototype developed using findings from the heuristic and TURF evaluations of the existing interface. Design standards used to support design efforts.	Design team: Students in a graduate level interface design course: physician nurse social worker students with technology backgrounds	- Prototype
	Nanji et al., 2021	- Prototyping	- Requirement used to develop the design.	Nil information provided	- Prototype
	Afrash et al., 2022	- Prototyping	- Information gathered through the needs assessment and workflow analysis used to develop the design.	Led by: Informaticians Oncologist	- Prototype

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HCD Activity	Studies which used HF and safety analysis methods relevant to the corresponding HCD Activity	HF and safety analysis methods used	Further detail	Individuals applying the HF and safety analysis method/s	Outcomes or outputs
	Larsen et al., 2022	- Prototyping	- Information gathered through data review and interviews used to develop a prototype.	Nil information provided	- Prototype
3. **Evaluating the design**	Marien et al., 2019	- Prototyping Interviews Group discussions/ workshops Participant surveys/ questionnaire Usability testing	- Three phased iterative evaluation of low, medium and high-fidelity prototypes. Methods used to collect data on usability from users and inform enhancements in phases included: group discussions questionnaires scenario based testing interviews completion of the SUS	Evaluation conducted by research team: Computer scientists Usability experts Physicians Pharmacists Sociologist Lawyer	- Design enhancements SUS results
	Melton et al., 2016	- Prototyping Interviews Usability testing Participant surveys/ questionnaires	- Two prototypes developed by a pharmacogenomics expert, a HF engineer, informatics experts, and pharmacists were evaluated. Clinicians provided feedback on screenshots of prototype 1 prior to testing. Simulated patient scenarios used to support scenario-based usability testing of both prototypes. Debrief interviews conducted to seek further feedback. After testing, participants completed the CSUQ.	Nil information provided	- Design enhancements CSUQ results Efficiency measures: Time on task Time spent with the tool
	Chan et al., 2011	- Prototyping Heuristic checklist/ evaluation	- Evaluators assessed prototype's interface against Nielsen's usability heuristics using dummy patient data. Usability violations informed redesign of a more user-friendly prototype for future usability testing.	Heuristic evaluators: Experienced staff physician (clinical experience, limited heuristic evaluation experience) Engineers with HF training and experience with heuristic evaluation	- Heuristic violations
	Devine et al., 2014	- Prototyping Heuristic checklist/ evaluation Participant surveys/ questionnaires	- Two sets of heuristics used to evaluate prototype: Principles customised by Zhang for the health domain based on usability heuristics from Nielsen Clinical knowledge heuristics designed to measure knowledge utilisation in healthcare Participants performed heuristic review while completing clinical scenarios using the prototype and 'thinking aloud'. Following evaluation, participants completed the PSSUQ.	Heuristic evaluators: Cardiologists Oncologists	- Data on: time to completion types of clinical knowledge resources accessed participants' statements and associated tasks Qualitative data mapped to positive and negative evaluation heuristics and heuristic violations Design enhancements PSSUQ results
	Harrington et al., 2011	- Prototyping Heuristic checklist/ evaluation Task analysis Representational analysis Functional analysis Interviews	- Prototype was evaluated using heuristic and TURF evaluations.	Heuristic and TURF evaluators: students in a graduate level interface design course, including a physician, nurse, social worked and students with technology backgrounds TURF methodology experts	- Heuristic violations TURF analysis results
	Vincente Oliveros et al., 2017	- Prototyping Heuristic checklist/ evaluation Usability testing	- Iterative heuristic evaluation of typical user tasks. Usability testing of 34 versions of the application by observing users complete typical tasks.	Heuristic evaluators: Hospital pharmacists (including some with knowledge of usability evaluations) Nurses	- Usability problems Heuristic violations and severity ratings

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HCD Activity	Studies which used HF and safety analysis methods relevant to the corresponding HCD Activity	HF and safety analysis methods used	Further detail	Individuals applying the HF and safety analysis method/s	Outcomes or outputs
				Usability testing: One evaluator from the heuristic evaluation (hospital pharmacist)	
	Akhloufi et al., 2019	- Usability testing	- Usability testing with think-aloud protocol. Observer watched participants complete typical tasks based on clinical scenarios. Usability problems identified were assessed using augmented classification scheme combining the UAF, with Nielsen's severity ratings.	Usability testing: Observer Usability problem assessors: Physician Hospital pharmacist experienced in CDS Researcher in the field of quality	- Usability problems assessed using an augmented classification scheme combining the UAF with Nielsen's severity ratings
	AbdelRahman et al., 2016	- Prototyping Cognitive walkthrough Usability testing Participant surveys/ questionnaires	- Structured cognitive walkthroughs with content experts and users to ensure prototype supported users' needs. Recommendations were incorporated into design. In usability testing with think-aloud protocol, participants were observed as they completed tasks based on clinical scenarios. Results informed refinement of the user interface. Following testing, participants completed the PSSUQ.	Nil information provided	- Design enhancements Efficiency and other usability measures: Time to complete tasks Number of clicks to complete tasks Task success User perceptions of task ease/difficulty PSSUQ results
	AbdelRahman et al., 2020	- Prototyping Cognitive walkthrough Usability testing Participant surveys/ questionnaires	- Structured cognitive walkthroughs with content experts and users conducted to assess the prototype's efficiency, ease-of-use, and user satisfaction. Recommendations were incorporated into design. In usability testing with think-aloud protocol, participants were observed as they completed tasks based on clinical scenarios. Results informed refinement of the user interface. Following testing, participants completed the PSSUQ.	Nil information provided	- Design enhancements Efficiency and other usability measures: Time to complete tasks Number of clicks to complete tasks Task success User perceptions of task ease/difficulty PSSUQ results
	Baysari et al., 2021	- Usability testing Interviews	- Two rounds of scenario based formative usability testing with users using think-aloud method. Following completion, users participated in brief semi-structured interview to gather further feedback.	Testing scenario developers: Professor of geriatric pharmacology Pharmacist researcher HF researcher eHealth experts Testing session facilitators: Pharmacist eHealth expert Transcript reviewers/ analysers: HF researchers	- Usability issues Design enhancements
	Genes et al., 2016	- Prototyping Usability testing Participant surveys/ questionnaires Interviews	- Usability test sessions based on clinical scenarios were conducted with users, resulting in iterative redesign improvements. At conclusion of each usability session, participants provided feedback via the SUS, a facilitator-led structured favorability questionnaire and open ended narrative feedback.	Usability testing: Nil information provided User feedback reviewers: multidisciplinary team including ED physicians and study investigators	- Design enhancements SUS results Favorability questionnaire results Coded data around: frequency of CDS intervention appearance appropriateness of CDS appearance participant acknowledgement of CDS

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HCD Activity	Studies which used HF and safety analysis methods relevant to the corresponding HCD Activity	HF and safety analysis methods used	Further detail	Individuals applying the HF and safety analysis method/s	Outcomes or outputs
					whether CDS resulted in desired actions
	Nguyen et al., 2019	- Prototyping Usability testing Interviews Participant surveys/ questionnaires	- Prototype iteratively evaluated via scenario-based usability testing sessions with users using think-aloud method. Following testing, participants took part in debrief interview. Participants completed the CSUQ.	Usability testing: Two moderators with experience in usability sessions	- Design enhancements Usability measures: learnability usability errors efficiency satisfaction CSUQ results
	Schachner et al., 2016	- Prototyping Usability testing Participant surveys/ questionnaires	- Five iterative cycles of usability testing of paper-based prototypes conducted with users. Findings used to iteratively improve and further test the prototype. After each test, a survey was conducted.	Nil information provided	- Design enhancements Survey results
	Hundt et al., 2015	- Proactive risk assessment	- A three-phased PRA of the design and implementation of the CPOE was conducted to identify and rate vulnerabilities.	PRA team: HF engineering researchers Staff from various departments i.e. IT, management and clinical staff.	- Potential vulnerabilities associated with proposed workflow and interface
	Garvin et al., 2019	- Prototyping Interviews Usability testing Participant surveys/ questionnaires	- Two rounds of semi-structured interviews with users using a scenario-based, formative approach were undertaken to enhance the prototype. In round 1, users read clinical scenarios and reviewed screenshots of a prototype. In round 2, an interactive version was used. At the end of each session, users completed the SUS and EHRUS.	Nil information provided	- Design enhancements SUS results EHRUS results
	Siegel et al., 2021	- Prototyping Usability testing Interviews Participant surveys/ questionnaires	- Formative testing using think-aloud with users based on scenarios to identify iterative enhancements. Summative testing of enhanced alert using scenarios followed by debrief interviews and use of the TAM.	Nil information provided	- Design enhancements Data on: effectiveness efficiency user satisfaction TAM results
	Nanji et al., 2021	- Prototyping Interviews Group discussions/ workshops	- Group and individual design feedback sessions with front-line clinicians and subject matter experts to gather feedback on the usability of the CDS application interface by showing mock-ups. Application was refined iteratively based on user feedback.	Nil information provided	- Design enhancements
	Nanji et al., 2022	- Prototyping Usability testing Participant surveys/ questionnaires	- Scenario-based usability testing with think-aloud conducted in a simulation setting Participants completed the Single Ease Question and SUS Rating of usability issues	Usability issue assessors: Human factors and usability expert Medication safety and CDS expert	- Efficiency quantitative data: Time on task Mouse clicks Distance travelled on the screen Design enhancements SUS results
	Kernebeck et al., 2022	- Prototyping Usability testing Interviews	- CTA with users conducted requiring users to verbalize their thoughts about a user interface while using the software to complete tasks Following testing, semi-structured interviews were conducted to gather further feedback about the usability of the medication module and potential modifications	Two researchers with experience in CTA	- Design enhancements

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HCD Activity	Studies which used HF and safety analysis methods relevant to the corresponding HCD Activity	HF and safety analysis methods used	Further detail	Individuals applying the HF and safety analysis method/s	Outcomes or outputs
	Larsen et al., 2022	- Prototyping Usability testing Participant surveys/ questionnaires Mental workload assessment	- Eight rounds of iterative user testing with think-aloud to gather user feedback on the prototype Completion of the SUS and Kano Model Survey Administration of the NASA TLX to measure cognitive load	Nil information provided	- Design enhancements SUS results Kano Model Survey results NASA TLX results

App = application; CDS = clinical decision support; CPOE = computerised provider order entry; CTA = Concurrent think-aloud; CSUQ = Computer System Usability Questionnaire; ED = Emergency Department; EHRUS = Electronic Health Record Usability Scale; HCD = human centered design; HCI = Human-computer interaction; HF = human factors; IT = information technology; NASA TLX = National Aeronautics and Space Administration Task Load Index; PRA = Proactive Risk Assessment; PSSUQ = Post Study System Usability Questionnaire; SUS = System Usability Scale; TAM = Technology Adoption Model; TURF = Task Analysis, User Analysis, Representation Analysis and Functional Analysis; UAF = User Action Framework.

Appendix 4 – Table containing nomenclature for human factors and safety analysis methods used in this review

Human factors/safety analysis method nomenclature used in this review	Corresponding method names used within included studies
Cognitive walkthrough	• Structured cognitive walkthrough
Design standards	• Design standards
Functional analysis	• Functional analysis
Group discussions/workshops	• Group discussions Focus groups Participatory design sessions Design workshop Group design feedback sessions
Heuristic checklist/evaluation	• Heuristic checklist Heuristic evaluation
Human Factors principles	• Human Factors principles
Interviews	• Interviews Semi-structured, qualitative interviews Contextual interviews Individual design feedback sessions
Literature and data interpretation	• Review of literature and other information e.g. clinical guidelines
Mental workload assessment	• National Aeronautics and Space Administration Task Load Index (NASA TLX)
Observations	• Observations
Participant surveys/questionnaires	• System Usability Scale (SUS) Post Study System Usability Questionnaire PSSUQ Computer System Usability Questionnaire (CSUQ) Electronic Health Record Usability Scale (EHRUS) Facilitator-led structured favorability questionnaire Technology Adoption Model (TAM) Single Ease Question: Overall, how difficult or easy did you find this task? Kano Model Survey
Proactive risk assessment	• Proactive risk assessment
Process charting	• Process charting Workflow flowchart
Prototyping	• Prototyping Solution representation in a low-fidelity environment Mock-ups Software used for testing and evaluation
Representational analysis	• Representational analysis
Requirements analysis	• Requirements analysis Needs assessment Development/identification of user requirements
Storyboarding	• Storyboarding
Task analysis	• Task analysis
Usability testing	• Usability testing Usability testing with think-aloud Scenario-based usability testing Formative usability testing Summative usability testing Concurrent think-aloud (CTA) User testing
User analysis	• User analysis
User stories	• User stories

Appendix 5 – Quality assessment of studies using the mixed methods assessment tool (MMAT)

Study	Criteria met (n = 7)		
	Yes	No	Can't tell
Abdel Rahman et al., 2016	5/7	1/7	1/7
Abdel Rahman et al., 2020	5/7	1/7	1/7
Afrash et al., 2022	7/7	0/7	0/7
Akhloufi et al., 2019	7/7	0/7	0/7
Baysari et al., 2021	7/7	0/7	0/7
Chan et al., 2011	7/7	0/7	0/7
Devine et al., 2014	7/7	0/7	0/7
Garvin et al., 2019	7/7	0/7	0/7
Genes et al., 2016	7/7	0/7	0/7
Harrington et al., 2011	3/7	3/7	1/7
Hundt et al., 2012	7/7	0/7	0/7
Kernebeck et al., 2022	7/7	0/7	0/7
Larsen et al., 2022	4/7	3/7	0/7
Marien et al., 2019	7/7	0/7	0/7
Melton et al., 2016	6/7	0/7	1/7
Nanji et al., 2021	7/7	0/7	0/7
Nanji et al., 2022	7/7	0/7	0/7
Nguyen et al., 2019	7/7	0/7	0/7
Schachner et al., 2016	2/7	4/7	1/7
Siegel et al., 2021	7/7	0/7	0/7
Vincente Oliveros et al., 2017	7/7	0/7	0/7

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