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Safety and Usability Guidelines of Clinical Information Systems Integrating Clinical Workflow: A Systematic Review

Yura Lee, MD, PhD[1], Min-Young Jung, RN, MS[1], Gee Won Shin, MS[2], Sangwoo Bahn, PhD[3], Taezoon Park, PhD[4], Insook Cho, RN, PhD[5], Jae-Ho Lee, MD, PhD[1,6]

[1]Department of Biomedical Informatics, Asan Medical Center, Seoul, Korea; [2]Department of Industrial Engineering, Human Interface System Lab, Seoul National University, Seoul, Korea; [3]Department of Industrial and Management Systems Engineering, Kyung Hee University, Seoul, Korea; [4]Department of Industrial and Information Systems Engineering, Soongsil University, Seoul, Korea; [5]Department of Nursing, Inha University, Incheon, Korea; [6]Department of Emergency Medicine, University of Ulsan Collage of Medicine, Seoul, Korea

Objectives: The usability of clinical information systems (CISs) is known to be an essential consideration in ensuring patient safety as well as integrating clinical flow. This study aimed to determine how usability and safety guidelines of CIS consider clinical workflow through a systematic review in terms of the target systems, methodology, and guideline components of relevant articles. **Methods:** A literature search was conducted for articles published from 2000 to 2015 in PubMed, Cochrane, EMBASE, Web of Science, and CINAHL. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement method was employed. Articles containing recommendations, principles, and evaluation items for CIS usability and safety were included. The selected articles were classified according to article type, methodology, and target systems. Taking clinical workflow into consideration, the components of guidelines were extracted and classified. **Results:** A total of 7,401 articles were identified by keyword search. From the 76 articles remaining after abstract screening, 15 were selected through full-text review. Literature review (n = 7) was the most common methodology, followed by expert opinions (n = 6). Computerized physician order entry (n = 6) was the most frequent system. Four articles considered the entire process of clinical tasks, and two articles considered the principles of the entire process of user interface affecting clinical workflow. Only two articles performed heuristic evaluations of CISs. **Conclusions:** The usability and safety guidelines of CISs need improvement in guideline development methodology and with consideration of clinical workflow.

Keywords: Hospital Information Systems, Patient Safety, User-Computer Interface, Guideline, Workflow

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Corresponding Author
Jae-Ho Lee, MD, PhD
Department of Emergency Medicine, University of Ulsan College of Medicine, 88 Olympic-ro 43-gil, Songpa-gu, Seoul 05505, Korea.
Tel: +82-2-3010-3350, E-mail: jaeholee@amc.seoul.kr

I. Introduction

Many errors regarding clinical information systems (CISs) have been reported [1-4]. Research on errors and potential hazards has led to review and updating of CISs to promote patient safety [5-7]. Efforts to reduce errors have assessed CISs in light of human factors [8]. As a result, guidelines have been developed and distributed to consider usability from the CIS design stage.

However, efforts to pursue patient safety have sometimes had conflicting results regarding usability. An alert function

that can filter out simple input errors may interfere with the flow of work, which may adversely affect usability [9-11]. On the other hand, functions to improve usability can cause errors. For a novice user, shortcuts or abbreviations for work efficiency could threaten patient safety. Therefore, user-centered CIS design guidelines are needed, not only to prevent errors but also to improve clinical workflow [12-15].

The accumulation of structured (coded) data enables the development of decision support rules. Improvements in network speed allow immediate feedback to users, with processing of evidence-based medicine and patient data. Consequently, system-level controls to reduce user mistakes (or for best practices) have become easier. Moreover, professional considerations of usability are needed as CISs become more complex and sophisticated because novice personnel regularly enter the field and must be adapted to the system [16-18]. We should consider the diverse functions of CISs and various fields of labor in CIS design and maintenance, as well as upgrades in CIS guidelines.

We conducted this study to help establish guidelines to improve the safety and usability of CIS through a systematic review and to analyze how the clinical workflow and usability principles are reflected differently in existing articles [12,19,20]. We divided the steps of clinical workflow and performed a guideline review. Furthermore, this review sought clues to balancing CIS usability and safety.

II. Methods

This review of CIS guidelines was based on a systematic review of the literature based on the results of searches on the related keywords. Detailed recommendations and principles of evaluation were extracted by reviewing the selected articles, whose components were classified and reassembled according to various criteria referenced in the selected literature to analyze how they affect clinical workflow. The present study protocol was reviewed and approved by the Institutional Review Board of Asan Medical Center (No. 2016-0980).

1. Systematic Review of Relevant Articles

Literature searches were performed in PubMed, Cochrane, EMBASE, Web of Science, and CINAHL using keywords related to health information technology (HIT), safety, and usability in guideline development published in English between January 2000 and December 2015 (Table 1). The protocol for this review was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.

The keywords used in the search were selected through discussions by the research team. Keywords were classified into three categories: guideline, HIT, and safety/usability. Each category was searched using OR for keywords and synonyms and AND between categories.

Articles containing recommendations, principles, and

Table 1. Selected keywords and their categories for the literature search

Guideline	Health information technology	Safety/usability	
Best practice	Clinical decision support	Adverse event	Effectivity
Consensus	Clinical information system	Error	Efficiency
Guideline	Computerized physician order entry	Harm	Environment
Principle	Dashboard	Mistake	Ergonomics
Recommendation	Electronic health record	Risk	Heuristic
Rule	Electronic medical record	Safety	Human factor
Systematic review	Health information system		Human-centered design
	Health information technology		Human-computer interaction
	Information display		Satisfaction
			Usability
			User interface
			User-centered design
			Utility
			Work flow

Each category was searched by OR for keywords and synonyms, and by AND between categories.

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evaluation items for CIS design, usage, or evaluation were included. On the other hand, those with 'content vague or with too narrow focus', 'issues irrelevant to safety or usability principle', 'no suggestion for guideline/recommendation', or 'unable to find full-text article' were excluded.

Two researchers independently checked the titles and abstracts of the searched articles and conducted the first selection (Figure 1). Upon agreement between these two researchers, the selection of the documents to be included in the final evaluation was made through discussion with a third researcher. After securing the full text for the final selection, secondary review was performed independently by the first two researchers. Conflicts were resolved, and the final selection for the full literature review was made through a discussion by all three researchers. In case of non-agreement, the research team reached a decision through consultation.

2. Review of Selected Articles and Extraction of the Guideline Components

The selected articles were reviewed in terms of objectives, the type of articles, and nationality. The target system and methodology of the articles were also classified according to whether they presented a guideline or principle based on existing knowledge (e.g., literature review), empirical content (e.g., expert opinion or group discussion), user opinion (e.g., user survey or testing), or heuristic evaluations. The guidelines, recommendations, principles, or evaluation items from the articles were then extracted as guideline components.

3. Review and Re-classification of Guideline Components Affecting Clinical Workflow

We stratified the clinical workflow according to the following types of actions. A user identifies and selects patients' data, records medical documents, orders medications or investigations, gets feedback from the system by alert or Clinical Decision Support (CDS), and manages and maintains the system [12,21-24]. Therefore, the guideline components were classified according to clinical tasks (data identification & selection, document entry, order entry, clinical decision support & alert, and management) and usability principles (screen recognition, data view & entry, running & control, and feedback) following considerations of clinical workflow. The research team determined the final categories and methods for classifying the guideline components through discussion.

III. Results

Among a total of 7,401 searched articles, 15 articles were finally selected through the systematic review [7,9,10,17,25-35]. Table 2 summarizes the characteristics of the studies included in this systematic review. All but one of the studies were written in the United States (73%, 11/15) or Canada

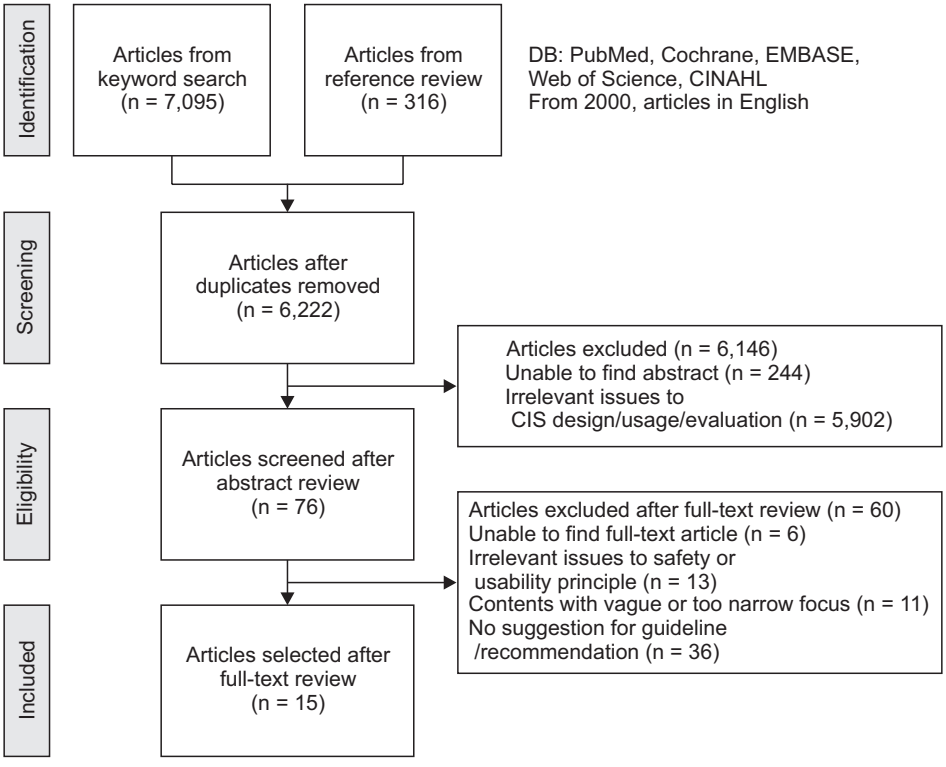

Figure 1. Flowchart of the systematic review.

Table 2. Summary of the selected articles

Study	Year	Nationality	Article type	Findings and implications	Extracted guideline components
Avery et al. [27]	2005	UK	Original research	Through structured group discussion, 55 of 80 statements were considered important by 90% or more of respondents. Indicating clear themes and priorities that need to be addressed in further improvement of safety features in primary care computing systems.	Key themes around which consensus was achieved from the text, statements considered important by 90% or more of respondents in Table 2.
Bates et al. [9]	2003	USA	Perspective, opinion, and commentary	Ten commandments for effective CDS, presenting generic lessons from own experiences that may be useful to others, including informaticians, systems developers, and health care organizations.	Ten commandments for effective CDS.
Bell et al. [26]	2004	USA	Original research	Sixty recommendations for electronic prescribing expected to have a positive effect on at least one important dimension of healthcare performance. Offering a synthesis of evidence and expert opinion that can help guide the development of electronic prescribing policy.	Sixty electronic prescribing recommendations.
Carvalho et al. [28]	2009	Canada	Original research	Twelve outcomes of heuristic evaluation expected to be applied to a hospital information system (VA CPRS). The developed evidence-based heuristics would be effective in assessing the safety of the VA CPRS.	Outcomes of heuristic evaluation in Figure 2.
Chan et al. [30]	2011	Canada	Original research	Ninety-two unique usability heuristic violations for the CPOE test order set system, encourage development of a user centered interface, improving CPOE usability.	Nielsen's usability heuristics in Table 1, and unique usability heuristic violations for the CPOE test order set system in Table 2.
Green et al. [35]	2015	Canada	Original research	Clinical reminder designed based on human factor principles shows that the response rates rose steadily, reaching a stable plateau with no evidence of reminder fatigue. It implies that reminder fatigue can be avoided by designing and implementing a clinical reminder system with careful consideration of current knowledge of cognitive science and human factors engineering.	Guidelines for clinical reminder system design and implementation, core principles of reminders in Table 1.
Horsky et al. [10]	2012	USA	Review	Summary of recommended attributes of CDS in EHR systems, clarifying the goals of optimal CDS design for appropriate design strategies to develop meaningful decision support systems that meet the grand challenges of high-quality healthcare.	Design recommendations for medication ordering (Table 4), design recommendations for alerts and reminders (Table 5).
ISMP [32]	2012	USA	Perspective, opinion, and commentary	Guidelines for standard order sets to aid in safe order communications.	Guidelines for standard order sets, categories of 'Format', 'Content', 'Approval', and 'Maintenance'.
Zopf-Herling [31]	2011	USA	Perspective, opinion, and commentary	Eighteen 'rules of thumb' for EMR screen design to promote usability for improved performance and workflow.	Categories and rules for enhancing usability in EMR screen design (Table 1).

Table 2. Continued

Study	Year	Nationality	Article type	Findings and implications	Extracted guideline components
McGreevey [33]	2013	USA	Perspective, opinion, and commentary	CDS, order set development, sharing CDS/order set development process taking into account usability and patient safety.	Ten CDS commandments with corresponding HIMSS usability principles and order set relevance (Table 1).
Corrao et al. [29]	2010	USA	Original research	One hundred ten usability issues were identified by novice users, and a majority of the experienced users had a high degree of dissatisfaction with efficiency and general functionality. It implies improvement of the chances that the EHR design is integrated with existing workflow and business processes by usability testing.	Categories of heuristic violations (Table 1).
Nolan [25]	2000	USA	Perspective, opinion, and commentary	Suggested 5 categories of tactics for reducing errors and adverse events. Outlined an approach to designing a safe system of care based on the work of human factor experts and reliability engineers.	Tactics for reducing errors and adverse events.
Sengstack [6]	2010	USA	Review	Suggested a CPOE design checklist through literature review. More evaluative research is needed to figure out the potential of CPOE systems to reduce medication errors.	CPOE design checklist (Table 1).
Vartian et al. [34]	2014	USA	Original research	Through the refined version of the combined CPOE and CDS SAFER Guide - 22 recommended safety practices, providing a practical starting point for organizations to assess and improve safety and the effectiveness of their CPOE system.	Recommended practices from frequencies of endorsement of practices to improve safety of CPOE (Table 2).
Zahabi et al. [17]	2015	USA	Review	Usability guidelines for EMR interfaces based on literature review, under 10 categories of usability problems. Identified EMR-related interface issues and formulated design guidelines and a concept for enhanced EMR interfaces.	Summary of usability guidelines for EMR in Table 5.

CDS: Clinical Decision Support, CPOE: Computerized Physician Order Entry, EMR: Electronic Medical Record, EHR: Electronic Health Record, ISMP: Institute for Safe Medication Practices, VA CPRS: US Department of Veterans Affairs Computerized Patient Record System.

(20%, 3/15); the other was from the UK (Table 2). Almost half (47%, 7/15) of the articles were original research papers, followed by perspective, opinion, and commentary (5/15) and review articles (3/15). The article types were assigned based on information from the journals. For the target system, Computerized Physician Order Entry (CPOE) was the most frequent system, whereas Electronic Medical Record (EMR) was the least frequent (Table 3). Article review was the most common methodology (7/15), followed by expert opinion (6/15). An article review was followed by additional analysis in the majority of cases (4/7). Three articles concerned the results of user testing or surveys, and only two articles conducted heuristic evaluations.

Clinical components such as 'drug-patient age checking' were classified under 'clinical tasks', and usability components such as 'clearly legible font' were classified under 'usability principles' [10,34]. There were some conflicts within a given category. For example, default values for medication prescription are sometimes recommended ("The system should provide for selection from the dosages and forms that are available and appropriate for a given medication," by Bell et al. [26]) and sometimes not ("System should limit or not use defaults for medications," by Carvalho et al. [28]). A brief explanation, such as 'Only enter default values for drug, dose, frequency, and route *if it will always be correct*', balanced safety and usability [7].

Table 4 shows the results of the categorization of guideline components according to clinical workflow. Four of the 15 selected articles [10,17,26,32] were classified as applicable to the entire process of the clinical tasks affecting clinical workflow. For example, "Content should be limited to 1–2 lines, with a justification separated by white space" by Horsky et al. [10] for data identification & selection; "Monitor use of C/P functions in record preparation and limit use of 'boilerplate' content across records" by Zahabi et al. [17] for document entry; and "Conducts a verification process to ensure that all medications comply with recommended dosing based on current evidence-based literature" by the Institute for Safe Medication Practices (ISMP) [32] for order entry and CDS & alert. Within the clinical tasks, CDS and alert (13/15) and system management (9/12) were commented on by a majority of the articles. General principles of alert systems, such as alert priority or reduction of alert fatigue, were most frequently discussed in the articles (Table 5).

Table 3. Target systems and methodologies of selected articles

Study / year	Target system				Methods				
	CPOE	CDS	EMR	Other CIS	Article review	Expert opinion	Group discussion	User testing or survey	Heuristic evaluation
Avery et al. [27] / 2005				√			√		
Bates et al. [9] /2003		√			√	√			
Bell et al. [26] / 2004	√						√		
Carvalho et al. [28] / 2009				√	√				√
Chan et al. [30] / 2011	√								√
Green et al. [35] / 2015		√						√	
Horsky et al. [10] /2012		√			√				
ISMP [32] / 2012	√						√		
Zopf-Herling [31] / 2011			√			√			
McGreevey [33] / 2013	√	√				√			
Corrao et al. [29] / 2010			√			√	√	√	
Nolan [25] / 2000				√	√	√			
Sengstack [6] / 2010	√				√				
Vartian et al. [34] / 2014	√				√	√		√	
Zahabi et al. [17] / 2015			√		√				
Total	6	4	3	3	7	6	4	3	2

CPOE: Computerized Physician Order Entry, CDS: Clinical Decision Support, EMR: Electronic Medical Record, CIS: Clinical Information Systems, ISMP: Institute for Safe Medication Practices.

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Table 4. Components of guideline/principles for clinical tasks or usability principles affecting clinical workflow

Study / year	Clinical tasks						Usability principles				
	Data identification & selection	Document entry	Order entry	CDS & alert	Management	Sum	Screen recognition	Data view & entry	Running & control	Feedback	Sum
Nolan [25] / 2000					√	1			√	√	2
Bates et al. [9] / 2003				√		1			√		1
Bell et al. [26] / 2004	√	√	√	√	√	5	√		√		2
Avery et al. [27] / 2005		√	√	√	√	4			√	√	2
Carvalho et al. [28] / 2009	√	√	√	√		4					0
Corrao et al. [29] / 2010				√		1			√	√	2
Sengstack [6] / 2010	√	√	√	√		4	√	√	√		3
Zopf-Herling [31] / 2011		√			√	2	√	√	√	√	4
Chan et al. [30] / 2011				√		1	√		√	√	3
Horsky et al. [10] / 2012	√	√	√	√	√	5	√	√		√	3
ISMP [32] / 2012	√	√	√	√	√	5	√				1
McGreevey [33] / 2013				√	√	2			√		1
Vartian et al. [34] / 2014		√	√	√	√	4	√			√	2
Green et al. [35] / 2015				√		1				√	1
Zahabi et al. [17] / 2015	√	√	√	√	√	5	√	√	√	√	4
Total	6	9	8	13	9		8	4	10	9	

CDS: Clinical Decision Support, ISMP: Institute for Safe Medication Practices.

Two articles [17,32] were classified as applicable to the entire process of selecting the usability principles affecting clinical workflow (Table 5). Running & control was the most frequently considered principle (10/15), and data view & entry was the least (4/15). The article by Zahabi et al. [17] concerned the clinical tasks and usability principles affecting clinical workflow. The methodologies of the 5 commented articles were article review [10,17], group discussion [26,32], and expert opinion [31].

IV. Discussion

In this study, we selected articles presenting guidelines or principles for CIS safety and usability that should be taken into account in the design, use, and management of such systems. We reviewed the target system and methodology

Table 5. Guideline components for clinical tasks and usability principles considering workflow in selected articles

		Category	Number of articles	Ref.
Clinical tasks	Data identification & selection		6	[6,10,17,27,29,33]
	Guidelines to ensure that the process of identifying and selecting a list of target patients and information to perform tasks efficiently with minimal errors, to ensure that users can verify accurate and up-to-date patwient and drug information, to ensure that information is delivered efficiently and can be easily implemented with subsequent work	Patient identification: -Patient list -Patient verification/confirmation	4	[6,17,27,33]
		Presentation of clinical information: -Dashboard/summary -Patient history/information -Measurements/exam results -Medication history/drug information	6	[6,10,17,27,29,33]
	Document entry		9	[6,10,17,27-29,32,33,35]
	Guidelines for enabling users to enter patient records efficiently and accurately, to ensure that medical records are efficiently linked to decision-making, prescribing, and communication in the clinical workflow.	Standard, Terminology	3	[17,28,33]
		EMR data entry: -Direct input -Automatic input -Overlap/renew -Copy and paste	5	[17,27,32,33,35]
		Entry formats and templates: -Check boxes -Diverse formats	5	[6,10,17,29,32]

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Table 5. Continued 1

	Category	Number of articles	Ref.
Order entry		8	[6,10,17,27-29,33,35]
Guidelines to provide an order system that allows users to enter prescriptions efficiently and to provide an environment that minimizes errors during prescribing, and to minimize possible errors that may occur during the completion, processing, interruption and cancellation of orders.	Basic requirements of order system: -Configurations of order system -Contents of order system	6	[6,10,17,27,33,35]
	Medication order entry: -Medication dose entry -Medication route/form entry -Default values/mandatory fields -Repeat prescribing	7	[6,17,27-29,33,35]
	Order set	3	[10,27,33]
	Order processing/completion: -Order process/result tracking -Completion of tasks -Notification of incompletion/discontinuation	4	[6,17,27,35]
CDS & alert		13	[6,9,10,17,27-29,30,31,33-36]
Guidelines to reduce errors through appropriate notifications or warnings, to recover from errors efficiently for the best performance, and to assist efficient clinical workflow through information provision or CDS.	General principles of alert: -Priority/severity -Override/reducing alert fatigue -Providing solution/recovery -Providing information/rationale	12	[6,9,10,17,27-29,30,31,33,34,36]
	CDS & alert for medication order: -Contraindications/cautions, -Dose calculation/forms -Medication recommendation -High-alert medication	5	[6,27,28,33,35]
	Other alerts and reminders: -Lab/order critical value report -Patient monitoring -Other reminders/alarm	3	[17,27,28]

Table 5. Continued 2

		Category	Number of articles	Ref.
	Management		9	[10,17,25-27,31-34]
	Guidelines for the efficient exchange of information between systems and between healthcare providers, to help users to consistently use the system safely and effectively.	Information transfer: -Data transmission between systems -Communication between healthcare providers	2	[26,34]
		Maintenance: -Monitoring/safety check -Regular knowledge base update -Set order management -Security	9	[10,17,25-27,31-34]
		Help/user education, Patient education	2	[26,34]
Usability principles	Screen recognition			
	It should be designed so that the user can clearly perceive the various internal functions of the system using minimal perceptual resources.	Visibility, Distinctiveness, Emphasis	8	[6,10,17,26,30-32,34]
	Data view & entry			
	Users should be able to design mental models for their systems easily and clearly and arrange information in a familiar and logical manner so that they do not go far beyond the user's general expectations and the overall flow of the system.	Clarity, Predictability, Briefness, Consistency, Structurality, Familiarity, Status display	4	[6,10,17,31]
	Running & control			
	By providing a specialized system environment that meets the various requirements for user's work, it helps to achieve the desired goal flexibly and efficiently.	Controllability, Extendability, Task support, Task migratability, Simplicity, Customizability, Elasticity	10	[6,9,17,25-27,29,31,33]
	Feedback			
	It increases the responsiveness of the system to user behavior and provides users with the necessary information promptly and continuously so that they can work more smoothly and quickly. When an error occurs, a user can identify, correct, and repair the problem himself / herself. Users should be protected from dangerous environments.	Feedback, Error prevention, Safety and security	9	[10,17,25,27,29,30,34,35]

EMR: Electronic Medical Record, CDS: Clinical Decision Support.

and reviewed and summarized the guidelines and evaluation items to date. Also, we divided the steps of clinical workflow into the aspects of clinical tasks and usability principles. Articles focused on specific tasks (CDS and alert) (13/15). Also, among the usability principles, the components of data view & entry were relatively small (4/15). Articles showed a lack of diversity in clinical task and principle for each step of clinical workflow. All articles with inclusive clinical workflow components were based on existing knowledge or experience [10,17,26,31]. To our knowledge, no study has reviewed the CIS safety and usability guidelines according to the detailed steps of clinical workflow.

1. Balance in Conflicts of Safety and Usability of CIS

Although improvement of usability is directed toward pursuing patient safety, some cases had conflicts, as mentioned above regarding default values for medication prescription. Recommendations like "Omit items for which the information is not available to the user," which are intended to reduce cognitive load, could threaten patient safety if clinical workflow is not taken into consideration. Similarly, "Cluster related information on the same screen" [17] and "Avoid too much information on the screen at one time" [29] seem to be mutually contradictory without a consideration of the clinical situation.

Participation of clinicians and feedback to users can mitigate the conflicts in safety versus usability, as comments on the role of clinicians in system adaptation and order set pointed out [32,35]. Some override functions have the risk of bypassing critical alerts, though they prevent alert fatigue, which reduces workflow efficiency [11-14,26-28]. However, profiling and reporting the history of alert overrides can be helpful in cases where critical alerts are of overridden [26,27]. Therefore, the consideration of clinical workflow from the user's point of view is important to balance safety and usability.

2. Challenges of Previous Studies: Localized Methodologies and Target Systems

As the terms of the systematic review were set to English articles, and all the selected articles were North American and UK studies. Among the selected articles were seven original research articles according to the publishers' classifications, but expert survey/group discussions constituted the majority of these articles. Few methodologies of heuristic evaluation were given [2], and only one article conducted a retrospective cohort study [35]. The majority included existing knowledge (article review, expert opinion, or group discussion), and there were few articles on user testing/surveys.

Much of the content concerned CDS, actions, and management, but that on data presentation was relatively small. Only one-third (5/15) of the articles included all the steps of clinical tasks and/or usability principles affecting clinical workflow. Moreover, these 5 articles were based on existing knowledge, not up-to-date user experiences or experimental evidence. Article reviews and empirical knowledge are essential for the improvement of past error and usability problems. However, considering improvements in the speed of system performance and the development of infrastructure such as a CIS network, more active experiments and studies of systems-in-use and/or systems-in-advance will be needed.

There was no specific recommendation or consideration of the size or specificity of the medical institutions except for one document related to a GP system in primary care, Avery et al. [27] (Table 2). The use of computers in medical institutions of various sizes has expanded the management of patient data. The need for the development of principles of information systems to ensure the efficient and safe exchange of information with primary care institutions and hospitals has increased.

Our findings were similar to those of previous systematic reviews on CIS safety/usability, in that most of the articles lacked a consideration of overall clinical workflow. In methodology, the majority were based on existing knowledge or empirical content and lacked an explicit theoretical framework or model, as Yen and Bakken [19] commented.

3. Limitations

In this study, the components of more specific functions or tasks (e.g., patient lists, dashboards, or override alerts) were not included. Also, non-English articles and guidelines were not included, and as this study was a part of the guideline development process, experimental articles not containing guidelines or principles were excluded. This factor might have served to exclude more experimental research articles.

4. Conclusion

There was a lack of consideration of the entire clinical workflow in the selected articles. Also, in many cases, guidelines were developed through the synthesis of existing knowledge rather than through user testing or heuristic evaluations. Development of CIS guidelines affecting clinical workflow is needed for usability and patient safety. To promote the safety and usability of CIS, more user-oriented guidelines that take into account the clinical work-flow are needed.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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