*A Review*

# Healthcare Usability Evaluation Methods

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In today's high-tech healthcare system, medical device and healthcare information technology (IT) and software applications are widely used in providing patient care by physicians, nurses, biomedical engineers, technicians, administrators, and patients.[1,2] During user interaction with healthcare devices/software, many usability problems can be identified, including poor legibility, feature clutter, poorly distinguished alarms or alerts, lack of intelligent design, poor feedback about system state or behavior, no provision for online help, poor support in local languages, and right-handed design.[1,3]

Such usability problems may effectively contribute to medical errors, which can lead to patient injury or death.[4,34] Poor usability may also affect training or support costs and lead to medico-legal cases (MLC) and liability claims.[5] Therefore, there is a vital need for evaluation of medical device and healthcare application usability.

In addition, as electronic medical records (EMR) become more common, a variety of medical devices must be connected to the computer server to extract patient data. Achieving this goal requires that each of the elements of this complex system be tested for usability to reduce errors and maintain reliable patient data.

Several types of usability evaluation methods (UEM) are used to assess software, and more extensive research is needed on the use of UEM in early design and development stages by manufacturers to achieve the goal of user-centered design. This article is a literature review of the most commonly applied UEM and related emerging trends.

## Background

UEM evaluate various elements of a medical IT system in relation to human factors engineering (HFE) or usability, including user interface, display, position of buttons or knobs, organization of information, visual alerts, and icons. UEM examine human-computer interaction (HCI) to identify aspects that can be improved to increase usability at a particular stage of system development.[6]

There are several healthcare UEM practiced by usability professionals and system designers. UEM can be based on case studies or lessons learned that are collected from several experimental studies across many domains and organizations. Some well-known and widely used UEM include heuristic evaluation; cognitive walk-through; task analysis; video analysis; rapid prototyping; field study; goals, operators, methods, and selection rules (GOMS) analysis; usability testing; keystroke-level model (KLM); think-aloud method; structured interview; cluster analysis; and severity ratings.[7,8]

**UEM examine human-computer interaction (HCI) to identify aspects that can be improved to increase usability at a particular stage of system development.**

The UEM are classified in a number of ways. First, they are categorized as expert- or user-based.[8]

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**Usability evaluation is an integral part of the product lifecycle management process.**

- *Expert-based methods* aim to uncover potential usability problems from the point of view of an expert—a professional with significant experience in HFE, HCI, usability, cognitive psychology, or a related field. The expert evaluates the user interface of the system under study with a set of heuristics guidelines or questions in mind, or by performing a step-wise approach derived from general knowledge about how humans process tasks.
- *User-based methods* include user performance measurements such as time taken to complete the task, ease of use or amount of errors faced,[9] based on log-file, keystroke analysis, cognitive workload assessment, satisfaction questionnaire, interview, and participatory evaluation about real-life users.

UEM are also classified according to stage of evaluation: formative and summative.[6,7]

- *Formative methods* focus on usability problems that can be solved by improving the prototype, intermediate, or existing designs.
- *Summative methods* are conducted to evaluate the efficacy of the final design or to compare competing design alternatives in terms of usability.

Usability evaluation is an integral part of the product lifecycle management process. It should be conducted at every stage of the process in order to improve healthcare system usability.

## Methodology

A literature search was conducted on Google Scholar for all English-language articles from peer-reviewed journals published between January 1980 and March 2013 with the keywords "usability," "medical devices," and "information technology." Articles from conference proceedings, white papers, or editorial communications were not included.

Articles on usability issues of computerized, onscreen user interfaces of medical devices and healthcare software applications were selected. As a result, a total of 30 journal articles were reviewed in this research study. The articles were organized in three groups: The first group had eight articles based on general concepts of usability in healthcare; the second had 12 articles on medical device usability; and the third had 10 articles on usability of healthcare applications. A synthesized summary of the studies reviewed with respect to medical devices

and healthcare applications/software is provided in the Tables 1 and 2, respectively.

This review was conducted with respect to the following items of interest, which are highlighted in the U.S. Food and Drug Administration's (FDA) draft guidance on human factors and usability engineering for medical devices[10]:

- **Number of participants:** 0–9, 10–19, 20–30, or more than 30 participants.
- **Items of study:** Therapeutic device, monitoring device, diagnostic device, healthcare information system (HIS), decision support system (DSS), EMR system, user manual, operating manual, or intensive care unit (ICU).
- **Evaluation settings/environments:** Hospital, ICU, usability laboratory, clinic, out-patient department (OPD), or patient home.
- **UEM used:** Heuristic evaluation, task analysis, cognitive walkthrough, usability testing, field study, structured interview, think-aloud method, GOMS analysis, or other UEM.

## Results of Review

### *Number of Participants*

The usability studies discussed in this article involve groups of participants such as usability/domain experts or medical users. These groups were of different sizes (Figure 1). In seven usability studies, the data about the number of participants are not stated. Of the remaining studies, about 80% (12/15) of usability studies definitely had small groups, with fewer than 20 participants. Gaining access to medical users, like busy physicians or nurses and their healthcare environment is also difficult.[30] Just three studies had a group of more than 20 participants.

### *Items of Study*

The most commonly studied medical devices are further categorized into therapeutic, monitoring, and diagnostic devices. Healthcare applications include HIS, DSS, and EMR systems in the healthcare domain.[31] Other items of study include user/operating manuals and ICU. In Table 3, about 48% (12/25) of the studied items were medical devices (blue), and about 40% (10/25) of the items were healthcare applications (red). The most prominent items were therapeutic medical devices and healthcare information systems.

### *Evaluation Settings/Environments*

The usability studies were conducted in different evaluation settings or environments such as hospitals, ICU, usability laboratories, clinics, OPD and patient homes (Table 4). In seven studies, data about evaluation settings/environments was not stated. Among remaining studies, 40% (8/20) were conducted in hospitals; 25% (5/20) in ICU, and 20% (4/20) in usability laboratories. The most prominent evaluation settings are hospitals, ICU, and usability laboratories. As real-life environments like hospitals and ICU present combinations of conditions that cannot be accurately simulated or predicted, these environments are widely preferred in user studies than are usability laboratories.[32]

### *Usability Evaluation Methods Used*

Table 5 shows the frequency of application of a range of UEM methods in the studies reviewed. Several commonly used methods include expert-based UEM such as heuristic evaluation, cognitive walkthrough, task analysis and GOMS analysis, as well as user-based UEM such as usability testing, field study, structured interview and think-aloud method. Expert-based (blue) and user-based (red) UEM, complement each other, and shared equal dominance in the findings.

## Discussion

The FDA received more than 230,000 adverse medical device event reports in 2010 and 2011. The rate of adverse events is growing 16%

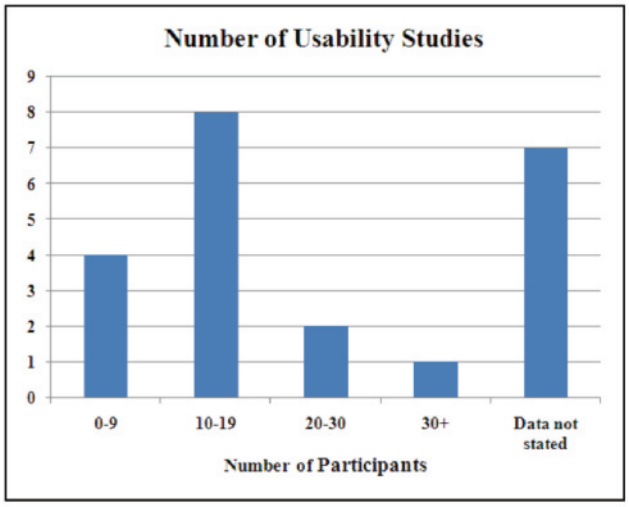


**Figure 1.** Histogram of Usability Studies by Number of Participants

### What is Usability?

A 2007 study by Daniels et al. states that usability has five main components:

- Learnability
- Efficiency
- Memorability
- Errors
- Satisfaction

The study describes a framework for evaluating the usability of clinical monitors via direct, indirect, and inspection methods of usability testing, and concludes that fitting technology to the user's need is the key factor in acceptance of a product.[12]

yearly[33] due to amplified complexity of medical devices/healthcare applications and increased compliance in reporting such errors. Of the 230,000 events, about 30,000 were serious conditions, involving hospitalization, disability, and life-threatening situations, and caused 5,300 patient deaths.[35]

The FDA released a draft document on application of human factors and usability engineering in medical device design in June 2011,[10] providing details of HFE and usability techniques that should be applied in the design and development of medical devices to overcome related usability issues. This document lists analytical approaches (contextual inquiry, heuristic evaluation, interview techniques, and task analysis) and formative evaluations (cognitive walkthrough and usability testing) as two main categories of identifying, evaluating, and understanding user-related errors.

| Article | Study Objective | Item(s) Under Study | Number of Participants | Evaluation Environment(s)/ Setting(s) | Usability Evaluation Method(s) | Product Lifecycle Management Phase(s) |
|---|---|---|---|---|---|---|
| Beard et al. (1994)[11] | Find optimal display area and response time of interpretation of the image for CT workstations | Three CT workstations (diagnostic device) | Not stated | Not stated | GOMS time-motion method | Useful in making the purchase decision |
| Bhutkar et al. (2008)[1] | Identify applicability of ergonomics in Indian ICU | ICU environment and ventilator system (therapeutic device) | 15 users | ICU and hospitals | Structured interview with the end users and field observation/users of seven ICU in different hospitals | Investigation (post-implementation) |
| Bhutkar et al. (2010)[38] | Study usability issues of user manuals provided with medical devices | User manuals (therapeutic device) | 16 users including 10 physicians | ICU and hospitals | User survey with medical users | Investigation (post-implementation) |
| Daniels et al. (2007)[12] | Develop a framework for evaluating the usability of patient monitoring systems | Patient monitoring system (monitoring device) | Not stated | Not stated | Thinking aloud, question asking, interviews, ethnography, inspection | Purchase decision |
| Garmer et al. (2004)[13] | Develop user requirement specification in purchasing the patient ventilators | Ventilator system (therapeutic device) | Two groups with six and five nurses in each | ICU and hospitals | Focus groups with usability tests | Purchase decision |
| Ginsburg (2005)[14] | Assist in hospital procurement decision making | General purpose infusion pumps (therapeutic device) | One human factors engineer, 14 nurses and three anesthetists | Hospital | 1) Heuristic evaluation and task analysis by human factors engineer 2) User testing in clinical scenarios: observation by human factors engineer | Purchase decision |
| Graham et al. (2004)[15] | Identify the design and user interface deficiencies of infusion pumps | Infusion pumps (therapeutic device) | Three experts and one clinical staff | ICU | Heuristic evaluation | To help the end users develop policy recommendation during the purchase |
| Liljegren et al. (2004)[16] | Investigate cognitive engineering methods as tools of usability evaluation of medical devices | Three patient monitoring systems (monitoring device) | Seven groups with assistant nurses, nurses and doctors, varying in size from seven to 13 members | Hospital wards | Cognitive walkthrough, user questionnaires, and usability testing | Purchase decision |
| Liu et al. (2004)[17] | Evaluate the new circular display prototype graphic user interface (GUI) of a ventilator machine | Ventilator system (therapeutic device) | Six expert nurses and 20 nursing students | ICU, usability laboratory | Usability test with six defined scenarios | Early design stage |
| Rogers et al. (2001)[18] | Demonstrate how human actors/ ergonomics tools can be applied to medical devices in general, and blood glucose meters in particular | Blood glucose meter (monitoring device) | 26 users | Patient home | Task analysis | Investigation (post-implementation) |
| Turley et al. (2006)[19] | Suggest the use of operating manuals as a tool of usability evaluation | Operating manuals of five volumetric infusion pumps from three manufacturers (therapeutic device) | Not stated | Hospital | Heuristic evaluation | Purchase decision |
| Zhang et al. (2003)[4] | Use a modified heuristic evaluation method for evaluation of medical device's usability problems | Two one-channel volumetric infusion pumps (therapeutic device) | Four experts | Not stated | Heuristic evaluation | Design and modification phase |

**Table 1**. Summary of the studies on medical device usability analyzed in this review (in alphabetical order)

### *Regional findings*

In meta-analysis, there were very few usability studies applying UEM in the healthcare domain in China and India, which, when combined, are home to more than one third (2.6 out of 7 billion) of the world's population.[36] This region lacks research in healthcare usability, device design, and ergonomics, as there is less awareness about patient or physician safety and medico-legal aspects in the society.

There is a need to improve usability of medical devices and healthcare applications by accommodating regional culture, diversity, languages, and economics. International agencies like the World Health Organization (WHO), could encourage research initiatives and projects to improve the usability and make healthcare services safer and more accessible around the world.

One finding in this study was the relative absence of usability studies in China and India, and the need to incorporate regional culture, diversity of languages, and economics in UEM (Figure 2).

### *Test group size*

The FDA's guidance document recommends that usability evaluation be conducted with a minimum of 15 users from each group of intended device users (physicians, nurses, biomedical engineers, technicians, and patients).[10] Our review did not find a single study including 15 users in each group, and found only three usability studies in which usability evaluation had more than 20 participants.

The latter three studies were conducted with different medical devices, including patient monitoring system,[38] ventilator system,[39] and

| Author(s) | Objective of the Study | Item(s) Under Study | Number of Participants | Evaluation Environment(s)/ Setting(s) | Usability Evaluation Method(s) | Product Lifecycle Management Phase(s) |
|---|---|---|---|---|---|---|
| Bates et al. (2003)[20] | Analyze role and effect of IT on safety; consider the implications of medical care, research, and policy | IT, Computer-based Decision Support Systems (DSS) | N/A | Not stated | Not stated | IT investigation (post-implementation) |
| Beuscart-Zephir et al. (1997)[21] | Discuss cognitive evaluation phase in the process of evaluation of IT in healthcare | Healthcare information technology/systems (healthcare IT/HIS) | Not stated | Usability laboratory, hospital | Field study, cognitive evaluation | In early design |
| Borycki et al. (2005)[22] | Describe a framework for the analysis of technology-induced errors | HIS | 10 users | Simulation/ laboratory | Audio and video data analysis | HIS investigation (post-implementation) |
| Carroll et al. (2002)[23] | Design and evaluate a clinical decision support system (CDSS) to support cardiovascular risk prevention in Type 2 diabetes | DSS | 14 participants (7 patients and 7 physicians) | Hospital | Heuristic evaluation, cognitive walkthrough, usability testing, think aloud | Prototype design |
| Karsh et al. (2010)[24] | Discuss 12 fallacies and their implications for healthcare IT design and implementation | HIS | N/A | All | Cognitive task analysis, usability testing | HIS investigation (post-implementation) |
| Kushniruk (2002)[25] | Examine the role of evaluation in the design of healthcare information systems | HIS | 8 participants | Not stated | Usability testing | All phases of system development life cycle |
| Kushniruk et al. (2005)[26] | Describe an innovative approach to the evaluation of a handheld prescription writing application | Handheld prescription writing application, HIS | 10 participants | Out-patient clinic | Think aloud, protocol analysis | HIS investigation (post-implementation) |
| Kushniruk et al. (2004)[27] | Provide insights of system evaluation, motivation/rationale for methodological approaches underlying usability and cognitive engineering for CIS. | HIS | N/A | Not stated | Heuristic evaluation, cognitive walkthrough, usability testing | Purchase and investment decision (post-implementation) |
| Saitwal et al. (2010)[28] | Evaluate the usability of an EHR system and suggest areas of improvement in the user interface | Armed Forces Health Longitudinal Tech Application (AHLTA, HIS) | Two analysts | Clinics, hospitals | GOMS analysis, keystroke level model (KLM) | Investigation of current interface of AHLTA (post-implementation) |
| Thyvalikakath et al. (2009)[29] | Compare the results of a heuristic evaluation with formal user tests to determine usability problems detected by both methods | Four Dental Computer-based Patient Records (CPR, EMR) | Three (2 PG students + 1 faculty), 10 users (2 groups, 5 members each) | Laboratory | Heuristic evaluation, user testing | Redesign of commercial clinical software applications (post-implementation) |

**Table 2.** Summary of the studies on health information systems' usability analyzed in this review (in alphabetical order)

blood glucose meter.[40] Most participants included secondary medical users[1] like patients, students, or healthcare assistants.

No study of healthcare applications was found that had more than 20 participants. Although user group size should meet the FDA's suggested numbers, medical device regulators seem comfortable with user studies of small groups.[32]

### *Trends*

Research studies on usability of medical devices (seven of 12) have focused on the purchase decision of the medical devices, rather than focusing on the design and development stage of the devices. Similarly, most of the usability studies noted (six of 10) related to healthcare software applications focus on healthcare information systems rather than DSS and EMR systems.

In seven of 10 articles related to healthcare software applications, summative usability evaluations were conducted in the post-implementation rather than initial stages—a clear indication of a lack of published usability studies during the product development stages. Therefore, medical device and healthcare software development industries must put more effort into conducting usability studies in the design and development stages.[41]

The concept of user-centered design is increasingly important in the medical device industry where device usability evaluations are conducted. However, they are not published because manufacturers consider them to be proprietary. Only regulators such as the FDA may see them, but such studies are rarely published. Results of these studies should at least be shared with hospital authorities during purchasing negotiations in order to decrease the burden on hospitals conducting usability tests before purchase.

| Item of Study | Number of Studies |
|---|---|
| Therapeutic device | 08 |
| Monitoring device | 03 |
| Diagnostic device | 01 |
| Healthcare information system (HIS) | 06 |
| Decision support system (DSS) | 02 |
| Electronic medical record (EMR) system | 02 |
| User/operating manual | 02 |
| Intensive care unit (ICU) | 01 |

**Table 3.** Items of Study in Usability Studies

| Evaluation Settings | Number of Studies |
|---|---|
| Hospital | 08 |
| Intensive care unit (ICU) | 05 |
| Usability laboratory | 04 |
| Clinic/out-patient department (OPD) | 02 |
| Patient home | 01 |
| Data not stated | 07 |

**Table 4.** Settings/Environments in Usability Studies

| Usability Evaluation Method | Frequency |
|---|---|
| Heuristic evaluation | 07 |
| Cognitive walkthrough | 04 |
| Task analysis | 03 |
| GOMS analysis | 02 |
| Usability testing | 07 |
| Field study | 03 |
| Structured interview | 02 |
| Think aloud method | 03 |
| Other methods | 05 |

**Table 5.** Frequency of Usability Evaluation Methods in Journal Publications

## Conclusions

Kushniruk (2002) examined the role of usability evaluation in healthcare information system design. The article discussed system development based on prototyping and iterative usability testing to accommodate changes needed in the system, and expressed a need for integration of data collected from multiple usability methods at several stages during design and development with due consideration of complexity of work environments and decision making in the healthcare system.[25]

Our review of UEM in the healthcare domain is a step in the direction of this holistic aim. The results of this review of articles published prior to March 2013 lead us to the following conclusions and recommendations:

1. UEM are mainly used for evaluating therapeutic medical devices and healthcare IT systems. *All other medical devices/software should also go through usability evaluation prior to launching the product.*
2. Usability of healthcare devices is prominently evaluated in hospitals, ICU, and usability laboratories. *Usability should also be tested in the home healthcare environment (a challenging task) if required.*

3. Heuristic evaluation and cognitive walkthrough are the most popular expert-based UEM in the healthcare domain.
4. Very few usability evaluation studies conducted by the manufacturers have been published. *It is necessary that results are published, potentially through collaboration between manufacturers and academic/research laboratories.*
5. Currently, usability evaluation of medical devices and healthcare applications or software is not usually conducted as a part of product lifecycle management. *Usability evaluation should be conducted at every important stage of the product development process, and a strong collaboration between the medical device industry and hospitals is required to cover the cost of this evaluation.* ■

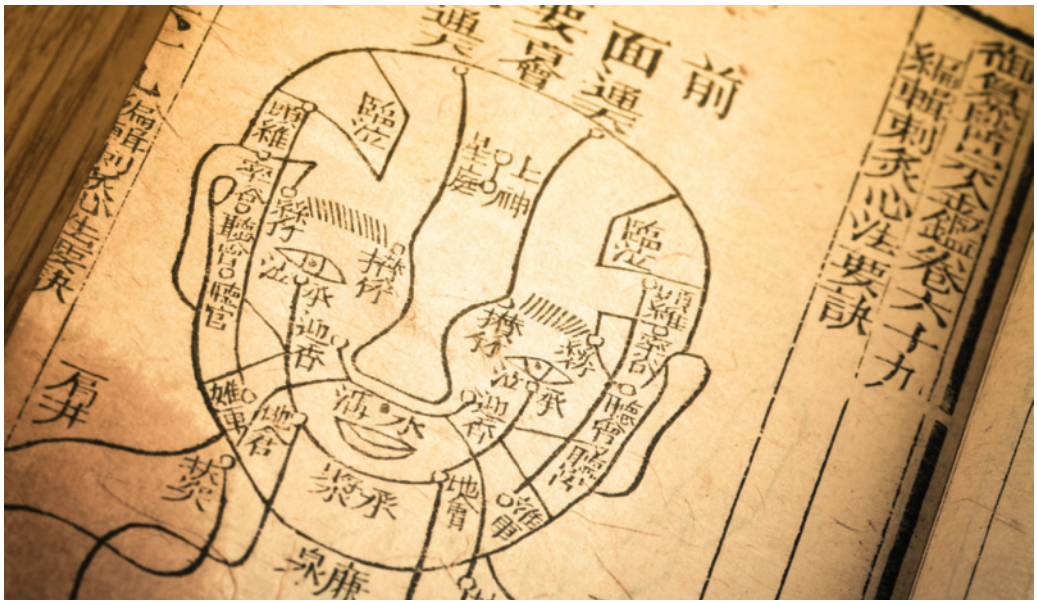

**Figure 2.** Qing Dynasty medical book illustrating use of acupuncture and herbs. Usability evaluation methods should take into account culture, language, and economics.

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**Very few usability evaluation studies conducted by the manufacturers have been published.**

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