Usability Evaluation of Medical Devices during Clinical Studies: First Results of a Scoping Review

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Abstract: This scoping review is interested in mapping the clinical studies protocols of medical devices on usability evaluation. The research question is as follows: *How is usability of medical devices evaluated in clinical studies*? The paper presents some first results from a sample of 47 protocols within a set of 188 potentially eligible protocols. Results highlight that a non-negligible part of usability evaluations are carried out combined with clinical studies. Very often, usability outcomes are part of the secondary outcomes of the clinical study. The most claimed usability-related outcomes are *ease of use*, *handling* and *satisfaction.* Usability is mainly addressed through questionnaires which provide actually perceived usability (not usability *per se*). Some protocols appear to be quite comprehensive in terms of usability evaluation methods.

1 INTRODUCTION

Medical devices diagnose, prevent, monitor, treat, alleviate, or compensate for disease or injury (World Health Organization, 2018). Their importance is rising due to several factors, including advances in technology, increases in lifestyle-associated disease (Menotti, Puddu, Maiani, & Catasta, 2015; Weisburger, 2002), and an aging population. Medical devices developed with usability principles and methods not only make devices easier to learn, more efficient to use, more satisfying, and better able to fit into peoples' lives, but they also reduce the likelihood of injury to patients, caregivers, and health-care providers (Wiklund & Weinger, 2011).

The EU's Medical Device Regulations (The European Parliament and the Council of the European Union, 2007, 2017) regulate the market access of new medical technology. Since 2010, these regulations have included the obligation to adopt a usability engineering process. The main objective is to optimize medical device usability as it relates to safety, but also to task accuracy, completeness and efficiency, and user satisfaction.

The usability engineering process is supposed to be applied as early as possible during the development process of a medical device. It includes iterative usability evaluations of medical devices (i.e. formative evaluations) and a final validation (i.e. sommative evaluation). This final validation must prove that the residual risk as it relates to usability is acceptable. The EU regulation also mentions the importance of the usability post-deployment monitoring to follow-up the usage of the medical device.

One of the challenges of this usability process is to anticipate as well as possible the risks of use errors before the deployment in real life of the medical device. This supposes to conduct usability evaluations as close as possible to the reality of clinical settings. There is a need to "*bring context into the design and evaluation of usable and safe health information technologies*" (Kushniruk et al, 2013). With this in mind, clinical studies are a good opportunity to test usability and gather information about the usage of a device. To our knowledge, no studies have focused on usability studies conducted in combination with clinical studies. This is precisely

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the aim of this scoping review. The objective is to identify the outcomes of clinical studies related to usability evaluation and the methods used to collect corresponding data. This paper presents the method and first results of the study.

2 MATERIALS AND METHODS

We used the scoping review as the method for this study. Our aim is to map the clinical studies protocols of medical devices on usability evaluation. The research question is as follows: *How is usability of medical devices evaluated in clinical studies?*

2.1 Information Sources

The US National Library of Medicine database, ClinicalTrials.gov, was searched. It is a well-known database of privately and publicly funded clinical studies conducted around the world.

2.2 Search Strategy

The search strategy was developed by two authors (JS and LD). The general search terms were usability, human factor, usage, use errors, satisfaction, acceptability, acceptance, utility. Searches were conducted between September 2020 and October 2020.

The following search string was used: (usability OR satisfaction OR usage OR use errors OR acceptability OR utility OR acceptance OR human factors OR adherence OR adoption).

Any protocol about medical devices using empirical methods of usability evaluation published between January 2015 and October 2020 with the .pdf protocol attached was considered. This means that the following additional criteria were used as filters: only *Study Protocols* as *Study documents* in the ClinicalTrial.gov database, *01/01/2015* as *Study start date*, and *Medical device* as *Intervention/treatment*.

2.3 Inclusion and Exclusion Criteria

The eligibility criteria were developed by two authors (JS and LD). The usability definition provided by the ISO 9241-11 was considered: "*Extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.*" All protocols that included the collection of device usage data to link device effectiveness and efficiency to its intrinsic qualities were included in the analysis. Objective data (e.g. *use* of a device, *handling*, *ease of use*, *safety* of the procedure, *adverse events*, *successes*) as well as subjective data (e.g. *satisfaction*, *perceived usability*, *barriers to adherence*) were considered for the analysis. The terms usage, compliance or adherence if motivations were collected, in terms of barriers for example, were included in the analysis.

All in all, a protocol was included for analysis if the following criteria were met:

- The protocol included evaluation of a medical device or a combination product.
- The protocol concerned usability evaluation as described in the outcomes of the protocol (e.g. satisfaction, perceived usability, ease of use, difficulties to use, handling, safety of the procedure, utility).

A protocol was excluded of the analysis if the following criteria were met:

- The protocol evaluated a product that was not a medical device or a combination product (e.g. a drug, a behaviour, a procedure).
- The protocol didn't evaluated usability (e.g. evaluate rather comfort, time spent for procedure, clinical performance).
- The protocol focused only on the satisfaction of a patient and/or his/her family while they were not the end users (e.g. medical device used by healthcare professionals, while the patients and their families were the beneficiaries).
- The protocol concerned adherence to the medical device without gathering information about the motivations/reasons for the adherence (or non-adherence) or acceptability.
- The protocol was not a clinical study (e.g. authors claimed in the protocol that it was not a clinical study, but a "classical" evaluation).

2.4 Search Results and Selection

Two authors (JS and LD) searched the ClinicalTrials.gov database which yielded 883 protocols for possible inclusion in the scoping review (Figure 1). In a first step, two of the authors (JS and LD) independently screened 50 protocols on titles and outcome measures.

Then, they pooled the results and discussed non-agreements until consensus was reached. This first step allowed a refinement of the eligibility criteria. In a second step, the same two authors (JS and LD) independently screened 300 other protocols on titles

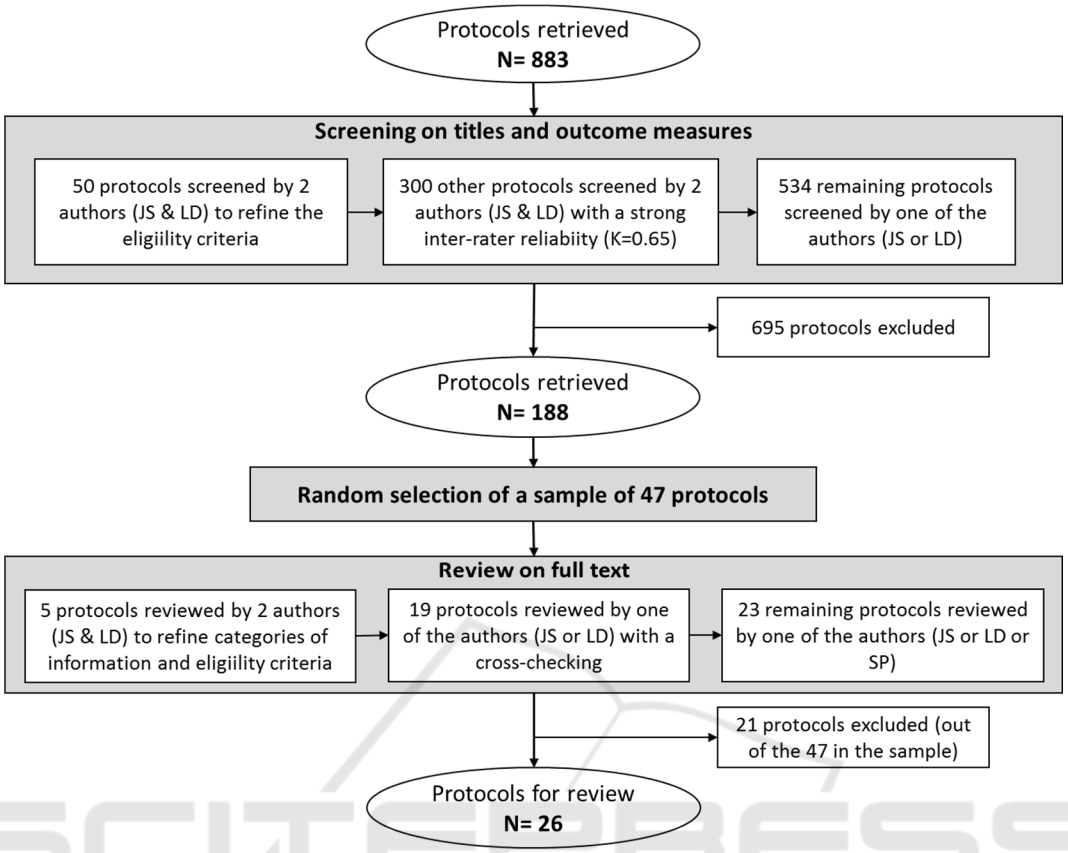

Figure 1: Flowchart of protocol selection.

and outcome measures. Then, they pooled the results to assess the inter-rater reliability; the Cohen's kappa was 0.65 which indicated a strong agreement (Krippendorff, 2013). The remaining protocols (534 protocols) were therefore screened by one of two authors (JS and LD).

The screening of the protocols based on the titles and the outcome measures led to 188 protocols to be reviewed on their full text. A random selection of 47 protocols among the 188 was made for analysis. Among these 47 protocols, 21 were excluded since the studies did not met the eligibility criteria. Twenty-six protocols were finally included for the next step.

2.5 Data Extraction and Categorisation

As for the selection of the protocols, the different categories of information extracted from the protocols were the result of an iterative and collaborative work. In a first step, 5 protocols were independently reviewed by two of the authors (JS and LD) and then pooled in order to validate the categories of information and their definition and to refine the eligibility criteria. Then, in a second step, 19 protocols were reviewed by one of the authors (JS or LD with respectively 9 and 10 protocols) to extract the information. All the 19 protocols were cross-checked to verify the extraction and completion of the information. The remaining 23 protocols were reviewed by one of the authors (JS or LD or SP).

General and specific information about the 26 protocols was extracted from the .pdf document protocol and some metadata provided by the ClinicalTrials.gov database in the study design. Table 1 lists all the extracted information along with their definition.

Data extracted from each protocol was recorded on an Excel computer worksheet in order to categorise and compare characteristics. This study was a scoping review with a focus on mapping the clinical studies protocols of medical devices on usability evaluation. As the objective was not to collect the best available evidence, critical appraisal of the selected articles was not performed.

Table 1: Information categories extracted during the analysis and their definition.

	NCT	ClinicalTrials.gov Identifier.
	Title	Title of the protocol.
Medical device specification	Condition or disease	Disease, disorder, syndrome, illness, or injury that is being studied. On ClinicalTrials.gov, conditions may also include other health-related issues, such as lifespan, quality of life, and health risks.
	Device	Medical device that is the focus of the clinical study.
	End user considered in the clinical study	Person that will use the medical device during the clinical study, i.e. Patient and/or Healthcare professional or Other
Study design	Study type	Nature of the clinical study, includes interventional studies (also called clinical trials), observational studies (including patient registries), and expanded access.
	Intervention model	Intervention model of the study includes one group assignment, parallel assignment, crossover assignment or cohort.
	Number of participants	Number of participants that is planned to be recruited.
	Post Market Surveillance	Is the clinical study a post market surveillance study?
Usability evaluation*	Category of primary outcome measure related to usability	Category of the planned outcome measure that is the most important for evaluating the effect of the medical device, if related to usability evaluation.
	Category of secondary outcome measure related to usability	Category of the planned outcome measure that is not as important as the primary outcome measure for evaluating the effect of the medical device but that is still of interest, if related to usability evaluation.
	Type of usability-related methods	Methods specified in the protocols to collect usability-related outcomes.

* The values of these categories were established by the authors based on the information provided in the protocols.

3 RESULTS

3.1 Medical Device Specifications

Several types of medical devices are concerned by the clinical studies including usability evaluations (Table 2), e.g. digital health devices (e.g. app to monitor glucose, virtual reality systems, image guidance system), biomaterials, orthoses, contact lenses, therapeutic boot or shoe. The medical devices are intended for both patients and healthcare professionals.

3.2 Study Design

From our sample, the clinical studies incorporating usability assessment that are reported in ClinicalTrials.gov are essentially intervention studies (Table 3), only one observational study has been identified, a cohort study. These clinical studies are either follow-up studies of the use of a medical device with one group of participants, crossover studies or comparative studies (2 groups). Only one post market surveillance study has been identified. Sample sizes are highly variable.

3.3 Usability Evaluation

Among the 26 analysed protocols, 5 protocols have primary outcomes related to usability evaluation. Figure 2 presents the different categories of outcomes considered in each of the 26 protocols. Seventeen protocols include one outcome related to usability while 9 protocols include at least two usability-related outcomes. The three most claimed outcomes (at least 8 protocols from our sample) correspond to the ease of use of the medical device, its handling and the satisfaction it provides when using it. Some studies are interested in use errors or barriers to medical device adherence (at least 3 protocols from our sample). Other outcomes are also sometimes used, such as willingness to use, acceptability, user-friendliness, clarity of information or usefulness as related to usability.

Figure 3 shows the different methods on which the protocols are based on. The classical methods of the usability field are used, e.g. shadowing, questionnaires, interviews, user testing. The questionnaire is the most widely used technique, followed by the interview. Most of the protocols (16/26) rely on one technique to collect usability-

Table 2: Specifications of the medical device concerned by the clinical studies included in the analysis.

Condition or disease	Device (NCT)	End user considered in the clinical study
Diabetes	Sealed therapeutic shoe (NCT04085926)	Patient
	Offloading boot (NCT02783066)	Patient
	Diabetes app to assess diabetes control (NCT03252964)	Patient
	Continuous glucose monitor combined with an activity tracker (NCT03165110)	Patient
Myopia, Astigmatism, visual acuity	Contact lens (NCT03086447; NCT03024970; NCT03006458; NCT03139578; NCT03098745; NCT03707821; NCT03679741)	Patient
Accidental falls	Ankle Foot Orthoses (NCT02819011)	Patient
Hearing Loss	Successor hearing aid (NCT03086018)	Patient
Amblyopia	Virtual reality based digital therapeutic that applies therapeutic modifications in real-time to cinematic content to rebalance visual input and treat amblyopia (NCT03608150;)	Patient
Fecal Incontinence	Anal tape (NCT02989545)	Patient
Stroke	Smart Glove (home based virtual reality biofeedback system) (NCT03559829)	Patient
Asthma	Propeller Health device + asthma navigator (NCT03065205)	Healthcare professional & Patient
Medication Adherence	Device for Dispensing Pain Medications in Hospice Patients (NCT03940534)	Healthcare professional & Patient
Feeding tube dysphagia	Enhanced enteral feeding device (NCT03007511)	Healthcare professional
Hypothermia Neonatal	Non-Electric Infant Warmer (NCT03031431)	Healthcare professional
Spinal Diseases	New image-guidance software (NCT03015142)	Healthcare professional
Wounds and Injuries, Lacerations, Surgical Incision	Polyurethane-based skin adhesive (NCT03688880)	Healthcare professional
Coronary Artery Bypass Grafting	Pliable and absorbable bone hemostats (NCT03085017)	Healthcare professional
Aortic Valve Stenosis	Portico TF and ALT Delivery System (NCT03056573)	Healthcare professional

Table 3: Study designs of the clinical studies included in the analysis.

		Interventional model			
		Single group assignment	Parallel assignment	Crossover assignment	Cohort
Interventional study	PMS	1	/	1	/
	No PMS	7	10	6	/
Observational study	PMS	/	/	/	/
	No PMS	/	/	/	1
Number of participants: Mean (SD) Min-Max		95, 33 (122,04) 15-400	116, 4 (91, 34) 10-267	49, 42 (36, 41) 20-120	240 screw placements (15 to 25 patients)

related data, mostly on questionnaires. Almost 40% of protocols (10/26) combine several techniques, quite often interviews and questionnaires, but also shadowing and interview. The category *Other* refers to techniques used once in one of the protocols; the *log analysis* was used once, as the technique of the diary study (the end user document in a journal some

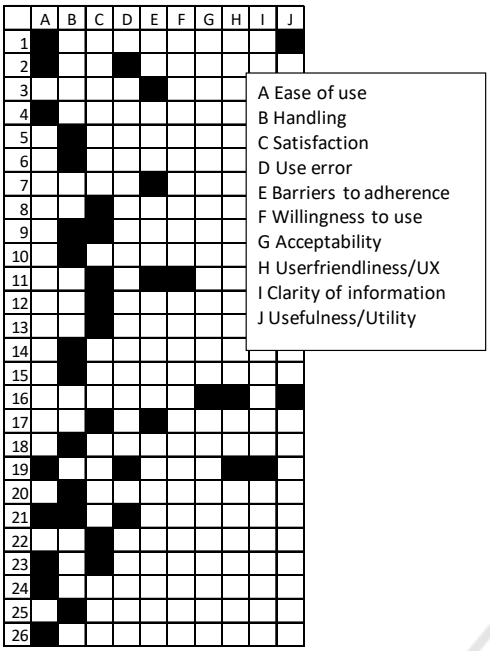

Figure 2: Categories of outcome concerned by each of the protocols.

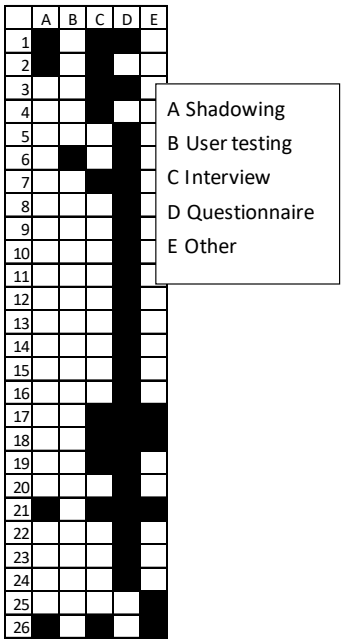

Figure 3: Methods concerned by each of the protocols.

elements related to the use of the device), or the analysis of adverse events to identify use errors.

When crossing outcomes with methods (Table 4), not surprisingly questionnaires are used to address *ease of use* or *satisfaction* of the participants with the medical device, but more surprisingly also to collectinformation on the *handling* of the device which is supposed to be more objective data. Interestingly the shadowing technique is exclusively used with healthcare professionals (Table 5).

Table 5: Methods depending on the participants in clinical studies included in the analysis.

	Healthcare professional	Patient	Other
Shadowing	6	0	0
User testing	0	1	0
Interview	3	8	1
Questionnaire	7	26	0
Other	2	2	0

Table 4: Categories of outcomes and methods of clinical studies included in the analysis.

	Shadowing	User testing	Interview	Questionnaire	Other
Ease of use	5	0	5	7	2
Handling	1	1	3	11	2
Satisfaction	0	0	0	8	0
Use error	3	0	3	2	1
Barrier to adherence	0	0	3	3	1
Willingness to use	0	0	0	1	0
Usefulness/Utility	0	0	0	2	0
Acceptability	0	0	0	1	0
User friendly/User Experience	0	0	0	2	0
Clarity of information	0	0	0	1	0

4 DISCUSSION

The first results of this scoping review highlight that a non-negligible part of usability evaluations is carried out combined with clinical studies (or planned to be carried out as only protocols have been analysed). Very often, usability outcomes are part of the secondary outcomes of the clinical study. The most claimed usability-related outcomes are *ease of use*, *handling* and *satisfaction*. Usability is mainly addressed through questionnaires which provide actually perceived usability of the medical device instead of usability *per se*. While several protocols appear to be quite comprehensive in terms of usability evaluation methods, the vast majority of protocols refer to notions close to that of usability, but not to usability.

But this paper presents only some first results of the scoping review and are maybe not representative of the results out of the total of 188 protocols. Moreover, not all usability studies conducted with medical devices are necessarily reported on a database such as ClinicalTirals.gov. But these first results show the validity of the methodology and some interesting trends.

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