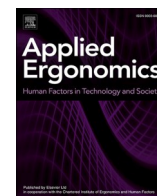


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Usability issues in the operating room – Towards contextual design guidelines for medical device design

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ABSTRACT

Most usability assessments of medical devices describe the problems of individual devices in detail, but few account for the real context of use or provide designers with actionable guidelines for improvement. To fill this gap, this paper reports the results of a case study on the usability of operating room technologies and documents the creation of contextual design guidelines for operating room device design. We spent 64 h in a gynecological operating unit conducting interviews with staff and observing device use during surgery. With qualitative analysis methods and based on existing usability principles, we created 21 design guidelines for the operating room context. The new guidelines highlight interactions between multiple devices, staff members, as well as other contextual factors. While the guidelines require further validation, they can potentially support the creation of more safe, ergonomic, and intuitive medical devices.

1. Introduction

“It is imperative to figure out how to develop design safety features that make it easy for the user to do the right thing” (AAMI/FDA, 2010). This call for help in medical device development highlights the importance and lack of guidelines for medical device design to improve usability and reduce human error. The importance of usability is highlighted in operating rooms, where the complexities of technology, procedures, multidisciplinary teamwork, and decision making are at their highest. Lackluster usability in operating rooms (ORs) is frequent, can put patients in danger, and can incur significant costs, as 16% of operations experience an equipment-related incident with nearly half of them causing time delays (Wubben et al., 2010).

The aim of this study is to enable the design of useable devices for the OR context by developing a set of context-specific design guidelines. Design guidelines are evidence-based textual instructions of how design should be carried out (Fu et al., 2016). Various sets of guidelines exist for other contexts, such as design for assembly (Boothroyd and Dewhurst, 1989) and design for environment (Telenko et al., 2016). In the healthcare field, guideline-like tools, such as heuristic evaluation, have primarily been used to analyze device usability (e.g., Zhang et al., 2003), but few prescriptive guidelines for designing usability exist.

2. Background

2.1. The roles of technology and people in OR work and design

Many studies look at the prevalence of various types of disruptions and interruptions in the OR (Rivera-Rodriguez and Karsh, 2010), but the influence of technology on these interferences is rarely analyzed. Arguing for the interconnectedness of interferences in the OR, Weerakkody et al., 2013 found a strong correlation between the frequency of technology-related errors and other errors. Moreover, technology-related errors are rarely caused by direct device failure, but more frequently happen due to poor usability, OR layout, misplacement, and other more contextual factors (Palmer et al., 2013; Pennathur et al., 2013), which suggests that device functionality is not the only factor to consider. Functionality in the form of new features was found in only 20% of award-winning medical devices, compared to more than 60% of the devices showing improved architecture, environmental interactions, and user interactions (Hölttä-Otto et al., 2010), again highlighting the importance of context. Thus, in the complex OR environment, where healthcare professionals (HCPs) are continuously performing tasks that influence others and whose effect is often mediated by technology (Catchpole, 2011), it is key to account for the way technology shapes

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and is shaped by the wider context, and not only look for improvements in device features, or coordination and other practices.

While several scholars highlight the importance of human factors engineering, including considering interactions between technologies and humans as well as the needs and limitations of individuals (Carayon et al., 2006; Gurses et al., 2012; Hignett et al., 2013; Russ et al., 2013; Ward and Clarkson, 2004), there is still little research on how to involve patients and practitioners in medical device design. There are even some indications that medical device manufacturers and developers prefer to involve practitioners primarily for marketing purposes instead of improving device design (Martin and Barnett, 2012; Meek, 2017; Money et al., 2011). Regulations require user interaction and thus it is included in some form in medical device design, but often via external user consultants, although some firms also engage in more immersive user studies (Privitera et al., 2017). Further, practitioners generally perceive that they could help in designing better devices, but they are not involved much in the development process outside clinical trials and the idea stage (Hani and Marcellis-Warin, 2016). Such problems in user involvement can result from a mutual lack of understanding between developers and users (Privitera et al., 2017). Thus, while there is a need to understand stakeholders better to develop more useable and useful technology for ORs, gathering and using such understanding in practice is challenging.

2.2. Design guidelines and design for X

Design for X (DfX) is a general term for tools that aid product designers in achieving a specific design goal, such as usability, ease of manufacturing, or ease of assembly. These tools can apply to various stages of the product design process, from problem definition to detail design, and can be of various forms, such as checklists, mathematical models, practical methodologies, and textual instructions (Chiu and Okudan Kremer, 2011). Textual instructions in DfX can be divided into *principles*, *guidelines*, and *heuristics* (Fu et al., 2016). Design *principles* are the most general and should be applicable relatively independent of context, e.g., “change the physical dimensions of an object to bring about an increase/decrease in occupied volume primarily along an axis, in a plane or in three dimensions.” *Heuristics* are more specific to a certain domain or area of application, e.g., “a properly designed bolt should have at least one and one-half turns in the threads.” *Guidelines* are between the two, being both more evidence-based and prescriptive than heuristics and more context-dependent than principles, e.g., “use feedback mechanisms to inform the user of current status of the process” (Telenko and Seepersad, 2010).

In the healthcare field, as in other fields, the above three terms have been used interchangeably. However, when differentiated, we find that design *principles* have been used in evaluating medical devices and device-specific assessment *heuristics* have been created, but little documentation exists for design *guidelines* aimed at not only analyzing but also improving medical device usability. The most frequently used assessment *principles* are Nielsen (1993) principles for human interface design that have been utilized as-is in quantifying violation types for radiotherapy systems (Chan et al., 2012) and infusion pumps (Zhang et al., 2003) as well as with slight modifications in various other medical device assessments (Hermawati and Lawson, 2016). Device-specific *heuristics* exist for touch-screen-based ventilators (Katre et al., 2010) and health information systems (Carvalho et al., 2009), detailing requirements for screen elements, controls, and other features. While *guidelines* are rare in healthcare literature, Furniss et al. (2014) created a list of 7 guidelines to aid in contextual medical device assessment, based on observations of blood glucose meters in an oncology ward. In this study, existing principles and guidelines for device assessment will be used and built upon to develop a set of prescriptive guidelines for OR device design.

3. Material and methods

In this study, we used three methods to collect qualitative data on OR technology use, analyzed the data by deductively and iteratively coding it for usability violations, and reworded the codes into contextual design guidelines (Fig. 1). This study adopted a constructivist research framing, where we acknowledged both the subjectivity of each participant's experiences and that these experiences could be influenced by the social context of the studied unit.

3.1. Participants and data collection

All data collection was carried out during a 3-month period in 2018 at the Women's Hospital's Operating and Anesthesia Unit in Helsinki, Finland. The unit performs gynecological laparoscopic and open surgeries in eight operating rooms and employs roughly 125 healthcare professionals. All data collection was carried out concurrently within the time period. The final dataset comprises 64 h of time spent in the unit and includes 11 semi-structured interviews, 30 filled usability forms, as well as transcribed field notes from eight observed surgical operations and several informal discussions with HCPs.

Everyone working in the ORs of the Women's Hospital were eligible to participate in the study. The study was approved by the Helsinki Biobank's Scientific and Ethical Review Committee. Interview and survey participants were recruited via convenience sampling, by sending emails to the unit mailing list and by approaching people face-to-face in the unit itself. Low-risk laparoscopic hysterectomies involving ASA 1–2 patients (Owens et al., 1978) were chosen to be observed and videotaped since they represent the most typical operation type in the unit and were most conveniently accessible to the researchers. Details about the unit can be found in Appendix A.

The interviews focused on aspects of technology that the participants felt annoying or somehow hindering their work. This focus was motivated by design practice, where similar methods such as the dislike method and contextual inquiry encourage users to discuss their own experiences in detail (Otto and Wood, 2001).

The practical interview outline was semi-structured and consisted of two parts. First, participants were specifically asked to describe a typical operation and its technological interactions in detail. The purpose of the first part was to open-endedly capture a broad range of technological issues that were important to individual HCPs, with minimal bias imposed by the researcher. Second, the researcher asked for comments on technologies that had been mentioned during prior data collection. This part was used to increase the depth of the data for issues that had already been identified. The interview participants included primarily circulating and scrub nurses, anesthesia nurses, and anesthesiologists (Table 1). All interviews were held in the participants' native language.

The usability forms, modeled after simple design probes (Matalmäki, 2006) and minute papers (Angelo and Cross, 1993), included two open-ended questions asking the participant to explain what annoyed them in a device and how they believe the situation could be improved. The forms were left in a mailbox-type box in the unit's break room. This method enabled HCPs to quickly report their annoyances and ideas as they occurred during the day without the researcher being present. The main purpose of the usability forms was to uncover targets of annoyance that could then be elaborated upon with interviews and contextual inquiry.

The contextual inquiries, i.e. observations and informal discussions during the HCPs' work, focused on tasks carried out in the OR as well as nuisances HCPs experienced during operations. Similar informal methods have been reported in other contextual OR studies (such as Furniss et al., 2014; Martin et al., 2012), and conducting product interviews in the real use context generally produces more specific data (Otto and Wood, 2001). Fig. 2 illustrates the observation situation. As with the semi-structured interviews, the researcher both used information gained during prior data collection to focus on issues where more

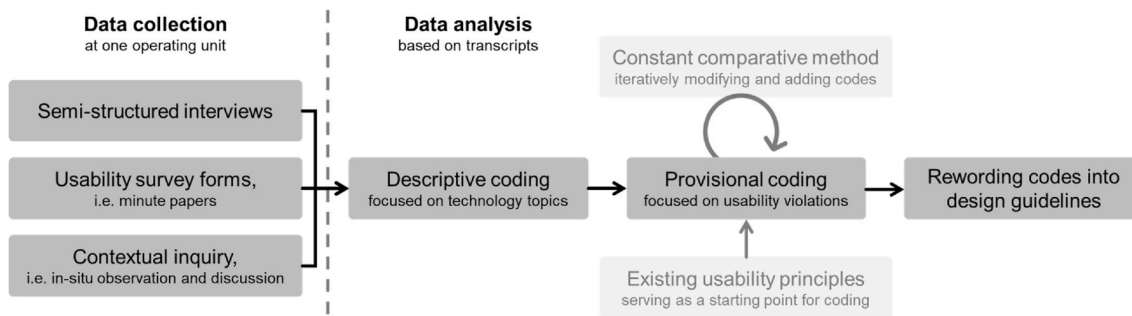


Fig. 1. An overview of the data collection and analysis in this study.

Table 1

The interview dataset collected in this study. The total duration of the interviews is approximately 11 h and 32 min, and the interviewees' median working experience in healthcare is 17 years.

Profession	N	Average duration, h: mm	Experience, years for each participant
OR nurse	5	1:07	2.5, 3.3, 3.3, 30, 30
Anesthesia nurse	4	1:06	8, 8, 8, 39
Anesthesiologist	2	0:46	14, 20

depth was needed, and asked open-ended questions to increase the breadth of technologies covered in the study.

3.2. Data analysis

All data was analyzed equivalently via a combination of descriptive and provisional coding (Saldaña, 2013). The step-by-step analysis procedure was as follows:

1. Familiarizing with the dataset by conducting interviews and observations as well as transcribing the resulting audio files and notes.
2. Descriptive coding: inductively coding for the device or technology topic being discussed. The purpose of this phase was to filter the transcripts and to enable the later aggregation of device-specific usability violations.
3. Provisional coding: deductively coding for violations of existing usability principles (Nielsen, 1993; Shneiderman and Plaisant, 1998) and contextual assessment guidelines (Furniss et al., 2014). This phase was guided by the constant comparative method (Charmaz, 2006), where coded excerpts were compared to each other and categories split and merged as well as new categories created as analysis progressed.

For coding purposes, usability issues were defined as anything with potential to influence the practitioners' work and/or patient safety. This definition includes disruptions, distraction, and anything hindering the practitioner's awareness.

4. Creating design guidelines by adjusting category descriptions to be more prescriptive and actionable. In this phase, we benchmarked the wordings of other principles and guidelines for device design, such as design for assembly (Boothroyd and Dewhurst, 1989) and design for environment (Telenko et al., 2016).

The starting point for the provisional coding, along with our operationalization of usability issues, was based on three prior usability assessment schemes. This initial scheme adapted existing usability principles created by Nielsen (1993) and Shneiderman and Plaisant (1998), and, to complement the principles focused on single interfaces, the categories Furniss et al. (2014) created for contextual evaluation of medical devices were also included. These categories helped capture broader notions of how devices interact with other system elements as well as what knowledge users lack. The category *Workarounds* and the principle *Prevent errors* were originally coded, but later recoded into other existing and new categories to better serve as prescriptive and actionable design guidelines. The category *Impact of policy* was left outside the scope of this study as our research focus was on characteristics of the technologies and adjacent interactions instead of the ways in which new technology had been implemented in the organization. Appendix B presents the coding scheme we began our analysis with.

Two types of discrepancies in the data were discovered during coding: disagreements on whether some technology or feature was annoying or not, and disagreements on the reasons for experienced usability issues. Our method for resolving the discrepancies was driven by us wanting to assure that no potential design flaws were unintentionally excluded. Thus, disagreements on annoyingness were resolved in favor

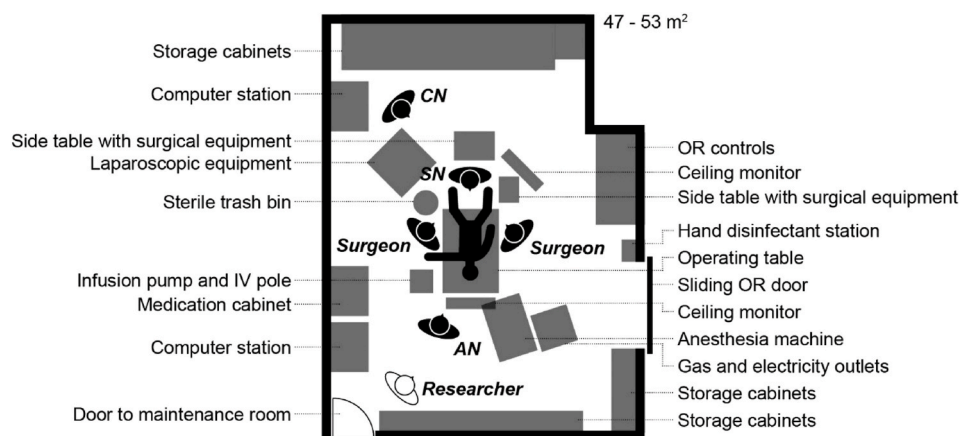


Fig. 2. The approximate layout of the observed operating rooms during laparoscopic surgery. The researcher was primarily located on the anesthesia side. CN = circulating nurse, SN = scrub nurse, AN = anesthesia nurse.

of the annoying point of view, and all different reasons provided for usability issues were noted when aggregating device-specific summaries.

4. Results

4.1. Contextual guidelines for designing usability

The provisional coding resulted in 489 tagged excerpts describing violations of 21 design guidelines. Table 2 presents the full list of contextual design guidelines for OR device design, along with examples of violations found in the data. Of the 21 guidelines, 5 match existing design principles, 11 are modified from principles, and 5 are newly created. Additionally, we identified two themes, comprising an additional 63 tagged excerpts, that provide opportunities for new device development but could not be translated into design guidelines (Table 3).

The guidelines remaining in their original form are *Good error messages*, *Reversible actions*, *User in control*, *Language*, and *Gaps in users' knowledge*. These five guidelines comprise elements of digital interface usability that readily translated into OR devices. *Gaps in users' knowledge* includes users both not knowing why a device needs to be used and not knowing about the existence of a feature or device altogether.

For the modified guidelines, *Consistency* and *Feedback* were split into a total of 5 subcategories to better capture the nuances in each. Then, the *Minimize need for recall* category was created from an original principle addressing memory load in general, due to the prevalence of recall-related usability issues in the dataset, such as HCPs forgetting to turn on specific devices or to fetch items from the storage. Further, the *Minimalist* category originally focuses on the number of interface elements and information provided, and we expanded it to cover the physical features in devices. Lastly, *Fit with wider tasks and equipment* was split into several subcategories, all of whom were hinted at in the original definition (Furniss et al., 2014), to make the guidelines more actionable for designers.

New guidelines include *Ease of physical interaction*, *Fit with OR infrastructure*, *Fit with practitioner characteristics*, *Inconsistent preferences*, and *Infrequent use*. The *Ease of physical interaction* guideline was added to capture HCPs' complaints about devices and systems requiring too much dexterity or care to operate. This includes, for example, smart keys that had to be inserted to locks slowly to open them, bulky equipment that needs to access small areas, as well as the difficult alignment and attachment of replaceable parts. *Fit with OR infrastructure* and *Practitioner characteristics* were added to capture issues missing from the original *Fit with wider tasks and equipment* category. In the violations of *Fit with OR infrastructure*, HCPs mentioned equipment blocking OR lights, columns blocking speakers and compromising the acoustics of the OR, and the placements of the OR door and operating table making it difficult to maneuver a patient bed next to the table. In *Practitioner characteristics*, it was mentioned that HCPs with distinct characteristics, such as reduced hearing or excess bodyweight, had experienced difficulties with hearing requests and reaching certain places. Lastly, *Inconsistent preferences* and *Infrequent use* were added to remind designers of two salient characteristics of work in the OR: many HCPs have worked in multiple units and with various device models, and not all devices are used with equal frequency as some might be solely reserved for unusual situations.

We also observed two usability-related categories that did not directly translate into design guidelines: *Extraneous tasks* and *Inadequate device performance* (Table 3). *Extraneous tasks* comprises tasks that HCPs felt were necessary for the operation but that would be easy to automate or simplify, such as having to manually squeeze pressure infusion sleeves to ensure appropriate pressure levels, and having to manually log anesthesia parameters on paper. This category also includes HCPs' wishes for certain functionalities, such as enabling the pulse sound in the patient monitoring device (so that the anesthesia nurse can briefly turn

Table 2
Usability guidelines for OR device design.

Design guideline	Description	Example violation	Note
Consistency <i>Functionality</i>	The device should function reliably with similar logic in all situations.	<i>An electronic anesthesia logbook system had allowed the anesthesiologist to input their own comments, but the comments were not always displayed when the logs were printed on paper.</i>	Modified
<i>Layout</i>	The physical dimensions of devices and the locations of features should support their intended use.	<i>"I think the [operating table's] railings are in somewhat silly locations, and they kind of don't serve their purpose. Meaning that at the location where you'd need to attach [the armrest], there's no railing at all.</i>	Modified
<i>Task</i>	Similar tasks should be performed with similar tools and techniques within a device and its adjacent systems.	<i>"And [the IT systems] work differently, so that in one you use your mouse and a search bar, and in the other you don't do anything with the mouse but rather input numbers and press keys. It's stupid; everything should work easily, logically ..."</i>	Modified
Feedback <i>Visibility of system state</i>	The device should continuously display its internal state and any parameters relevant to the HCPs' work.	<i>"This operating table, it doesn't say whether it's on or not. Or well, now I can see that it's on when the light is green. But I don't always remember to look under there in the morning. I don't really look over there."</i>	Modified
<i>Reaction to input</i>	The device should promptly provide feedback in response to its user's actions.	<i>"The remote control we have [for the operating table] reacts really slowly. When you press the button, nothing usually happens right away."</i>	Modified
<i>Good error messages</i>	The device should provide a diagnosis of its error states that is both actionable and understandable to the user.	<i>"[The electrosurgical instrument] doesn't make any sound until you try to activate it. I mean, it shows the red graphic telling it's not properly attached, but if you don't pay attention to it, you'll only notice it when it beeps, saying it's not attached."</i>	Original
<i>Reversible actions</i>	The device should allow users to easily undo their actions and return to previous states.	<i>"But if I press [the light switch] one too many times, then I need to pound it who knows how many times to get back to the same level where the brightness increases."</i>	Original
<i>Users in control</i>	The device should not initiate actions without sufficient permission from and/or notification to the user.	<i>"The [infusion pump's] flow sensor, it's very sensitive for movement, so that if the bag swings, the infusion pump will stop administering the medication."</i>	Original

(continued on next page)

Table 2 (continued)

Design guideline	Description	Example violation	Note
Minimize need for recall	The device should not require users to memorize distinct steps in its operation.	<i>"All of our electro-surgical forceps don't even fit our generators, so that we can't use some of the devices in these laparoscopies. And then you just have to remember which forceps fit which generators. Real handy."</i>	Modified
Ease of physical interaction	The device should not require too much skill, "touch", or awareness to operate efficiently and safely.	<i>"Those screens have some specific technique where you have to press them gently with love for them to shut down. That's what I do here for minutes on Friday afternoons."</i>	New
Minimalist	The device should not have unneeded features or possibilities for adjustment.	<i>"Again, we go back to the fact that [OR doors] have a lot of technology in them. There are buttons people can press, and when they don't know how to use it, they press all of the buttons and make the door go crazy."</i>	Modified
Language	The information provided by the device should be understandable to the average user.	<i>"[An alert] tells you the wing, the floor, and maybe the room, but the wing is kind of big and there are wards all over the place ... So where are you really supposed to go?"</i>	Original
Gaps in users' knowledge	Devices should be designed so that users can easily learn why they exist as well as how and when to use them.	<i>"It has never dawned upon me that why I need to [re-encode my smart key daily] ... Because this is, this must have a feature that recognizes it's me or my key that's opening the medicine cabinet."</i>	Original
Fit with wider context			
OR infrastructure	The device should not block or otherwise hinder the operation of fixed OR infrastructure (e.g., cabinets, lights).	<i>"The ceiling attachment arm of the laparoscopy system can sometimes cover the lights in the ceiling so that the scrub nurse's working area is left dim."</i>	New
Practitioner tasks	The device should not hinder or be hindered by the tasks of its user or other HCPs in the OR.	<i>"So, it's bad that if the infusion bag is moved, the pump can stop the infusion and yap about it. [...] If the surgeon is close to the drape, they might move it, and the infusion bag could move too."</i>	Modified
Patient characteristics	The device should fit different types of patients as well as consider their safety and experience.	<i>"If there's a really skinny person, then the [grounding pad] will bend more when it's on. And then, I don't know, it just usually starts peeling off. It's made of a somewhat thick material."</i>	Modified
Operation characteristics	The device should accommodate the	<i>"When we get to the phase where the uterus is</i>	Modified

Table 2 (continued)

Design guideline	Description	Example violation	Note
	distinct tasks, processes, and activities in the types of operations it is designed for.	<i>almost detached, where we have the metallic pliers in the vagina and cervix, then [the electro-surgical instrument] always hits it and makes that sound, that alert."</i>	
Other devices and ways of working	The device should accommodate other devices and consider the existing ways of working at distinct OR units.	<i>"When I'm moving the patient bed next to the operating table, when we're about to move the patient, then usually one of those cords, when they're in use, gets stuck under the bed."</i>	Modified
Practitioner characteristics	The device should be useable by and not hinder the work of HCPs with different skills, abilities, and capabilities.	<i>"I have reduced hearing. And then there are many devices, like these fan-heated covers, with different fans and cooling systems and others. [...] Then I sometimes can't hear what they're saying in the surgical field."</i>	New
Inconsistent preferences	The design of the device should consider different preferences among HCPs.	<i>"The brand of laparoscopic instruments we use in a specific operation only depends on what the operating surgeon likes to use."</i>	New
Infrequent use	The design of the device should consider the frequency of its use by different groups of HCPs.	<i>"But I must say that [central venous catheters] are kind of a grey area for me too, because I use them so rarely. I've maybe encountered one twice during my time here."</i>	New

Table 3

Challenges observed in OR system design that we weren't able to transform into actionable design guidelines.

Name	Description	Example violation	Note
Extraneous task/missing function	Expressing potential for development, through unnecessary-feeling tasks as well as missing devices and features.	<i>"There's a table missing from next to the operating table. For example, when we're cannulating the patient, we have no place to put all the equipment on."</i>	New
Inadequate device performance	Manufacturing errors and other issues with measurable performance where the device did not improve the status quo.	<i>"It was kind of a disappointment to realize that the thermal power [of the heated mattress] is so small. I mean, you can feel that it is warm with your hand, but it won't influence the patient's thermo-economy at all."</i>	New

away from the patient and still hear their condition), and slots in the anesthesia machine to help store and identify different sensors and their cords. *Inadequate device performance* describes manufacturing faults and lackluster performance of technology as well as their impact on use. This category is exemplified by failures, such as automatic hand disinfectant dispensers building clogs around their nozzles and spraying disinfectant horizontally, and replacement parts being broken off-the-shelf. Examples of lackluster performance include thermal mattresses not heating up enough to battle patient cooling, and certain medication tubes kinking under their own weight.

4.2. Usability issues in the operating room

Through descriptive coding of the data, a total of 40 distinct systems were found to display some level of usability violations (Table 4), with four additional systems displaying either workarounds or issues related to internal policies that were outside the scope of this study.

The following sections present the major usability issues found in four exemplary categories: two that span across devices, *Environment* and *Alarm*, as well as two focused on individual devices, *infusion pumps* and *operating tables*. A list of example usability issues in all categories can be acquired from the corresponding author.

4.3. Environment

The environment category violated 17 of 21 usability guidelines. The category itself encapsulates a broad range of devices and situations, focusing on the interactions between multiple devices and systems as well as between devices and the tasks of multiple users. Recurring themes in this category included cross-brand integration and use of overlapping technologies.

First, there were cases where multiple device brands were present for one purpose, resulting in integration problems. For one, the monitor screens, OR control system, and laparoscopic camera instrument were designed and manufactured by different companies, and the system had issues with properly setting up the camera image on all necessary monitor screens, including the devices not always recognizing they were plugged in and screens occasionally blacking out after setup (Consistency - Functionality).

Second, there were instances where multiple technologies were used to achieve one goal. The anesthesia nurses mentioned that the unit uses smart keys that unlock dressing rooms and medication cabinets, but that you still have separate keys for some places, such as the anesthesia cabinet in each OR and the cold storage for medication (Minimalist). Further, the patients' heat economy was maintained with both a heated

Table 4

Technological systems covered in the dataset of this study. The ordering of the categories is alphabetical and does not indicate frequency or importance.

Spanning multiple systems	Individual systems		
	Anesthesia side	Surgical side	General/Shared
1 Alarms	6 Anesthesia machine	17 Electrosurgical equipment	22 Armrests
2 Cords & tubes	7 Anesthesia suction	18 Foot pedal control	23 Defibrillator
3 Environment	8 Arterial blood pressure measurement	19 Patient skin preparation	24 IT systems
4 Noise in the OR	9 Infusion and syringe pumps	20 Surgical lights	25 Emergency buttons
5 Non-OR usability	10 IV cannulation	21 Surgical suction	26 Hand disinfection
	11 Medication		27 Legrests
	12 Patient monitoring		28 Monitor screens
	13 Temperature measuring		29 Operating table
	14 Ultrasound/IR vein locating		30 OR computers
	15 Ventilation		31 OR doors
	16 Video laryngoscope		32 OR lights
			33 Paper hand towel dispenser
			34 Patient positioning & transfer
			35 Pen-and-paper reporting
			36 Side tables
			37 Smart keys
			38 Thermal blanket
			39 Thermal mattress
			40 Trash bins

mattress and a blow-heated blanket, as the heat output of the mattress had been deemed inadequate after procurement (Inadequate device performance).

4.4. Alarms

Alarm systems were found to violate 16 of 21 usability guidelines. Several issues related to false positives in everyday use, missing alarms, and use of unclear language in error and alert messages.

First, there are several sources of false positive alarms caused by everyday activities in the OR instead of changes in the patient's condition (Consistency - Functionality). These include the insertion of trocars causing a laparoscopic gas pressure alert, planned disturbances in the patient's breathing causing apnea alarms in later phases of surgery, known leaking of the oxygen mask causing hyperventilation alarms, and blood pressure sleeves blocking blood flow causing SpO2 alarms. False positives were also caused by alarm limits being too close to an individual patient's normal values, which had been the case with the oxygen intake of athletic patients (Fit with patient characteristics). While an experienced practitioner can routinely tell apart these false positives, some claimed that they can disturb you in special situations, such as when intubating difficult airways (Fit with practitioner tasks, Fit with operation characteristics).

Second, practitioners thought that some events were missing an alarm or that current alarms and alerts provided inadequate information. For example, especially older laparoscopy devices did not provide an audible alert when the grounding pad was poorly attached to a patient (Good error messages). Similarly, there were no audible or visual alerts for neither the anesthesia suction tube being detached nor the optical cables in the video laryngoscope being loose. Multiple alerts in infusion pumps were seen as not descriptive enough (Good error messages, Gaps in users' knowledge), thus resulting in dismissed alerts, device restarts, and calling maintenance, instead of attempting to debug the device. Also, a scrub nurse mentioned that surgeons rarely heeded alerts sounded by new electrosurgical equipment as they were used to the older models allowing "rougher" handling without alerting about damage in the instrument (Fit with existing devices, Inconsistent preferences).

4.5. Infusion pump

Infusion pumps were found to violate 14 of 21 usability guidelines. The issues in infusion pumps centered around their external flow sensor and insufficient presentation of infusion-related information.

First, several HCPs felt that the pump's external flow sensor is an outdated component and a source of unnecessary alarms and potential mix-ups. Regarding alarms, the sensor is easily disturbed by contact and movement, which happens frequently when a surgeon leans against it (Fit with practitioner tasks). This causes the device to sound an error alert and stop administering medication (User in control). Then, regarding mix-ups, nurses said that when multiple medications are being administered, extra care is needed to make sure each flow sensor is connected to the right medication (Ease of physical interaction). Even when all sensors are connected, the phone-wire-like design of the sensor cord was told to make it difficult to see which sensor is connected to which infusion bag (Feedback - Visibility of system state). Frustration with the flow sensor was highlighted as some of the interviewed nurses had experienced infusion pump models where the flow sensor was integrated into the device, so that the need for external wires and clips was eliminated (Extraneous task).

Second, while the pump does display how much medication has been pumped into the patient, it has potential to present information that would ease the nurses' work and reduce ambiguity in special situations. One missing piece of information was how long a medication would last with its current dosage (Feedback - Visibility of system state). This shortcoming was highlighted by anesthesia nurses, because they must

anticipate upcoming situations as much as possible (Fit with practitioner tasks). In a busy operation, it was thought important that the pump would alert when there is enough medication for 5 min, so that the nurse can complete their ongoing tasks and plan for replenishing the medication. With the current system, the pump alerts only when the medication is out and immediately stops administering it (User in control).

4.6. Operating table

The operating table was found to violate 11 of 21 usability guidelines. The key issues focused on patient positioning and maneuvering the table.

First, positioning the patient on the table requires attaching armrests to railings on each side of the table and supporting the patient's head. However, the railing is not continuous (Consistency – Layout), thus often preventing proper placement of armrests (Fit with existing equipment). Also, the table has an integrated headrest, but the patient's head can rarely reach it because the patients in the unit are placed low on the table in a gynecological position (Fit with operation characteristics).

Second, the table is tilted, raised, and lowered to various positions throughout any surgery, using a wireless remote control. The anesthesia nurse operating the remote must remember to check if there's anything under or near the table before moving it (Minimize need for recall). However, the tables somewhat frequently crash with patient beds and side tables when lowered (Fit with existing equipment), sometimes damaging the equipment. Further, as the table is often lowered at the end of the surgery, the nurses were worried that loud crashes would unnecessarily upset the patient (Fit with patient characteristics). A related frequent complaint was that the remote control reacts slowly to presses of its buttons (Feedback – Reaction to input), so that surgeons often repeat their requests before the table starts moving.

5. Discussion

In this study, we used semi-structured interviews, contextual inquiry, and usability forms to create contextual design guidelines for OR devices. We also presented exemplary violations of these guidelines in gynecological operating rooms. The final list of 21 guidelines is presented in [Table 2](#).

5.1. The importance of context in medical device design

Many of the guidelines modified and added by this study demand that device designers more thoroughly understand the context in which their devices are used. This is especially highlighted in Furniss and colleagues' (2014) original evaluation criteria of "Fit with wider context" being split into 6 distinct subcategories, including Fit with patient characteristics, and Fit with practitioner tasks, as well as cross-device categories emerging from inductive coding.

Poor fit with patient characteristics was seen in devices not being suitable for different patient sizes, ages, and medical conditions. We found little literature directly assessing how medical devices account for different types of patients. For example, Sharples et al. (2012) briefly describe how nurses using a newly-developed ultrasound working station needed to awkwardly reach around a pregnant mother's stomach, Martin et al. (2012) show that device manufacturers were surprised by the HCPs' thoughts of the approximate age ranges and medical conditions of patients who would benefit from a new imaging device. Furthermore, the principles of universal design advocate for solutions that suit everyone regardless of their abilities (Story, 1998). But, these examples only hint at the importance of considering patient characteristics in medical device design. While there are studies focusing on patients' experiences, including patients as users of medical devices (Ehmen et al., 2012; Lang et al., 2013), patients' perceptions of medical devices and alarms (Furniss et al., 2014; Martin et al., 2012), and HCPs' use of patient information in their decision making (Despins, 2017), the

current study is among the first to highlight the need of systematic focus on patient characteristics in medical device design.

Poor fit with practitioner tasks could be seen in routine tasks disturbing the operation of devices, or vice versa in the operation of a device hindering a HCP's ability to carry out tasks. This category has been present in qualitative medical device research, where issues have been brought up with charging battery-powered devices, performing quality checks, sharing information between HCPs (Furniss et al., 2014), shared use, weight during transportation, and time constraints due to other tasks than using the device (Martin et al., 2012; Zuzelo et al., 2008). Our results further highlight the potential to make the use of devices less disruptive to other tasks, and the Fit with practitioner tasks category adds emphasis on the need to consider not only the direct user but also other HCPs in the OR.

The importance of context is further highlighted by the inductive codes that focus on multiple systems and their interactions, such as Environment, Alarms, and Cords & Tubes. Examples in these categories include arms of devices blocking ceiling lights and crashing into each other, difficulties in integrating devices from different brands, false alarms sounding at critical moments in operations, and various cords hampering the mobility of HCPs and equipment. These results highlight the importance of device designers accounting for cross-device interferences in their work.

5.2. Practical implications

The contextual guidelines developed in this study have implications for both better device design and better device procurement. To showcase the types of design flaws that could potentially be avoided by adhering to a validated set of guidelines, this study provides detailed examples of usability violations in existing OR technologies. In product development, the design stage dictates a large proportion of costs that incur over the lifetime of a product, and Design for X tools have been shown to reduce costs in labor, parts, assembly time, development time, and redesign in magnitudes of 20–60% (Chiu and Okudan Kremer, 2011). Thus, designers would gain the largest wins by using the presented guidelines early in the design stage. For device procurement in operating units, the design guidelines can serve as a checklist of potential questions and demands to manufacturers. Research has shown that procurement decisions rarely consider the local context, instead focusing on engineering standards (Vincent and Blandford, 2017). Thus, the presented set of guidelines could be used by procurement decision makers as a reminder to focus on the human aspects of technology.

5.3. Limitations and future work

The main limitations of this study are the lack of formal validation for the created guidelines as well as a narrow geographic and medical scope. First, while the guidelines were developed based on observations and discussions in real context, their further validation would require a systematic study into their capability to capture real and important violations as well as improve the usability of new devices and systems. As shown by Hermawati and Lawson (2016), heuristic guidelines are often validated through expert use and by comparing their performance with other heuristics. It is a clear next step in this work. Second, our dataset was collected in one operating unit in one country and no surgeons were formally interviewed, thus encouraging caution in the generalizability of results. However, we have provided key information about the unit in [Appendix A](#) to support individuals in assessing the applicability of our results in different contexts, and surgeons, among other HCPs, were interacted with using the contextual inquiry method. Further, we believe that the usability issues found in the low-risk laparoscopic surgeries we focused on are to some degree applicable elsewhere, as laparoscopies in other medical fields use similar equipment and the issues found in low-risk operations tend to be present in more risky surgeries as well (Catchpole et al., 2005). In the future, it would be interesting to

carry out similar studies in different locations with different technologies in use as well as include surgeons and the devices they use more formally. This could enable the creation of a more robust and holistic set of design guidelines for OR devices.

6. Conclusions

Despite there being a disconnect between what medical device designers design and what medical professionals need in their daily work (Martin and Barnett, 2012; Ward and Clarkson, 2004), current research offers little input for designers to improve upon, instead focusing primarily on detailed descriptions of issues and their influences. Our study provides a holistic look into the various usability challenges in operating room technologies and shows that many issues are connected to not only multiple devices but also the wider context of work in the OR, such as the tasks of various HCPs and the varying characteristics of patients. To enable improved device design, we qualitatively analyzed real-world observations, interviews, and open-ended surveys to create a list of 21 contextual design guidelines for medical devices in the OR (Table 2). While the general usability principles of Nielsen (1993) and

Shneiderman and Plaisant (1998) capture most usability violations in individual user interfaces, our guidelines supplement them by adding reminders to consider the context of use, the need for different functionalities, and properties unique to physical devices. These new usability guidelines for medical device design can not only serve as instructions for designers to follow but also encourage device decision makers to utilize contextual information from end-users.

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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Appendices.

Appendix A. The Women’s Hospital’s Operating and Anesthesia Unit

The Women’s Hospital’s Operating and Anesthesia Unit is a 24/7 unit focused on gynecological and obstetric surgery. Laparoscopic hysterectomies are its most common gynecological operations, but the unit also carries out other gynecological surgeries, including cancer operations, curettages, and transvaginal mesh installations. The unit comprises 8 operating rooms and roughly 125 staff members, including 90 nurses, 15 anesthesiologists, and 20 surgeons.

The practicalities in the unit resemble those in place elsewhere in Finland. The Women’s Hospital is part of the Helsinki University Central Hospital, and thus there are frequently students and residents accompanying more experienced HCPs in the operating rooms. The core personnel in the operating room (OR) comprises 5 people. An instrument nurse (IN) and an anesthesia nurse (AN) are physically in the OR throughout the whole operation, while a circulating nurse (CN) is also present but can exit the room to run errands if necessary. The CN and AN have dischargers in the unit who may exchange places with the room’s primary CN and/or AN for a short period, to allow for a coffee or lunch break. An anesthesiologist is present during the induction of and emergence from anesthesia as well as when necessary in other situations, such as major bleeding or when significant anesthesia changes are needed. During the time of the study, anesthesiologists in the unit typically managed two operations simultaneously. Finally, a surgeon or surgeons check on the patient during room preparation and perform the surgery.

Multiple operations are carried out in each OR throughout a working day, with the patients anesthetized and woken up inside the OR and transported to a recovery room after their operation. The OR is quickly cleaned after each surgery by dedicated staff, and a more thorough cleaning takes place daily after office hours. After the room is cleaned, the CN, AN, and IN have 10–20 min to prepare the room and patient for the induction of anesthesia. In practice, nurses begin preparing for following operations during ongoing operations. The unit has a central patient monitoring system in place accompanied by an OR traffic control system, both of which are run and monitored from a central desk in the unit. The nurses in the ORs use a combination of pen-and-paper and digital tools to access and log relevant information. These tools include GE Opera to log and follow operation schedules, GE Uranus to read patient and lab test information, and paper forms to log anesthesia-related and other patient parameters during operations and recovery. Further, anesthesiologists use GE Uranus to prescribe post-operation medications.

The unit underwent organizational restructuring and migrated into a renovated space in spring 2017, where most of the medical devices in the unit had been renewed during the renovation. Some device brands and manufacturers present in the unit include Maquet, Merivaara, Olympus, GE, Medtronic, Fresenius Kabi, and Karl Storz.

A brief video introduction of the unit (in Finnish) can be found at: <https://youtu.be/atFBxBUOZqI>.<https://youtu.be/atFBxBUOZqI>

Appendix B. : Description of the initial coding scheme

Design heuristics created by Nielsen (N) and Shneiderman (S) were used as shown in Table D1.

Table D.1

Design heuristics by Nielsen (1993) and Shneiderman and Plaisant (1998), with comments on their adaptation for the current study.

Heuristic	Source	Original description	Note
Cater to universalizability	N&S	“Recognize the needs of diverse users and design for plasticity, facilitating transformation of content.” S	Combined with Furniss’ “Fit with wider tasks and equipment” category due to their similarity.
Consistency	N&S	“Users should not have to wonder whether different words, situations, or actions mean the same thing.” N	
Feedback	N&S	“The system should always keep users informed about what is going on, through appropriate feedback within reasonable time.” N	

(continued on next page)

Table D.1 (continued)

Heuristic	Source	Original description	Note
Good error messages	N&S	"They should be expressed in plain language (no codes), precisely indicate the problem, and constructively suggest a solution." N	
Use user's language	N	"The dialogue should be expressed clearly in words, phrases, and concepts familiar to the user, rather than in system-oriented terms." N	
Minimize memory load	N&S	"The user should not have to remember information from one part of the dialogue to another." N	
Reversible actions	N&S	"As much as possible, actions should be reversible." S	
Users in control	S	"Experienced operators strongly desire the sense that they are in charge of the interface and that the interface responds to their actions." S	
Simple and natural dialogue	N	"Dialogues should not contain information that is irrelevant or rarely needed." N	Expanded to include not only dialogues but also device features in general. Rarely used systems are acceptable in high-risk environments, such as the OR, as long as they serve a real need.
Closure	S	"Sequences of actions should be organized into groups with a beginning, middle, and end." S	Excluded as no excerpts were tagged under this category.
Help and documentation	N	"Even though it is better if the system can be used without documentation, it may be necessary to provide help and documentation." N	Excluded as no excerpts were tagged under this category.
Prevent errors	N&S	"Even better than good error messages is a careful design that prevents a problem from occurring in the first place." N	Excluded due to the category being overly generic, thus providing little aid for device designers.

The contextual medical device usability assessment themes, developed by Furniss et al. (2014), were used as shown in Table D2.

Table D.2

Furniss and colleagues' (2014) 7 themes for assessing the usability of medical devices and comments on their adaptation for the current study.

Assessment theme	Description	Note
Device usability	The usability of the system, including aspects like feedback, language, etc.	Not coded separately, as usability is split into more specific heuristics and categories.
Gaps in user's knowledge	The users not knowing features or other details of the system. Includes mental models of system use as well.	
Workarounds	Unofficial adaptations to using devices, including the HCPs tailoring devices to better suit their needs.	Coded under both workarounds and other categories; workaround categories are not reported in this study.
Fit with wider tasks and equipment	The integration of a system to its wider environment and practice.	Combined with the "Cater to universalizability" heuristic due to their similarity.
Patient interactions	Considering the patient and their experience as an active element.	
Connections between hospital and unit	Connections of the system with other systems outside the OR.	Excluded as no excerpts were tagged under this category.
Impact of policy	The influence of local management on the configuration and use of the system.	Outside the scope of this study

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