Chapter 1

Designing for medical device safety

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Introduction

Medical devices diagnose, prevent, monitor, treat, alleviate, or compensate for disease or injury (World Health Organization, 2018). They range from thermometers to left ventricular assist devices and include hospital beds, infusion therapy instruments, pulse oximeters, implantable devices, such as pacemakers, and some mobile apps (Branaghan, 2018). They even include in vitro diagnostic products, such as lab equipment, reagents, and test kits (United States Food and Drug Administration [FDA], 2018).

The importance of medical devices 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. For example, the world's population of people 65 years and older increases by approximately 850,000 every month (Kinsella & Phillips, 2005), and half of the people who have ever reached the age of 65 are alive today (Rowe & Kahn, 2015). As a result, focusing on the safety and usability of medical devices can improve human health drastically.

Medical devices developed with human factors (HF) 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 physical or psychological injury to patients, caregivers, and health-care providers (Wiklund & Weinger, 2011). The HF and patient safety literatures are replete with cautionary tales of death at the hands of use error. These stories play out in a predictable manner, with well-meaning users accidentally operating devices incorrectly, with tragic results. Typically, although the user was blamed, the device itself made the error possible. For example, Wachter (2012) describes an incident reported in Smetzer, Baker, Byrne, and Cohen (2010), in which an obstetric nurse accidentally connected an opiate

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pain medication intended for an epidural to a mother's IV line. The lines and bags for the IV and epidural lines were so similar that the nurse simply confused them, resulting in the mother's death.

In another example, provided by Zhang, Patel, Johnson, and Shortliffe (2004), a nurse, trying to program an infusion pump to deliver 130.1 mL/h, pressed the appropriate keys "130.1" but failed to realize that the decimal point on the device only works for numbers up to 99.9. Consequently, the pump ignored the decimal point and delivered the drug at 10 times the intended rate—1301 mL/h. These problems are not limited to a few devices but are more common than most people realize, with issues identified on insulin pumps, ablation systems, automated external defibrillators, duodenoscope reprocessing, and many more (United States Food and Drug Administration [FDA], 2016a).

Recognizing the gravity of this problem, this chapter provides an overview of HF as it relates to medical device design. It introduces the reader to the importance of HF, the process and methods of HF design and evaluation, and where these activities fit into a product development process. Following this, several principles of good HF design are provided. Applied with care, these principles can reduce many of the common HF problems in medical device design. Finally, a case study involving the design of a total artificial heart (TAH) is provided. This case study illustrates the application of these methods and guidelines to a real-world medical device.

Human factors design process

The HF design process involves an early and constant focus on users and their tasks to ensure that the device fulfills, and hopefully even improves, users' needs for safety, efficiency, effectiveness, and satisfaction. However, good designs do not emerge fully formed from solely considering users' needs. Good design involves redesign. That is, it develops through an iterative process which not only identifies user needs but also involves end users in the development and design-validation process.

In this section, methods and a process for implementing an HF design approach are provided. Regulatory bodies and standards organizations (such as the International Standards Organization [ISO], US Food and Drug Administration [FDA], European Conformity, and Association for the Advancement of Medical Instrumentation [AAMI]) have become instrumental in providing standards and guidance (see AAMI, 2009; United States Food and Drug Administration [FDA], 2016a,b; ISO, 2015) for executing these processes. Fig. 1.1 summarizes the information commonly found in these standards by representing the three main steps required for incorporating HF into medical device design and development. Ensuring compliance with the required regulatory standards and guidance is an important consideration in any medical device design.

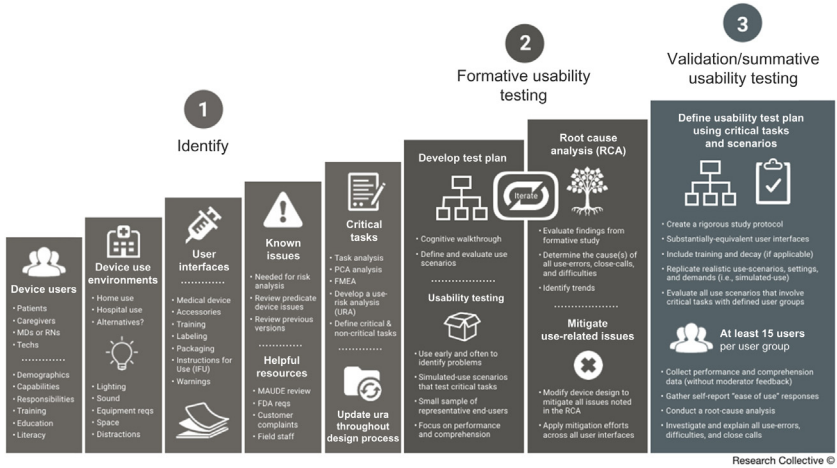

FIGURE 1.1 Process for incorporating HF into medical device design and development. *HF*, Human factors.

Identify device users, environments, interfaces

Device users

The first step in an HF design process is to identify and understand users, including their behaviors, needs, desires, capabilities, and limitations. This is critical for designing medical devices appropriately. For example, a user interface (UI) may need to be completely different for physicians and elderly patients. Begin to understand all the potential users by asking questions such as

- Who purchases the device?
- Who receives the device?
- Who unpacks the device?
- Who sets up the device?
- Who uses the device? Are there different users for different tasks?
- Who cleans, reprocesses, or provides maintenance for the device?
- Who disposes of the device?

Once these questions have been answered and the user groups are clearly defined, a second set of questions can help identify each user group's characteristics, abilities, and limitations, such as

- Do the users have physical or cognitive limitations?
- What is their level of education?
- Do they require specialized training?
- What is their emotional state when using the device?
- Are they in a state of panic because the device is used only in a state of emergency?

Device environments

The next step considers where the device is used. Different environments have unique characteristics; these distinctions greatly influence how a device is used, and these influence many aspects of its design. For example, there would likely be different design considerations for a device used in an outpatient clinic versus the one used in a patient's home. Specifically, users in health-care facilities are likely to be able-bodied, trained medical personnel. The use environment is likely to be well-lit and sanitized, with easy access to electrical power. This is not true of home environments. Patients at home may have a variety of physical and cognitive deficits. Homes are designed for comfort, intimacy, entertainment, and socialization. They are not, however, designed for medical devices.

Questions that can be helpful in identifying and characterizing intended use environments include the following:

- Where will each end user interact with the device?
- What is the lighting like?
- How about ambient noise?
- How much space do users have?
- How hot or cold does each environment get?
- What other equipment is also in the environment?

Device interfaces

Finally, to understand how users may interact with the device, it is important to identify all the device interface components. The term "UI" is often thought to mean a "graphical UI (GUI)," such as the screen on the device in Fig. 1.2. However, for medical devices, all elements that a user interacts with when using the device comprise the "device UI." The device UI therefore includes the packaging of the device and related equipment or accessories, any additional labeling provided on the device, the accompanying instructions for use (IFU), any hardware features, such as physical buttons, knobs, or levers, and of course, the GUI (Food and Drug Administration, 2016b). An HF design process should be applied to each component of the device interface.

Methods for identifying users, environments, and interfaces

HF applies knowledge and methodologies from human sciences to improve the match between people and their products by characterizing the users, their environments, and how they will interact with the device (e.g., Lee, Wickens, Liu, & Boyle, 2017). Two common methods include the following:

- *Contextual inquiry*

This is the process of observing and interviewing users in their use environments to reveal insights about their interactions with the device (Beyer & Holtzblatt, 1997). Contextual inquiry is a method that was derived from

FIGURE 1.2 The C2 Hospital Driver provides pneumatic power to the SynCardia temporary TAH from implantation through patient recovery in the hospital. *C2*, Companion 2; *TAH*, total artificial heart.

ethnography, a practice adapted from the field of anthropology, where researchers would study different cultures by immersing themselves in the culture for months or years at a time (Merriam, 2009). When designing medical devices, this type of observational work can be accomplished by observing surgical procedures, shadowing physicians or nurses during rounds, or performing a ride-along with emergency medical technicians (EMTs).

- *Interviews*

Aside from performing interviews in context (see the previous section), end users can also be interviewed individually or in groups to reveal insights about their interaction with a device (Kuniavsky, 2003). In addition, interviews are helpful for discussing in-depth scenarios and critical situations that occur infrequently and/or that are difficult to observe (Merriam, 2009). Interviews can be designed to be structured, semistructured, or free form, depending on the overall goals of the inquiry, and can be conducted in any location.

Identifying risks

Identifying potential risks with medical device design helps to ensure that devices do not cause harm to patients, caregivers, or health-care providers. It also helps to anticipate the ways in which the device could foreseeably be misused, enabling the medical device manufacturer to redesign that part of

the product or to develop mitigations to prevent those risks from occurring. This section describes methods for identifying those potential risks.

Critical tasks and known issues

A critical task is the one which, if performed incorrectly or not performed at all, would or could cause serious harm to the user or to a patient. Harm can include injury (both physical and emotional), discomfort, and even a delay in or lack of therapy (Story, 2012; United States Food and Drug Administration [FDA], 2016b). Critical tasks should be determined from the severity of outcomes or consequences resulting from potential use errors, using some variation of a risk analysis. Any task that could lead to harm, regardless of the likelihood of occurrence, should be defined as a critical task (Story, 2012). For devices that have predicate or similar devices already available in the marketplace, analyzing known hazards is another step to identifying potential critical tasks of the device as well as to ensure that the device is not repeating the same mistakes that have already occurred previously.

Method for identifying critical tasks and known issues

Identifying critical tasks involves breaking down all the potential ways that a user will interact with the device. Once all of the use-related tasks have been identified, it is important to consider the key perceptions, cognitive components, and behaviors (i.e., actions) that a user would need to complete in order to successfully perform each task. For any task where a user could foreseeably commit an error that could lead to a negative consequence (e.g., patient or user harm and delay in therapy), a plan needs to be in place for how to eliminate or mitigate that risk. Different approaches for identifying critical tasks include the following:

- *Task/Perception, cognition, action (PCA) analysis*

A task analysis is a process that identifies all of the steps and substeps involved in using or interacting with a device (Kuniavsky, 2003). For each substep, the PCA components are defined (Zhang et al., 2004). That is, any perceptual or cognitive processes as well as actions required for a user to complete a task can be used to understand where breakdowns in human interaction can occur. For example, if a person needs to hear an alarm in order to determine that a device is malfunctioning, the alarm must be designed so that it is at an appropriate decibel level and has a distinct enough sound to alert users appropriately.

- *Failure mode effects analysis (FMEA)*

An FMEA is another method for determining critical tasks (Israelski & Muto, 2004). An FMEA is typically developed by brainstorming possible

usage scenarios for a given device that could lead to a "failure mode." For each failure identified, an estimate is made of its occurrence, severity, and detection. Then, an evaluation is made of the necessary actions to be taken to minimize the negative consequence associated with the failure (Stamatis, 2003).

The FDA guidance for medical device HF provides a thorough list of resources for identifying known issues (Food and Drug Administration, 2016b), including current device users, journals, proceedings from professional meetings, and adverse event reports.

Formative usability process

Once the intended users, environments, devices interfaces, and use risks have been identified and design mitigations are in place, the device should be evaluated to ensure that the design is meeting the needs of the intended users in the intended use environments. The findings from those evaluations can then be used to iterate upon the design of the device. This routine comprises the formative usability process—design, evaluate, and repeat (Redish et al., 2002).

The formative usability process can be conducted at any stage in the development process. In fact, performing formative testing with rough prototypes early in the design phase can help to identify potential issues early in the design when modifications are cheap. As the device design is iterated on, continued formative testing will make it unlikely that usability problems will persist in later stages of product design and development. Methods for performing formative evaluations including the following:

- *Participatory design*

This method involves users in the design process and provides a forum for designers and device developers to interact, work with, and better understand end users (Sanders & Stappers, 2008; Sanders & William, 2002). Participatory design can be achieved in a number of ways, using velcro or foam modeling, sketching, and collaging (Hanington & Martin, 2012; Sanders & William, 2002). Regardless of the approach, the overall goal is for users to be actively involved in the design process by communicating and visualizing their needs.

- *Expert reviews*

Although involving users in the formative evaluations is critical, expert reviews by expert practitioners can be employed to complement user research in the medical-device-design process. One common and easily implemented method is a heuristic analysis, where a small set of HF experts will evaluate a device's UIs against HF design principles to identify usability and safety issues (Nielsen, 1994; Zhang, Johnson, Patel, Paige, & Kubose, 2003).

Another commonly used and effective method is the cognitive walkthrough, where HF experts identify usability issues by working through a series of tasks related to the device from the "perspective" of an end user (Polson, Lewis, Rieman, & Wharton, 1992).

- *Usability testing*

One of the most effective methods for evaluating device interfaces is by performing usability tests, where representative users conduct realistic tasks with the medical device in a simulated environment of use. The data from usability testing often includes success/failure rate, frequency and type of errors, time on task, and user responses to perceived ease-of-use and satisfaction (Rubin & Chisnell, 2008). During formative usability testing, it is important to focus on evaluating performance on critical tasks to ensure that users can perform those correctly. Wiklund and Weinger (2011) advise preparing and testing for the worst case scenario, including a difficult environment of use, for users who are not well trained, and thus under stress, and/or are not technologically sophisticated. Similarly, Rubin and Chisnell (2008) recommend preparing for the worst by including a few "least competent users" (LCUs) during formative usability tests. LCUs are end users who represent the least skilled person who could potentially use the device. The reasoning is simple: if the least expert group is successful with the device, most other groups will likely be successful as well.

Otherwise, it is important to identify users who are representative of the actual users of the product. To ensure that usability test results are valid, it is important to recruit participants based on the end users' characteristics, such as education level, training, technical sophistication, and age defined during the "identify" stage. Further, as devices are often used by several different types of end users, separate usability tests should be conducted with each group. Fortunately, for a formative study, only 5–7 end users per user group are needed to participate, as they will identify the majority of usability issues (Faulkner, 2003).

Finally, formative usability studies are a critical tool in preparing for validation testing. Some tasks are difficult to simulate and require props, mannequins, confederates, or special codes to trigger events. Preparing for validation testing can require several iterations of task materials, environment, and instructions. Conducting formative studies provides an opportunity to iterate on those study components prior to the validation study.

Validation testing

The goal of validation testing is to demonstrate through usability testing that the medical device can be used safely and effectively by the intended users, in the intended use environments. Validation testing is the final step in the HF design process before launching a medical device on the market.

There are several characteristics of a validation usability test which differentiate it from a usability test that would be performed during the formative stage. First, market-ready versions of the device, labeling, and training should be included in the study. In addition, realistic training needs to be provided to study participants to mimic the level of training that will be available to users when the device is on the market.

The number of participants will differ from formative testing as well. While guidance documents indicate that manufacturers should be responsible for making their own determinations of the necessary number of test participants in the validation study, the FDA HF guidance does specify a minimum of 15 participants per end user group.

The goal of the validation study is to demonstrate that use-related risks are minimized to an acceptable level. This is accomplished by having representative users' complete critical tasks via realistic simulated-use scenarios. Note that some critical tasks cannot be simulated. In this case, comprehension questions are appropriate for assessing users' understanding of the critical information. Depending on the device, it may be reasonable to provide users with resources they would normally have access to in real life, should they need additional information or help (e.g., helpline).

Three types of data will typically be collected during a validation study: participant performance, knowledge task comprehension accuracy, and qualitative interview responses. The performance, knowledge, and qualitative data collected are synthesized and analyzed to understand and describe the root causes of any observed use errors or difficulties that participants encountered. The details leading to the use error, what users said about it, and what they did will help to determine the root cause. The root cause is ultimately what determines which component of the interface was responsible for the use error. For example, the root cause should not be that the user was not paying attention, or the user was distracted, or the user was ignorant. Following this analysis, device designers will need to determine what potential harm- and risk-control measures, if needed, may be taken to mitigate resulting risks due to observed use errors. If the formative usability process was done correctly, it would have helped to identify and mitigate use errors early on in the development life cycle. While use errors on critical tasks do not necessarily mean the device cannot pass muster with FDA, it will always come down to the level of risk associated with any use errors. If the use-related risk is still high, the HF design process will need to be reevaluated and, in some cases, repeated.

The activities described previously provide a robust process for designing usable medical devices; the ones that address user needs, improve ease of use, and reduce use error. On the other hand, many HF issues identified in formative and validation testing could be eliminated simply by following the design principles outlined next. These principles are provided not because they obviate the need for implementing an HF process (they do not) but

because following them can make the HF process substantially more efficient.

Enable simple interactions

Even advanced technology can be made simple to use; and simplicity can improve safety. Start by providing only the functionality users need and avoid feature creep (Page, 2009; Rust, Thompson, & Hamilton, 2006). This reduces clutter, making items easier to locate. Next, streamline frequent and important activities by eliminating unnecessary steps. Then facilitate legibility and readability by making displays, labels, and texts that are easy to read from the typical distance of use. Provide consistent and familiar placement of information, labeling, color coding, and device behavior. Further, provide sensible grouping of interface items, since placing related items close together tends to facilitate learning of the UI (Branaghan, Covas-Smith, Jackson, & Eidman, 2011). Finally, where appropriate, support side-by-side comparisons of information. This reduces cognitive load because users do not need to maintain information in memory as they navigate between pages or screens.

Design for the environment of use

Effectiveness and safety of the medical device are influenced by the environment in which the device is used. Some environments are loud and hectic, whereas others are quiet. Make sure to understand, characterize, anticipate, and design for the intended environment of use. Do not forget to assess the usability of the device in the representative conditions of use.

Also, consider that devices, originally designed for medical environments, may eventually be used in patient homes (Bitterman, 2011; National Research Council, 2010). This is a concern, because professional health-care environments often have good lighting and ample space ideal for medical equipment. This can be quite different than the home environment, which can be cluttered, with low light, carpeting, cords, children, pets, and other things that get in the way of using the device.

Avoid physical strain and repetitive motion

Wiklund and Weinger (2011) point out that many medical procedures are repetitive, sometimes causing cumulative trauma stress. For instance, laparoscopic surgery is less painful than open surgery for patients, but it is more demanding for surgeons, leading to fatigue and discomfort. During laparoscopic surgery the surgeon holds a more static posture for a longer period of time, causing accumulation of lactic acid and toxins, and subsequent cumulative trauma disorder (Lowndes & Hallbeck, 2014; Supe, Kulkarni, & Supe, 2010).

Wiklund and Weinger (2011) advise to reduce the number of repetitive motions and the force required to operate a device. Also, eliminate pressure points and facilitate the use of neutral joint positions.

Provide timely and informative feedback

Provide informative feedback, enabling users to understand the device's status at all times (Lewis & Norman, 1995; Maglio & Kandogan, 2004; Nielsen, 1994). Despite the best efforts from medical-device manufacturers, device errors and failures occur periodically, and it is important to make users aware of these errors and failures. Ensure that errors are communicated effectively, and recovered from quickly, taking care to guide the user through error resolution. As a rule, in an error situation, a UI should convey: what went wrong, why it went wrong, what the user should do about it, and how to get additional information.

Design with accessibility in mind

Designers often design for able-bodied people by default, perhaps because they are not familiar with the needs of all users or because they do not know how to accommodate them. Human abilities are widely variable, partially due to physiological factors, and also due to differences in experience, motivation, and expectations. This is compounded by age and disability. Medical device users will vary in size, shape, physical ability, intellectual ability, reading ability, technical experience, and so on (Story, Schwier, & Kailes, 2009). Some users will have physical, sensory, or cognitive difficulties. For example, some may have a visual impairment, making it difficult for them to read small fine text. Others may have peripheral neuropathy making it difficult for them to discriminate different textures on button surfaces. It is important to make devices accessible to a wide range of users. Clarkson, Coleman, Keates, and Lebbon (2013) advocate for implementing inclusive design principles that focus on designing for the needs of all people. In essence, the approach is to change the definition of the user at the beginning of the design process to include a wider range of capabilities.

Do not overrely on training and instructions for use

Medical device manufacturers are often too optimistic about the effectiveness of training and IFU in helping users learn how to use new devices (Wright, Creighton, & Threlfall, 1982). Often, these materials are not available to users, especially home health-care providers who travel from one place to another. Finally, even when provided, users are often too busy to read through IFU's or engage in training (Morrow, Leirer, & Sheikh, 1988).

Design with user emotions in mind

Medical devices need to appeal to people emotionally and esthetically (Norman, 2004). Devices with appealing design suggest higher quality, which can generate greater confidence in the user. Well-designed and esthetically pleasing devices can be less intimidating than poorly designed products. They are more likely to facilitate user satisfaction and may look friendlier and reduce anxiety among patients. One example of emotional design, described by Kelley and Kelley (2013), involved redesigning the diagnostic imaging experience for GE Healthcare. Diagnostic imaging with MRI can be intimidating to children, with big machines, confined spaces, and scary noises. One industrial designer, Doug Dietz, recognized this problem, conducted observational research at a day care center, and interviewed experts at a children's museum. This led him to design an adventure, rather than a machine. The Pirate's Adventure uses environmental design and props to make the experience more fun. This resulted in a substantial increase in patient satisfaction, reduction in anxiety, and made it easier for children to stay still during the imaging, preventing doctors from needing to repeat scans.

Not every product can be turned into a Pirate's Adventure, but most products can be improved by implementing an HF process. Next, a case study involving the design of a TAH is discussed. The case study serves to illustrate the HF design process as well as the design principles described previously. In addition, it serves to illustrate the multidisciplinary nature of good design. SynCardia, the manufacturer, worked with an HF firm (Research Collective), an industrial design firm (Farm Design), and a product development firm (Sunrise Product Development). The success of the product hinged on the ability of these groups to work together.

Case Study: SynCardia

Every 10 minutes, a new name is added to the list of patients waiting for an organ transplant in the United States. As the list already has more than 120,000 names, most patients will be waiting months or even years before a donor organ becomes available. Unfortunately, many die while waiting. Each day, 22 people in the United States die while awaiting a donor organ. The problem is that there simply are not enough donors to meet the demand.

SynCardia Systems, LLC makes the world's most widely used temporary TAH. The TAH is implanted into patients suffering from end-stage heart failure to keep them alive and healthy while awaiting a donor heart. The TAH circulates blood in the body through a connection to a driver that provides pneumatic, pulsatile pressure. After the TAH is implanted, patients are connected to the Companion 2 Hospital Driver (Fig. 1.2).

FIGURE 1.3 The Freedom Driver is a portable pneumatic pump for the TAH, which offers increased mobility. Patients who meet discharge criteria can then be released from the hospital to live at home with their families and friends, while they wait for a matching donor heart. *TAH*, Total artificial heart.

After a patient becomes clinically stable, they can be switched to the Freedom Driver (Fig. 1.3), a smaller, lighter pneumatic pump that allows them to be released from the hospital to enjoy active and independent lives at home, while they wait for a matching donor heart.

In 2016 SynCardia implemented a human-centered design strategy to create the next-generation Freedom Driver. This approach began with deepening their understanding of the Freedom Driver users, developing prototypes based on users' needs and desires, and evaluating the prototype designs through user research (see Fig. 1.4 for the evolution of the prototype designs). The final step will be to demonstrate the device's usability through validation usability testing.

Phase 1: Contextual inquiry and participatory design

SynCardia's first step was to conduct user research to understand the needs and desires of device users, which included patients, caregivers, and clinicians. SynCardia performed contextual inquiry research by visiting nine current and former Freedom Driver patients in their homes and 16 clinicians including ventricular assist device coordinators, cardiologists, and cardiology nurses in the hospitals where they work (Fig. 1.5).

Conducting contextual inquiry research in the users' natural setting allowed SynCardia to observe the way users performed device-specific tasks, document the tools and equipment they used to accomplish those tasks, discuss critical instances that occurred in the past, and identify their

FIGURE 1.4 Foam models were used in formative studies to obtain feedback from patients and clinicians about the ideal shape for the next-generation driver, the orientation and size of the graphical-user interface, the location and style of batteries, the location of the driveline port, and more.

FIGURE 1.5 A patient and her caregiver demonstrate how they prepare to leave the house with the current Freedom Driver.

troubleshooting techniques and work-arounds. The findings from the contextual inquiry provided SynCardia with a detailed list of design criteria for the next-generation Freedom Driver. Findings include the following:

- *Simplify the process of transferring patients from one driver to another:* To do so, the current driver's drivelines have two connectors that must be swapped simultaneously. Swapping drivers is a high-risk task often performed under stressful circumstances when the driver has malfunctioned. Potential harm to the patient includes loss of consciousness or death. Sometimes, the patient has already lost consciousness and a caregiver is responsible for making the swap on his or her own. Patient

participants in the study described instances where they had to perform a driver swap in a car, a restaurant, or at a sporting event. The next-generation driver should simplify the process of transferring a patient from one driver to another. The transfer should be able to be performed with one hand within 2 seconds.

- *Provide timely feedback about the status of the pump, batteries, and alarms:* The current driver's LCD display provides important information about the pump's status, but it is small and lacks a backlight. Many patients said that they kept a flashlight by their bed so that they could check their pump's status in the middle of the night. The small font and poor contrast on the LCD made it difficult for patients to check the pump's status when the driver was more than 3 ft away. In addition, the small display does not provide the user with any additional information about the driver's battery status or alarm. The next-generation driver should include a GUI to display the status of the pump and batteries as well as provide alarm descriptions.
- *Provide actionable and easily recognizable instructions on the device*: The current driver does not provide any textual information to accompany an audible alarm. Patients and clinicians described situations where a lack of information about an alarm caused extreme anxiety. One patient said that he was flown by helicopter to a hospital 30 miles away because of a high alarm on the driver. He felt fine, and the driver seemed to be functioning, but the alarm gave him great concern so he called for emergency assistance. In the hospital, he was transferred to another driver, and it was later determined that the cause of the alarm was the failure of a backup system, and was thus not life threatening. He could have transferred to his backup driver at home with much less anxiety and without an expensive emergency flight. Alarm sounds should be unique to the driver, capture patients' and caregivers' attention, and display messages that explain the problem and provide a solution.

Clinician participants also took part in a participatory design exercise, where they were asked to draw their ideal Freedom Driver GUI. SynCardia used the results of this research to create design criteria that would improve the user experience and usability of the next-generation Freedom Driver GUI. A key finding of the participatory design exercise was the clinicians' desire for the GUI to display waveforms, similar to the Companion 2 Hospital Driver, that provide deeper information about the driver's performance. In addition, clinicians' drawings included a display with the ability to manage the driver's settings, including the TAH beat rate (Fig. 1.6). On the current Freedom Driver, clinicians set the beat rate by turning a screw on the back of the driver. The process takes several minutes as the clinician turns the screw, waits for the driver to settle in on the new beat rate, then evaluates if the beat rate is appropriate or should be adjusted again. If a

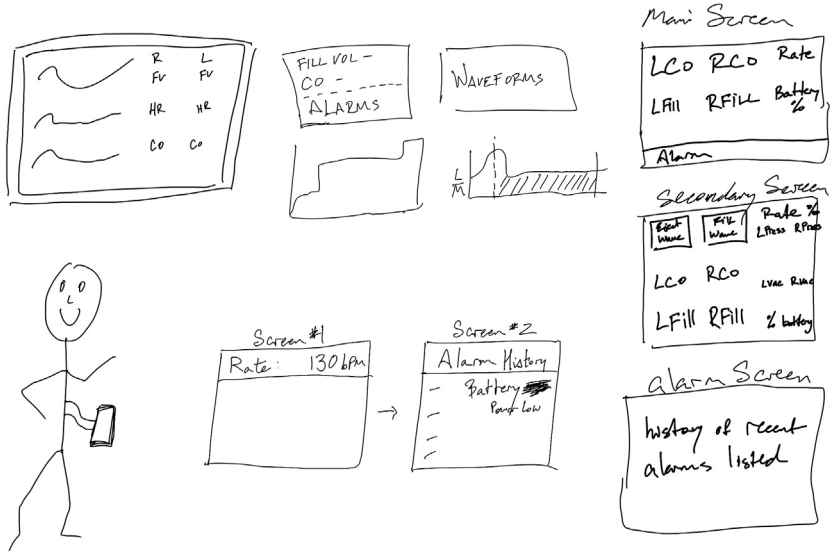

FIGURE 1.6 Drawings created by clinicians who work with Freedom Driver patients when asked to create their ideal Freedom Driver graphical user interface as part of a participatory design exercise.

clinician wants to set the beat rate to a specific value, it may take several attempts, turning the screw clockwise, then counterclockwise until the clinician is able to set the beat rate on that number.

With the design criteria set by the contextual research, SynCardia set out to create prototypes of the next-generation driver, GUI, batteries, and driveline connectors that could be evaluated in formative studies. SynCardia refined the design of the driver's UI elements through prototyping and formative studies with the goal of creating a next-generation Freedom Driver that minimizes potential harm and is easier for patients to live with than the current driver.

Phase 2: Graphical user interface wireframe prototype and formative study 1

As digital displays can be created faster than physical products, SynCardia first set out to make decisions about the GUI. SynCardia wanted to obtain feedback from expert users to determine the optimal size of the display. The display needs to be visible in a wide range of environments (home, hospital, outdoors, etc.) and clearly present information about the driver's status, alarm messages, and battery status. A unique wireframe prototype was created using Adobe XD for each of the possible display sizes (4.3″, 5″, and 7″) (Fig. 1.7).

The prototypes were placed on a tablet and interaction was added to allow users to navigate through the wireframes and perform the task of changing the driver's beat rate. Eight expert clinicians participated in the

FIGURE 1.7 Interactive GUI wireframe prototypes were presented on a tablet. *GUI*, Graphical user interface.

formative study. They performed the task of changing the beat rate and provided feedback about the content displayed on each display size. The study showed that users prefer to see the waveforms when making changes to the beat rate. The 4.3″ display was too small to provide all that contents on the screen at once. The clinicians liked the amount of information provided on the 7″ display but worried that the large display would cause the driver to be bigger and heavier. The 5″ display was determined to be the perfect size. It was big enough for users to see the waveforms when changing the beat rate and would not increase the size and weight of the driver.

Once the screen size was chosen, the focus for the GUI was to make the displayed content visible, legible, and understandable. There were a number of considerations that were taken when determining the characteristics of the display. The bond rule was applied, which states that the height of the letter is set to 0.007 times the viewing distance when both the viewing distance and the letter height are in the same units (Lee et al., 2017). Mixed-case text was used since all-caps is difficult to read, especially in long strings. Mixed-case text, on the other hand, offers a wider variety of word shapes, providing more sensory information that is more easily processed. A high-contrast display, with dark text on a white background contributed to legibility, making the display easy to read even when viewed by older patients and caregivers. Care was taken to minimize the amount of clutter in the display.

Roboto-Regular font, a sans-serif font, was chosen due to its familiarity with users and ease of reading on a computerized display (Lee et al., 2017). Since patients regularly need to read values that indicate the driver's status from a distance of 48 in., and with possible glare, a 30-point font size was chosen for those values. The GUI was refined and evaluated through subsequent formative studies.

Phase 3: Foam models, driveline connector prototypes, and formative study 2

SynCardia created three foam model driver prototypes (Fig. 1.8) and a prototype of the new driveline connector (Fig. 1.9) based on the design criteria determined through the contextual inquiry and participatory design exercise with experienced users.

FIGURE 1.8 Foam models used in the second formative study to obtain users' feedback about the size, shape, and the location of batteries, handles, and driveline ports.

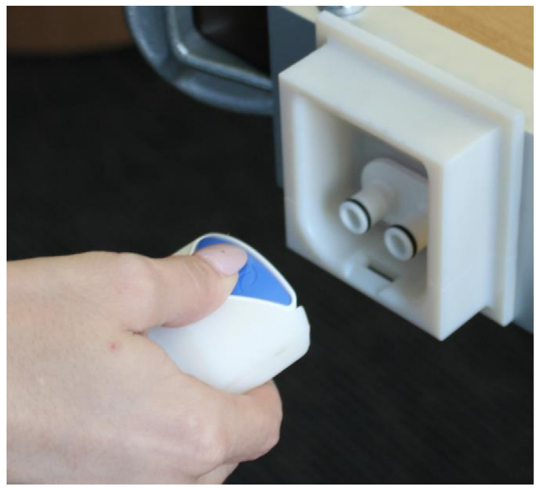

FIGURE 1.9 Functional prototype of the new driveline connector.

The foam models and driveline connector were evaluated with a mix of patients, caregivers, and clinicians in a second formative study (Fig. 1.10). The results of this study indicated that the shape of all three foam models would be uncomfortable for patients to carry. Experienced patients and caregivers said that the driver is almost always in a backpack worn by the patient. Therefore the driver should be taller and narrower to fit the shape of a patient's back. The study also revealed that the batteries and GUI should be placed on the top of the driver. Patients prefer to change the batteries when the driver is on the ground or on a table. In either location, the patient would be positioned above the driver so that the batteries would be most accessible on top of the driver. Similarly, a display on the top of the driver, angled as shown in Foam Model A, would be the easiest to see when the driver is at or below eye level. The driveline port should be low on the driver. All patients talked about getting their drivelines caught on things,

FIGURE 1.10 A former patient and his caregiver provide feedback about the shape and size of the foam models in formative study 2.

such as door handles and the corner of countertops. Keeping the driveline port low makes it easier for the patient to keep the drivelines close to their body and reduce uncomfortable snags. The usability of a new driveline connector prototype was also evaluated in this formative study. Participants were asked to transfer the drivelines using a mocked up driver port. Time on task and errors were documented as they performed the swap. All participants were able to perform the swap in less than 1.5 seconds with no errors; SynCardia's goal was for users to complete the swap in 2 seconds or less.

Phase 4: Appearance models, battery prototypes, alarm messages, and formative study 3

In the third formative study, participants evaluated two unique appearance models and foam prototypes that were painted to give the appearance of a finished product (Fig. 1.11), battery prototypes (Fig. 1.12), and alarm messages.

The previous study provided conclusive evidence that the driver's display and batteries should be positioned at the top of the driver, and both appearance models were designed accordingly. However, the models were designed to obtain additional feedback about users' preferences for the overall shape. In the previous formative study, users said that they wanted a driver that was shaped to fit more comfortably in a backpack. The shape of the appearance models was taller and slimmer than the original foam models. The results of the study revealed that the participants preferred the shape of appearance model 2 as it felt more comfortable when worn in a backpack, and the placement of the batteries allowed for quicker access (Fig. 1.13).

This formative study also evaluated five battery prototypes. Batteries with a loop had better usability results than the batteries that required users to pinch or squeeze. This result was expected because pinching is a fine motor skill, whereas grasping is a gross motor skill recruiting more muscles. Batteries with a large loop to accommodate fingers of all sizes were created and evaluated in subsequent formative studies.

FIGURE 1.11 Appearance models are used in the third formative study to obtain users' feedback about the size, shape, and the location of batteries, handles, and driveline ports.

FIGURE 1.12 Battery prototypes that allowed users to provide feedback about various handle and grip styles.

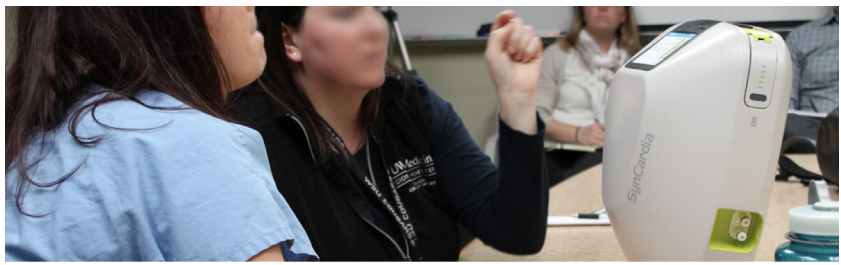

FIGURE 1.13 Two clinicians discuss the placement of the batteries on an appearance model in formative study 3.

FIGURE 1.14 The functional prototype that contained working pump mechanism, a touchscreen graphical user interface, and alarm sounds and messages.

Messages were developed to explain each possible situation that would cause an alarm to occur. The alarm messages provide the user with the reason for the alarm and instructions for resolving the problem. The messages are written in plain language, for example, "The Driver is getting hot. Make sure the Driver is not covered and has sufficient airflow." The messages do not contain error codes that do not help the user solve the problem, for example, "Error #405." The alarm messages were evaluated to ensure comprehension by each user group.

Phase 5: Functional prototype, auditory alarms, and formative study 4

With the overall shape of the driver decided, SynCardia put the working pump components and GUI into a fully functional prototype (Fig. 1.14). Another formative study was performed with this functional prototype to reevaluate the usability of the process of transferring a patient from one driver to another, setting driver parameters using the touchscreen, and responding to alarms and error messages (Fig. 1.15). Usability was evaluated by documenting participants' successes, difficulties, and use errors when performing tasks. There were no use errors on any of the 21 tasks completed by the 12 participants. This result was achieved by having evaluated all the tasks in the previous formative studies with lower fidelity prototypes.

This formative study also included an evaluation of the auditory alarms. The purpose of auditory alarms on the next-generation Freedom Driver is to bring

FIGURE 1.15 A former patient and his caregiver replace the batteries in the prototype driver in formative study 4.

attention to the display, where additional information about the alarm and steps to resolve the alarm are provided. The next-generation driver will have two levels of auditory alarms, a low and a high alarm. A low alarm indicates that the device needs attention, but nothing must be done immediately. For example, when the driver's batteries are depleted to 20% remaining, the driver will sound the low alarm and display a message informing the user of the low batteries and prompting the user to replace them. A high alarm indicates that action is needed right away, for example, when the driver malfunctions, the patient must be transferred immediately to the backup driver. The two alarms are designed to be discriminable from each other through the use of volume, frequency, envelope (e.g., a rising sound or a constant sound), and rhythm. The high alarm is louder and the tempo is higher than the lower one. To facilitate audition in a range of environments, the high alarm uses both high and low frequency sounds. The high alarm is designed to be 15−30 dB above the expected ambient noise expected in patients' homes, hospitals, outdoors, in restaurants, etc. Although the alarm is loud, it is not overly startling due to its use of a rise time that starts low and increases quickly. The alarms were triggered at various times in the formative study, and during each time, the users responded appropriately.

Phase	Purpose	Findings	Design recommendations based on human factors principles
Contextual inquiry and participatory design	Understand user needs, desires, limitations, and environments of use	Transferring patients from one driver to another is a high-risk task often performed under stress	The process of transferring patients from one driver to another must be easy
		The current driver does not provide clear status feedback	The driver should provide clear status feedback at all times
		The current driver does not provide instructions to remedy alarms	The driver should clearly explain why alarms occur and provide troubleshooting instructions
		Setting the driver beat rate is difficult and requires the use of tools	The driver should provide a simple process for clinicians to set the beat rate accurately without tools
Graphical user interface wireframe prototype and formative study 1	Evaluate the graphical-user interface information architecture	Clinicians prefer to see waveforms on the display that indicate TAH performance	The display size should be 5″ diagonally to provide enough space for clinical information while remaining light
		A 5″ display is the smallest size that still provides clinicians with important information about TAH performance	The graphical user interface should provide waveforms using line weight and typeface visible from 4′
			The graphical user interface should use a sans-serif 30-point font
Foam models, driveline connector prototypes, and formative study 2	Evaluate driver shape and handle, battery, display, and port placement	Participants all perform a driver swap effectively, but the latch mechanism on the prototype caused slight delays	The button on the driveline connector should be salient and provide haptic feedback when depressed
		Participants need the driver to be stable to avoid being knocked over and damaged	The driver should have a wide base to provide stability on multiple surfaces
		Participants prefer a display that is angled so that it can be seen when the driver is below or at the same height as the user	The driver should have an angled display

(*Continued*)

(Continued)

Phase	Purpose	Findings	Design recommendations based on human factors principles
Appearance models, battery prototypes, alarm messages, and formative study 3	Evaluate driver shape and handle, battery, display, and port placement as well as alarm messages	Participants preferred the driver that felt more comfortable when worn in a backpack	The driver should be shaped like a human back—wider at the top and narrower at the bottom
		Participants preferred batteries that had a large loop that facilitated quick removal from the driver	Batteries should provide a large grasping loop that accommodates a wide range of finger sizes
		Alarm messages were clear and all participants responded to them appropriately	Alarm messages should state the problem and clear steps to remedy the problem
Functional prototype, auditory alarms, and formative study 4	Evaluate the look and feel of a functioning driver and assess comprehension of audible alarms	Participants successfully responded to all alarms and successfully transferred from one driver to another	The driver connector that has been refined since formative study 2 appears to meet all requirements for usability to ensure safe transfers from one driver to another
		Participants could distinguish high alarms from medium alarms and alert tones	Alarm tones should be 15–30 dB above ambient noise and include both high and low frequencies

TAH, Total artificial heart.

Next steps

SynCardia's next step will be to complete the engineering and design of the next-generation Freedom Driver and all accompanying UI components (training, IFU, etc.). They will conduct another formative usability study with the completed product to determine if there are any additional usability problems. Once any remaining usability issues have been addressed, SynCardia will perform a final validation usability study to demonstrate that the intended users can safely and effectively use the next-generation Freedom Driver.

Conclusion

First, incorporating HF principles and methods into medical device design can reduce the likelihood of physical or psychological injury to patients, caregivers, and health-care providers. Second, HF can help to create devices that are easier to learn, more efficient and satisfying to use, and better suited to fit into peoples' lives. When implemented early in design, the application of HF principles can lead to a more streamlined development process—avoiding costly time delays when it becomes apparent that a device does not meet user needs or could lead to unnecessary injury or death.

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