The human factor

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Senior design engineer John Harverson and human centred designer Amber Davies discuss how human factors engineering informs their work developing new medical devices at Haughton Design

Medical devices constitute an inextricable element of modern health care. And while these devices make health care more effective, they can also make it more complex, which, in turn, can increase the risk of medical errors. According to a 2016 study by researchers at Johns Hopkins University, medical error was the third leading cause of death in the USA after heart disease and cancer (however, the methods used by the researchers have since come under question). Another analysis of reports from the US Food and Drug Administration found that in the decade to 2018, medical devices were involved in more than 1.7 million injuries and around 83,000 deaths.

When it comes to the design of medical devices, the stakes are high – when errors occur, they can lead to life-changing injuries and even death

Many of these incidents are put down to 'user error', but over the past few decades, it has become increasingly clear that it's no longer appropriate to blame users for a mistake made while interacting with a device. Instead, such 'mistakes' or 'user errors' must be regarded as a fault in the device itself and hence must be dealt with in just the same way as would a component failure.

This growing realisation has led to the implementation of what's now known as human factors engineering (HFE), or usability engineering, which focuses on the interactions between people and devices, and ultimately aims to

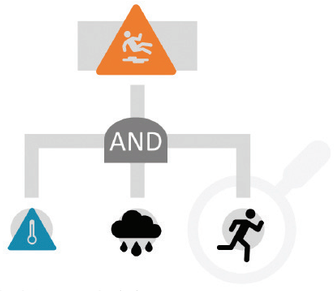
enhance safety by minimising use-related hazards.

As the statistics above make clear, when it comes to the design of medical devices, the stakes are high – when errors occur, they can lead to life-changing injuries and even death. These tragic outcomes can, in turn, have significant economic implications for the companies that produce the devices, potentially leading to product recalls and major reputational damage.

Beyond these grave scenarios, there are many wider benefits to incorporating HFE into device design, including devices that are simpler to use, with easier to read controls and displays; better user understanding of the device itself and its role in treatment; devices that are easier to maintain and repair; more intuitive devices, which reduces the reliance on manuals and the need for training; improved adherence to medication regimes; and wider inclusivity.

REDUCING RISK

So how do we, as medical device designers, use HFE to reduce the risks associated with our products? First up, it's crucial to understand the ways in which people (users) perceive and interpret information to make decisions about what to do and how to manipulate a device – whether it be adjusting settings, replacing components, or simply starting and stopping the device. But then it's also important to understand how the device itself receives inputs from the user and then responds to those inputs. From this it's clear that HFE is truly multi-disciplinary, relying on expertise from an array of disciplines, including engineering,



Fault tree analysis is used to refine the design

Human factors engineering involves taking a multi-disciplinary approach to design

design, cognitive psychology and risk management.

In fact, HFE is actually mandatory when it comes to developing a medical device. The process is governed by the international collateral standard IEC 62366 ('Application of usability engineering to medical devices'). IEC 62366 outlines a process of iteratively designing and testing a user interface to ensure user safety and then validating the interface to ensure that no unacceptable risks arise from use. The user interface includes all of the components with which the user interacts while preparing, using and maintaining the device – steps that typically include unpacking, setting up, calibrating, cleaning, replacing batteries and making general repairs.

In order to comply with standards such as ISO 14971 ('Application of risk management to medical devices'), it's crucial to demonstrate that you've applied a number of tools to analyse and mitigate risk. There are a number of methods for identifying failure modes throughout the device development process, including design FMEA (failure modes and effects analysis) and FTA (fault tree analysis).

FMEA is a proactive, systematic, 'bottom–up' method that's used to identify all of the ways in which a device might fail – reviewing as many of the different components, assemblies and subsystems as possible – and then assess the relative impact of the different potential failures. It involves looking at what could go wrong, why that might happen and what the consequences would be. Teams then look for ways to prevent the failure happening, rather than waiting for something to go wrong and then correcting the problem.

FTA, on the other hand, is a top–down approach in which the starting point is an analysis of the ways in which someone might get hurt when using the device and then trying to identify why that might happen.

DESIGN CONTROLS

HFE fits neatly into the 'design controls' process. Design controls are a set of regulations, practices and procedures that must be followed during the development of a new product. They ensure that the device meets its user's needs, its intended uses and any specified requirements. While they allow for some innovation in the design process, they ensure that designs remain feasible and allow for full traceability. Ultimately, design controls demonstrate that your medical device is safe, effective and meets the indications for use while also ensuring that you'll ultimately be able to repeatedly manufacture the device as intended.

The end result of all of these different processes will hopefully be a device that not only meets its intended purpose and operates in its intended manner, but does so in a way that minimises the risk of harm to users

Applying design controls isn't a singular activity – it's an accumulation of thorough planning, execution and documentation carried out throughout the design process. Usually, the process starts with capturing user needs in order to define intended-use statements/claims. These statements and claims are then used to define the project's design inputs, which guide the design process and, ultimately, generate design outputs, such as drawings, specifications and instructions – essentially everything required to manufacture and assemble the device correctly. The design process itself tends to be iterative, with the design being repeatedly refined throughout the design cycle based on feedback from testing by users, whether they be patients or health-care practitioners.

CASE STUDY

NIGHT DRAINAGE BAGS

PATIENT SAFETY ISN'T the only consideration that comes into play when designers utilise HFE – rather it's all about the entire user experience. The team at Haughton Design was tasked with re-designing urinary night drainage bags – opaque two-litre plastic bags used by urostomy patients to temporarily store urine during the night, during other periods of rest, or when a typical urostomy pouch is too small. Many users report negative attitudes towards the bags, due to their cheap, stereotypically medical appearance and the feelings of shame they experienced when using and emptying the bags. Hence, our aim was to understand and improve these key areas to produce a more user-friendly product focused on comfort, dignity and functionality.

Working closely with the client's in-house team, clinicians in the field and users themselves, the design team created a user-needs document that captured all of the key requirements set out by the user group. This informed the creation of a product-design specification that was then used to conceptualise, prototype and evaluate a number of different concepts. Once a final design was selected, it was further refined with input from occupational therapists, nurses and urostomy patients themselves.

The new design was more sustainable – unlike existing products, it was reusable – and had a larger volume, reducing the frequency of drainage and enabling better sleep quality for users. It was also more ergonomic, both for users and health-care practitioners who had to monitor patients' urine, and utilised high-quality materials that were easy to clean and make ready for immediate re-use. It even had collapsible features to increase portability. Most importantly, however, the design reduced the feelings of embarrassment that users associated with these devices. ■

One of the first steps is to assess products that are already on the market

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Humans are very adaptable; we're very good at finding 'work arounds' to compensate for poor design. But when it comes to medical devices, users – again, whether patients, nurses or doctors – are often fatigued, distracted, performing in stressful or emergency situations, or unfamiliar with the device, so it's more important than ever that the principles of HFE have informed design, so those so-called user errors never come to pass. ■

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