Centre Stage

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When it comes to medical devices, user-centred product design can play a key role in the development of, and adherence to, new treatments. With regulations being given greater attention, human factors engineering and usability testing aim to encourage better outcomes for patients

Like the emerging fields of predictive, personalised and preventative medicine, the key objective of user-centred healthcare is to improve the health outcomes of patients by taking into consideration their needs, values, preferences and situation. This approach is underpinning many of the healthcare reform discussions currently under way, as policies, systems and programmes are redefined to meet the demands of 21st century care (1-3).

Designing for People

In the field of drug delivery, a user-centred approach is already being applied to the design and development of new delivery systems and platforms through the use of human factors engineering (HFE) and usability engineering (UE).

Often referred to as ergonomics, HFE focuses on the way people interact – in terms of physical, sensory, emotional and intellectual aspects – with products, systems or processes (4). The Institute of Ergonomics and Human Factors captures the essence of HFE when it says ergonomics is about "designing for people" and ensuring that "designs complement the strengths and abilities of people and minimise the effects of their limitations, rather than forcing them to adapt. As a complementary area, usability focuses on the effectiveness of the user interface of a product in delivering efficiency, ease of use and end-user satisfaction" (5,6).

Keywords

Ergonomics
Usability testing
Human factors engineering
Medical device development
Best practice design

User Involvement

In the development of medical device innovation, HFE and UE place the user at the centre of product development from start to finish. Not only do they work to reduce or eliminate potential user error and injury from a device, but they also increase adherence by addressing many of the user factors that affect how well, or even if, a device is used. This type of engineering additionally considers the needs of a broad spectrum of people that are intended to use the device to support a patient's treatment plan; from caregivers such as family and friends of the individual – who may have little or no knowledge of administering medication – to the variety of healthcare professionals who will use the device under different pressures and in varying environments.

With increasing demand on clinical care and the rise of chronic conditions that put treatment further into the hands of the individual, medical devices need to be designed to minimise training requirements, maximise safety and provide optimal user comfort and convenience.

The benefits of HFE and UE are already being seen in the development of injection devices for multiple sclerosis (MS), where investment in design and development is focused not just on the mechanical innovations of the device administering the drug, but also on the ergonomics and usability of the product, as steered by user input.

Benefits of Insight

The process of incorporating HFE and UE testing alongside clinical studies has the benefit of enabling design and development teams to take a deep look into user requirements, concerns and challenges. This allows product designs to be created that address barriers to non-use, which in the case of auto-injectors can range from needle phobia to dexterity challenges. It can reduce or eliminate the risk of user error too. Furthermore, chronic conditions such as diabetes often impair sensory capabilities, and some of the injector innovations that have been suggested by HFE have

highlighted the need for larger visual displays on dosage settings, as well as alerts that indicate when a full dose has been administered.

HFE and UE can also be used to design new ways to counter issues that result in poor routine. In the case of injectors, for example, changing pen needles after use is part of a good injection routine, but infrequent needle change is common (7,8). After extensive HF testing, new design innovations have been introduced to make it more convenient for users to adhere to best practice guidelines – for instance, providing devices that make needle change an intuitive part of the treatment process (9).

HFE/UE Testing

While HFE and UE testing is not a new concept, it is receiving renewed attention across the industry as regulators look to improve quality in HFE work. HFE testing is required for medical devices in the EU to comply with EN 62366:2008 (10), while the FDA is currently reviewing the inclusion of human factors and usability testing as part of the US premarket approval process. Current guidelines recommend including HFE/UE testing as part of 510(k) submissions, and this is applicable to new products, as well as modifications to legacy products. Although not yet mandatory for premarket approval, a HFE/UE study may be requested by the FDA to support an application, and so incorporating it as a matter of protocol – in addition to clinical studies – will avoid the need to run a late-stage study, should the FDA request more information.

As well as improved user benefits, pharmaceutical providers applying HFE to their product innovations can enhance the effectiveness, appeal and success of their products, and minimise the risk of product launch delays due to late-stage usability redesigns or issues with regulatory approval.

Study Areas

The FDA has outlined three key HFE/UE study areas that are important to the development of medical devices under its guidance: these are intended users, intended use environments and device user interfaces (11). Within these categories are a number of criteria that require consideration, including: risk analysis relating to potential user error and use-related hazards; identification of known problems; usability testing with diverse user groups; function and task analysis; heuristics analysis; and design and clinical validations.

Information on intended users explores the impact of an individual's characteristics like physical strength, dexterity, sensory abilities, literacy, ability and willingness to learn a new device. Use environments look at attributes such as lighting, noise levels and possible distractions that could affect the user; while user interface addresses how patients interact with all components of the device, including buttons, switches, labelling, instructions, and the size and configuration of the device.

HFE testing involves designing formative and summative studies that define intended use and test the product in the user environments. In the formative tests, the product is put into the hands of the user early in the design cycle. At this stage, it is key to identify all the users of the product and how they would utilise it in real-world situations. Typically, consumers that would have the highest risk and frequency of use would be incorporated in the testing process. This ensures the product meets end-user requirements, as well as being ready for large-scale manufacture before the tooling process begins. These tests are different to clinical

Applying HFE to a new MS injection device

MS is a debilitating inflammatory disease of the central nervous system and currently affects 2.5 million people worldwide. Individuals often have to live with symptoms such as blurred vision, cognitive impairment and poor coordination.

Adherence Issues

Due to the chronic nature of MS, individuals may live with the disease for several decades (12). One particular treatment – interferon beta-1b – has shown some impressive results by reducing all-cause mortality by 47% at 21 years in patients with MS who received the treatment within their first two years of therapy, when compared with a placebo (13). But despite the benefits of this promising form of therapy, it still faces one major issue: adherence.

Poor patient adherence to interferon beta-1b is often the result of adverse events relating to injectable therapies, like anxiety of injecting, injection site pain (ISP) and injection site reactions (ISRs) (14). ISP and ISRs occur more frequently if users inject into the skin rather than the muscle, and because interferon beta-1b is injected into the skin, this can greatly affect how users adhere to their treatment schedule. Individuals with MS have to follow their treatment protocol to prevent relapse, and not obeying could put their health at risk (13).

Device Design

Owen Mumford created an original injection device for Extavia®, an interferon beta-1b, based on its clinically robust auto-injector platform: the Autoject2®. This device not only helps minimise ISP and ISRs, but also makes injecting easier and reduces patient anxiety. The company wanted to further explore refinements that could be made to its platform technology – specifically for those with MS – and the only way to do this was to ask the users themselves.

Through HFE and UE studies, users rated convenience and ease of use as the most important factors for an auto-injector. This feedback led to the development of the final device, called ExtaviPro® 30G, which is still based on the Autoject2 platform technology, but is further tailored for individuals with MS.

Incorporating Feedback

The new device is ergonomically designed, assisting one-handed use and enhancing patient confidence when injecting (15). As needle diameter is associated with greater ISP and ISRs, the device uses an ultra-thin, 30-gauge needle (13,16). Constant force spring technology is also incorporated to improve ease of use.

All these qualities are associated with convenience, which is an important factor that can lead to increased adherence and hold the potential to shift patient preference from one auto-injector to another (4).

tests and it is important to factor this into product development plans from the start. This will also enable early design mitigation.

The final test is the summative test, which validates that the device is effective, usable and safe. This includes testing the final device that is going to be launched to market.

Specialist Skills

To meet HFE and UE requirements, best practice product design, development and manufacturing should rely on human factor specialists who are experienced in developing the plan and testing procedures throughout the design to manufacturing lifecycle. This ensures studies are conducted and reported accurately and meet regulatory guidelines. As an iterative process, HFE/UE studies also give patients and caregivers the ability to inform and influence product design. From the in-use data, product teams have the ability to identify and eliminate errors early in the design cycle to ensure optimum safety and use of the final product, as well as minimise the potential cost of late-stage design changes.

By integrating HFE into product design, user-centred processes become part of the product development cycle, and guarantee the entire design journey is consumer-focused and has the supporting in-use data, in addition to the clinical data required for approval. Incorporating human factors from the start of the design process has been integral to the development of many combination products and is instrumental in developing better devices for patients that they prefer to use.

The value of incorporating HFE and UE reflects best practice for creating products that provide safe, quality and cost-conscious treatments that lead to improved user outcomes.

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