Through the Lens of Human Factors:
Developing Connected Drug Delivery Devices

Designing Devices for Self-management
The market for drug delivery devices continues to grow at a rapid rate,[1] largely due to an expanding elderly population with an increasing frequency of chronic diseases. Biotherapeutics have played a significant part in this growth, with biologics frequently administered via subcutaneous injection. As a growing number of biosimilars come onto the market, it is likely the market for subcutaneous drug delivery devices will develop further.

More than ever before, chronic conditions are being treated outside of a hospital setting, with drugs administered by carers and patients themselves, without advanced medical training. As greater agency is placed on drug delivery devices, reliable and intuitive design is essential alongside ensuring safe and effective treatments, while maximising patient comfort and convenience.

Increasing Device Functionality with Connectivity

The growing trend of adding connected functionality to these devices allows the medical profession to simplify the capture, transfer and display of injection data; automatic upload of key treatment data can be crucial in tracking and improving patient adherence to treatments. Meanwhile, introducing additional electronic features to the device itself provides an opportunity to offer real time step-by-step feedback to the patient during the injection procedure. In addition, educational tools and instructions provided by digital content in the associated app can help to simplify the injection process.

As with any system, the temptation to increase the functionality of a medical device comes with potential to increase the complexity of the user interface and impact ease of use. A user-centred design approach is desirable to optimise the user experience and associated benefits, and essential to ensure that the potential for use error is managed.

This article will look at the importance of applying human factors engineering (HFE) during the development of new connected drug delivery devices and how we employed these principles when creating our first connected auto-injector.

Human Factors and Usability Engineering Requirements

In the EU, manufacturers must demonstrate compliance with requirements set out in the Medical Device Regulation (MDR). These requirements align with the international standard for IEC-62366-1:2007 (note it is recommended that HFE is conducted according to the 2015 update), with IEC-62366-2 (2016) as a guide. Meanwhile, in the US, the Food Drug Administration (FDA) provides recommended human factors engineering guidance for both medical devices and combination products, and more recently has provided further draft guidance on the inclusion of human factors and usability engineering as part of the market approval process. Therefore, most developers will incorporate usability engineering as a matter of protocol.

Although some differences exist between the various sources above as well as guidance drafted in other territories, the general principles are the same: understanding users and use, and use environments, generating user interface requirements, conducting a use-related risk analysis, and evaluating the product through formative and human factors validation tests.

Human Factors Engineering in Practice

In the US, the FDA identifies three key components that underpins human factors engineering and usability engineering: intended users, intended use environment and device user interface.[2] Typical profiles of intended users are built up by examining characteristics such as physical strength, dexterity, sensory abilities, literacy and the ability to learn how to operate a new device. Use environments consider factors such as ambient lighting and noise levels and possible distractions to the user that could impact the injection process. Lastly the device user interface considers all elements of the device with which the user interacts – those parts that the user can see, hear and touch. A good integrated human factors process ensures a focus on these three elements is sustained throughout medical device design and development.

Preliminary Analysis

Although formative evaluations are fundamental to many human factors initiatives, there are some key preliminary activities that should precede any user testing in order to optimise the interface and lay the foundation for successful user testing plans and outcomes. Preliminary activities are geared towards getting the best understanding of the intended users and their strengths and limitations, the intended context of use, and intended use scenarios. Early user research around these topics also seeks to understand the known use issues with similar on market devices. As early concepts and ideation start to formulate, these activities help to generate a picture of use related tasks, and inform the first iteration of a use related risk analysis (URRA).

Use Related Risk Analysis

A central pillar of any human factors programme is the identification of use related risk and its mitigation. The relationship between the human factors process and Risk Management Standard 14971 is perhaps best illustrated in IEC 62366; Human Factors activities are designed to systematically flush out potential use error, by examining the interface from different viewpoints (users), under different conditions (e.g., emergency, maintenance, low battery), in different environments (e.g., military, roadside, clinical).

Formative User Testing

The human factors testing process requires both formative and summative studies to evaluate the intended use of a product, test the device in anticipated use environments and demonstrate its effectiveness for different user groups. The group of test subjects must therefore represent the full range of potential device users, incorporating people of relevant ages, gender, training levels, reading ages, physical and sensory impairments, and previous device experiences.

In formative tests, products are placed into the hands of users early in the development cycle, deliberately testing

how patients and carers utilise devices in real-world situations. The results of that testing enable exploration of issues from needle phobia to dexterity challenges, to identify potential problems with the size of visual displays, dosage settings and alerts and to address these issues, before releasing the product to market. Finally, summative tests will evaluate the device that is going to be launched to market – validating its effectiveness, usability and safety.

When developing our own connected product, we prepared for the worst-case injection scenario. In practice, patients introduced to a drug delivery device would most likely initially be instructed directly by healthcare workers on how to use it. However, our study placed our auto-injector in front of patients with no training and without directions to read the instructions provided before use.

Human Factors for Connected Devices

In many ways the human factors programme for a connected device is no different to any other product. We began early with a preliminary analysis, including a contextual enquiry to establish an understanding of users interacting with existing on market products with and without electronic components and or connectivity.

The platform device interface was intended for a wide audience, so a broad use specification was established and used to inform and shape the ergonomics to ensure ease of use across multiple patient demographics. The psychology of the user interface design had a big impact on key decisions around the Bluetooth® connection process, placement of Bluetooth button, and power management. But designers were also clear that any added functionality should not in any way hinder safe and effective injection procedures.

The human factors team also conducted studies on the digital interface of devices once an acceptable level of reliability had been reached. A landscape-style generic IFU was also generated to clearly demonstrate intended user steps, and the team also experimented with different colours on the key touch points to guide loading and unloading of the syringe into the device. The smartphone application to go alongside the device was quickly generated and simulated in Adobe XD before writing the software, whereas the device components and electronics were developed at a slower pace, necessitating their testing at different points. With differing speeds of development resulting from various device components, our team was compelled to mimic connectivity in the app during studies to utilise testing time effectively.

Learnings from testing reinforced our initial commitment to creating a demonstrator app, a supporting element to promote safe and effective injection practices.

Importance of Human Factors in Future Developments

The integration of a human factors approach into the development and testing of connected drug devices is critical to create devices with a user-centric design. When users are prioritised from the very beginning of development, it helps to ensure that devices are intuitive and have considered the needs of different potential user groups.

Manufacturers wishing to seize a share of the expanding drug delivery device market must employ human factors approach to ensure products are suitable for patients in a new era for healthcare.

REFERENCES

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A highly experienced Human Factors Engineering Manager, Finola Austin boasts 20 years' experience in mentorship and management of human factors services in safety-critical industries. Her career began in Occupational Therapy within acute, long term and community settings, and her training in accessibility has given her special insight into the needs of impaired users. Since then, Finola has successfully planned and delivered Human Factors activities for hundreds of handheld medical devices, including auto injectors, emergency use devices, inhalers, injection pens, and lancets, and is proficient in the generation and review of documentation. She has executed numerous user evaluation studies in the UK and USA – including studies on safety engineered devices, injection pens, and colour differentiation.