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HARNESSING HUMAN FACTORS IN CONNECTED DEVICE DEVELOPMENT

In this article, Finola Austin, Human Factors Lead at Owen Mumford, looks at the role human factors testing plays in the development of connected drug delivery devices.

User-centred product design has a crucial role to play in drug delivery device development. The safety of medical devices relies on them being used as intended, which is why regulatory agencies place great emphasis on incorporating human factors (HF) and usability engineering in the design process to minimise potential use errors and potential harm. Intuitive, easy-to-use devices also encourage patient adherence, which, in turn, may help improve therapeutic outcomes.

The increasing availability of connected drug delivery devices offers patients new opportunities to manage their medical conditions from the comfort of their own homes, with key information – such as injection date and time, dose and injection site – automatically captured and shared with their healthcare providers. In addition, notifications can help remind patients when their next dose is due and alert them to missed doses, typically via a smart phone app.

However, incorporating connectivity poses new challenges in terms of the user interface. For example, adding authentication steps to protect data privacy and security can make it more difficult to set up and use the device in question – acting as a barrier to adoption for patients who are less familiar or confident with technology. Furthermore, the right balance must be struck with notifications and patient feedback; such information can be reassuring for patients but can also act as a distraction and introduce unnecessary complexity to the injection process – making it difficult for users to navigate from a physical and cognitive perspective.

For these reasons, HF studies are more important than ever with connected drug delivery device development. They enable design and development teams to take an in-depth look at user requirements, characteristics, concerns and challenges – and identify design features to support ease of use. HF studies also explore how intended users interact with all aspects of a device interface and accessories, including buttons, switches, visual and audible indicators, labelling and instructions, as well as the size and configuration of the device.

The digital interface is another key aspect of the user interface. Its impact must be incorporated into user studies to evaluate user experience, ensure that it supports the users' needs and does not adversely affect the drug delivery process in any way.

FORMATIVE AND SUMMATIVE STUDIES

Part of the HF process involves designing formative and summative studies that evaluate intended use and test the product in the intended use environments. Participants are recruited to ensure

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sufficient representation of all intended user groups and their characteristics, ranging from their role (patient, caregiver), age and gender to reading age. Intended users are invited into the design process as early as possible to ensure that the concept is sensitive to their needs. This also helps to ensure that there is sufficient time to shape the design interface and mitigate potential use errors.

However, it is always a challenge to hit the sweet spot when planning formative studies, as a balance needs to be struck between prototype/device readiness, project timelines and having sufficiently representative interface(s) to ensure that the study findings are reliable and useful.

CASE STUDY

A good example of user-centred design in action is Owen Mumford's first project involving connectivity – the UniSafe autoinjector, a companion device for the UniSafe 1 mL safety device (Figure 1). A key requirement for this reusable platform device was the prevention of needle exposure before, during and after the injection process, which was achieved by using the UniSafe sharps protection feature with the UniSafe safety device inserted into the autoinjector before use. The autoinjector incorporates connectivity and is suitable for a wide range of therapy areas, which helps to support and encourage patient adherence and provides healthcare professionals with access to patient medication data. The UniSafe 1 mL autoinjector has been designed to be safe and effective when used with or without connectivity.

During the early stages of device development, the use steps were simplified by incorporating the priming function for drug delivery into the device open/close action. The team also worked closely with design engineers to create the optimum user interface while accommodating the technical requirements. The HF emphasis was on desktop ergonomics, using anthropometric data to shape the physical interface and cognitive psychology to guide display solutions. In addition, early in-house user testing was conducted with device-naive participants to gain early insights into general handling, understanding of the display and controls, and interpretation of the signals for connectivity.

LEARNING POINTS

The HF team endeavoured to conduct user studies on each part of the digital interface as soon as they had an appropriate level of fidelity. However, a challenge was posed by the fact that the development of each part of the system progressed at different rates. It was relatively easy to storyboard the overall app structure and generate a simulation via Adobe XD before writing the software. This could then be modified and iterated rapidly based on desktop analysis and the findings of user evaluations. However, the device components and electronics developed at a slower pace – including the ability to connect the device. The team compensated for this by mimicking connectivity in the app. This was constructive, but it meant that the moderator had to intervene more than desired during the early studies – which had the potential to affect the study outcomes.

Learning from the formative studies helped to evaluate the app's content and flow – Owen Mumford was committed to creating a "demonstrator" app that would allow it to consider the full impact on safe and effective use of the device. As the prototype matured, there were inevitable stops and starts in the flow of app use. This required the creation of use scenarios that had to be mocked up in isolation, simulating the appearance of connectivity in several cases.

The HF studies for the UniSafe 1 mL autoinjector were also designed to evaluate worst-case use scenarios. Participants with mixed experience were recruited and interacted with the device with no training and no direction to read the instructions. Although the team did not want the users to be preoccupied with the app, it was an intrinsic part of the evaluation. The inclusion of an app, instructions for use (IFU) and new autoinjector with no training meant that users were confronted

Figure 1: The UniSafe autoinjector is a companion device for the UniSafe 1 mL safety device.

with quite a high workload in a single usability evaluation. In the real world, the user would typically be introduced to the components by a healthcare professional and the patient might be more inclined to explore the device and app separately, in their own time.

The formative studies also helped to develop a generic IFU for the device with a layout that meets user needs and aligns with potential packaging solutions – a landscape booklet emerged as the best way to provide enough space to present the intended use steps in an easy-to-follow sequence. The team was also able to experiment with colour in the studies – participants successfully loaded and unloaded the device guided by effective use of colour on key touchpoints. This emphasised the impact of colour on user interaction while competing with different aesthetic and marketing proposals.

CONCLUSION

Incorporating connectivity into drug delivery devices is a challenging process. While connectivity brings a wealth of possibilities, it can introduce some complexity for the patient. User-centred iterative design, coupled with multiple formative studies of the physical and connected interfaces, can harness this potential and optimise ease of use. The HF study participants surprised Owen Mumford with their immediate recognition of the connected element – and effective interaction with the connected device and app.

ABOUT THE COMPANY

Owen Mumford is a medical device manufacturer with a global presence across the UK, Europe, the US and Asia, pioneering the advancement of medical technology for 70 years. The company manufactures its own brand of medical products and is a trusted partner to many of the world's largest pharmaceutical and diagnostic companies. Its leading medication administration, blood-sampling and testing solutions are designed and manufactured for the comfort, safety and dignity of patients, healthcare professionals and caregivers as a priority. Driven by its purpose to do business in the right way, Owen Mumford is one of the first medical device companies in the world to achieve B Corp certification and has set science-based targets to achieve net zero by 2045, as part of its long-established and continually evolving sustainability agenda.

ABOUT THE AUTHOR

Finola Austin is a highly experienced Human Factors Engineering manager, boasting 15 years' experience in the mentorship and management of human factors services in safety-critical industries. Ms Austin has successfully planned and delivered human factors activities for hundreds of handheld medical devices, including autoinjectors, emergency-use devices, inhalers, injection pens and lancets.

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