Battling 'Operating Error'

What may be clear for a medical device manufacturer may not also be clear for the patient or end user. Human factors should be implemented to ensure that any possible design issues are rectified before they go into production

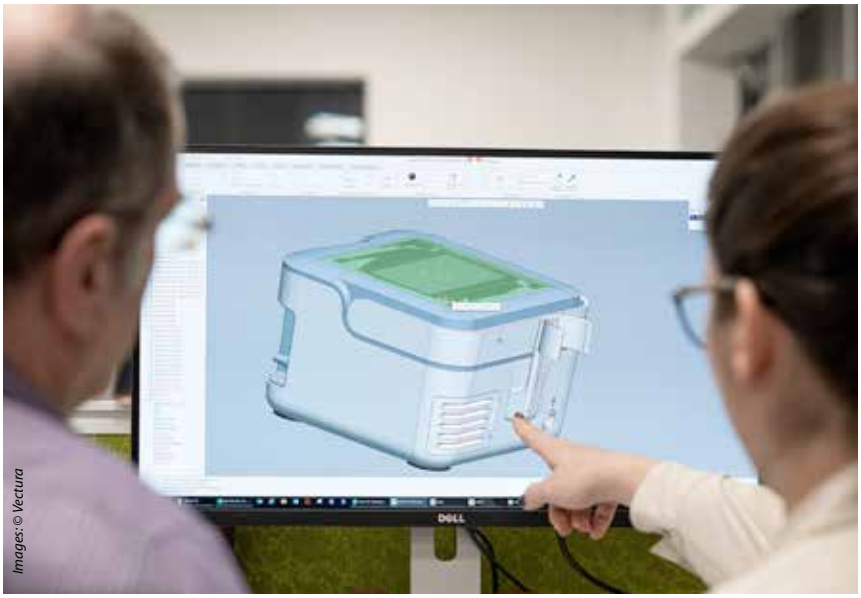
Andreas Meliniotis at Vectura

Patient compliance can be an issue for any medicine. Even a simple tablet taken once a day can present adherence problems – patients might be worried about side-effects, have problems swallowing, or could simply forget to take them, especially if timing around food is important. Compliance becomes even more challenging for treatments that have more complicated regimens, such as having to take multiple doses a day, at specific times, and potentially having to avoid conflicts with other medications.

For inhaled treatments, these challenges can be exacerbated if there is a difficulty in using the device effectively, as a patient may think that they are taking their medicine, but in reality, the intended dose of drug is not reaching the lungs properly. The consequences of this, and for all issues around patient compliance, is that potential treatments for patients are stopped or altered because of a perceived lack of efficacy. For device developers, ensuring that a patient is able to use a device both effectively and consistently is vital to improve compliance.

A robust device development process should be followed, giving the opportunity for multiple assessments of patient interaction with the device, whether for a new device design, or applying a current design to a different target user population.

From a designer's perspective, the most important factor is to understand



Images: © Vectura

how patients view a device, and how they interact with it. Some patient groups will inevitably find a device more difficult to operate, however easy a designer may believe it to be or how easy a healthy adult may find it. This can be due to physical interaction limitations, for example, pushing a button on a pressurised metered-dose inhaler (pMDI), or cognitive interactions where a number of steps need to occur in sequence, such as in nebulised therapies. For instance, elderly patients can have issues with dexterity and strength – osteoarthritis is common in this patient group – and diseases such as Parkinson's can further affect the ability to operate devices.

From a cognitive perspective, diseases such as dementia affect the ability to understand how to operate a device, and, therefore, the need for intuitive user interfaces is even more important. In the elderly, multiple factors and comorbidities can make device effectiveness even more challenging, requiring good ergonomic and intuitive design. At the opposite end of the age scale, children can also find it difficult to use an inhaled device because of a lack of strength or coordination, and even if a parent or carer operates the device for them, breathing in at exactly the right time may be difficult. In this instance, the patient's age may dictate the need for a spacer in respect to pMDI usage, or a face mask with a nebuliser, or, if possible, a dry powder inhaler might be most appropriate, as typically there is no need for coordination of inhalation with device operation.

> *Human factors studies are an important part of the device development process, as they give an insight into how a device will be handled*

The choice of delivery platform depends on many factors in addition to target user population, for instance, market volume, disease severity, type of drug, dosing regimen, and regulatory pathway. Ultimately, a balance has to be struck in order to achieve the most effective therapy, and inevitably, compromises are likely to occur. The designer's role is to ensure that the likelihood of poor compliance is reduced as far as possible by good product design. This may dictate increased design complexity in order to simplify the user interface, which will ultimately have an effect on production costs. These types of decisions should be made based on a balanced review of data, which should be undertaken as part of the device development process.

Testing in Patients

Human factors studies are an important part of the device development process, as they give an insight into how a device will be handled by the target patient population, and whether a device concept is likely to be tolerated and used effectively. They also give an indication about any changes that might make the device work better for users, and, therefore, increase compliance.

Studies will usually be carried out with prototype devices on a group of subjects of the target age group.

They will have been selected to have a similar pattern of dexterity issues and other relevant comorbidities to the patients for whom the device has been designed. The initial study group will be fairly small, and include those patients who are thought most likely to potentially have user errors. It is only by getting a prototype device into the hands of real people that a true assessment of whether they are likely to work can be made.

Results from these tests are fed back to the device designers, who can refine the design before repeating tests on the new devices. This iterative design-test-feedback-amend process may lengthen the early stages of development, but can ultimately lead to monetary and time savings by establishing an effective device from the outset of drug development. Ensuring any design issues are rectified before the device goes into wider, commercial-scale production is important, as having good compliance increases the potential success of a drug or therapy.

Understanding how successful the device is in delivering a dose is key, but what human factor studies can also show is whether the devices are being used correctly by patients, as the designers intended. What is perhaps most useful is the fact that the studies can indicate exactly how they may be misused, and this could be for reasons such as a minor error or slip by a patient ('operator error'), a disconnect between a designer's view on patient intuition when handling a device, or fundamental misunderstanding of the

device concept instructions for use (IFU) are provided with the marketed devices; however, there is no guarantee that patients will read these, therefore, testing without the IFU can be useful to determine how intuitive the design is, and how likely errors are to occur in the market. Exploring how well patients understand the device, and even how they imagine the mechanics and internal workings of a device look, can give an insight into how the device might behave in the hands of patients.

An example is the application of colour indicators. One might expect that a green indicator light on the device means 'go' and it is time to inhale. Conversely, a patient may interpret a red one to mean the device is not yet ready. But, realistically, not everyone thinks the same, and so presumption of perceptions should be avoided, and clear indications made to avoid potential for mistakes. Without the use of electronics, indicators are rarely correct in all device states. For instance, a red flag may show that a device is not in the inhalation state, but a user may incorrectly interpret this as the device being empty. Connected devices or nebulisers that contain electronics can give good audible or visual feedback, and can even be used to guide the inhalation manoeuvre, although good design and testing is, again, important to ensure compliance.

> *Realistically, not everyone thinks the same, and so presumption of perceptions should be avoided, and clear indications made to avoid potential for mistakes*

Other indicators on the device can prove even more confusing for some users. An arrow on the device might be intended to show that a lever needs to be moved down or a button pushed, but once it has been pushed, the arrow might be pointing in the wrong direction and confuse them. What might be obvious to the designer might not be obvious to someone who has never seen the device before, so it is essential that visual cues are clear and unambiguous. Each feature must be thought through, as the shape, or feel, of a button can have an impact for a user. If a designer is relying upon instinct and learned user behaviour to interact with a device, the familiarity of a feature must be obvious.

For elderly people and others with dexterity issues, larger features are of great assistance; this will also help those with visual impairment. It should also be obvious when a feature has a function, such as a button, as prototypes have proven to be unsuccessful for this very reason: if too many people with poor close vision mistake a button to be a design feature rather than functional, the device will not be appropriate for them.

Many of these problems can be avoided at the outset with careful design, understanding peoples' perceptions, and by taking into account the target market. Any features should

be bold and obvious, and the forces and torques needed to operate the device should be appropriate for the patient population. Functional specifications must be aligned with the ergonomics if it is going to work for those patients.

The patients' age must be considered; if the device is intended to be usable by children as patients, a balance must be struck to ensure it is also safe if non-patient children unintentionally touch it. The design features will, of course, depend on whether they are going to be using the device themselves, or whether it will always be used in conjunction with the supervision of an adult.

Compliance among younger patients – and sometimes older ones – can be aided by gamification: making a fun task out of a medical device. This interactivity with a device aligns with connectivity, as feedback may be through an app-based game, but the interaction can aid adherence, and keep patients motivated to use their device. To keep interest levels up, challenges can change regularly, with goals to achieve alongside keeping up with their medication plan.

A Generic Alternative

Compliance is also something that must be borne in mind when creating a substitutable generic device. Guidance issued by the FDA in 2017 lays down the process that should be followed when designing the user interface for the device in a generic product (1). At the outset, a threshold analysis will look at the labelling, make a physical comparison, and carry out a comparative task analysis. If the generic and original devices are sufficiently close, then it may not be necessary to carry out human factors studies on the new device.

It is more straightforward outside the US; in Europe, for example, a product can be considered an analogue device. While it would not be automatically substitutable at the pharmacy, it does mean that there is no requirement for it to have the same user interface, so it is possible to redesign the device to increase patient adherence is possible. In the US, even the smallest change to the user interface requires significant regulatory work.

While the purpose of a medical device is to deliver a drug to a patient, if it is too difficult to use, then adherence rates will be poor. Worse, patients may think they are using it correctly, but inadvertent misuse means they are not getting the full benefit from their medicine. Keeping the patient at the heart of the design process is the best way to ensure treatment compliance.

References

1. *Visit: www.fda.gov/files/drugs/published/comparative-analyses-and-related-comparative-use-human-factors-studies-for-a-drug-device-combination-product-submitted-in-an-anda--draft-guidance-for-industry.pdf*

Andreas Meliniotis is Director of Device Development at **Vectura**, and leads the engineering and device development group based in Cambridge, UK. With over 15 years' experience at Vectura, he has led the design and development of several multi-dose dry powder inhalers as well as nebulisers and connected device technology. Prior to joining Vectura, Andreas worked for the Cambridge Design Partnership and The Technology Partnership developing glucose measurement devices and industrial printing technology respectively. Andreas is a Chartered Mechanical Engineer and Chartered Manager, and holds a Bachelor's degree in Mechanical Engineering from the University of Nottingham, UK.