

Taking Healthcare Out of the Hospital: How Device Design Can Empower Users

From point of care diagnostics to auto-injectors, medical devices are increasingly enabling more procedures and healthcare activities to be conducted outside of the clinic. What is paramount to the success of these devices is making them simple and intuitive to use, so that they can be operated by non-clinically trained individuals. To achieve this, device manufacturers are utilising a range of tools and approaches, from digital support solutions to packaging innovations and more.

The Medical Devices Democratising Healthcare

Creating medical technologies to conduct healthcare outside of clinical settings often involves a certain degree of up-skilling non-specialist users. The idea is that by putting the right technology and support in the hands of more healthcare professionals (HCPs) and providers, patient access to care can be increased, a phenomenon known as the democratisation of healthcare.

There are many examples of devices being used to help democratise healthcare.

Wearable devices are empowering users to track and better understand their health, providing a wealth of digital biomarkers that can be used to better inform health decisions. Meanwhile, point of care diagnostics are providing lab comparable results in minutes, enabling faster diagnosis and greater access for patients.

Healthcare at Home – The Challenge of Training Patients

In addition to medical devices designed for use by clinicians and healthcare professionals, there are also occasions when patients are required to self-train and administer therapy which would otherwise be carried out by an HCP in a clinical setting.

Take for example home auto-injection systems for a condition like rheumatoid arthritis. Traditionally, a patient would be instructed in first use of an auto-injector by an HCP during a face-to-face meeting, who would be able to support the patient with challenges such as injection anxiety and how to rotate the injection site. Increasingly, patients are now expected to self-train in the use of auto-injectors, sometimes having to rely solely on instructions for use (IFUs) to learn how to use their device.

In reality, many people either don't read instructions fully or don't follow the use steps correctly. This has been a significant driving factor in the simplification of use steps in recent years, with many modern auto-injectors now following a simple two-step process of 'remove cap' and 'hold against skin'. Whilst this has reduced the opportunity for user error, it has also come at the expense of device complexity.

Even something as simple as an asthma inhaler poses significant challenges in terms of self-training and adherence for patients, as delivery technique is critical. With pressurised metered dose inhalers (pMDIs), users often struggle with coordinating the button press with inhalation, the result being that most of the drug is deposited on the back of the throat, which can lead to further complications. Inhaler spacers, which are plastic tubes that are attached to the mouthpiece, go some way to addressing the coordination challenge, but they are bulky and require cleaning. This has driven innovations in inhaler design such as breath actuation, where the plume of drug is not released until the user starts inhaling. The challenge here again is that this comes at the price of increased device complexity.



Figure 1

When you factor in all the additional support previously provided to a patient by an HCP, device manufacturers are therefore asking much more of their users and requiring more effective user-centred design. This has pushed companies to look beyond the device itself, to other elements of the design ecosystem such as the packaging and quick reference guides.

Figure 1 shows a flip-book packaging solution that walks the user through the features of an auto-injector pen before they've even removed it from the packaging. This draws upon a principle from digital User Interface (UI) design called 'progressive disclosure', in which features and information are presented to the user in bite-sized chunks, gradually building up a picture rather than bombarding them with all the information at once. The images on the packaging prime the user for how the device should be held and can include a QR code and 'call to action' to prompt the user to engage with digital training content on a companion app. Using digital content such as instructional videos has the potential to be more dynamic than traditional paper IFUs and perhaps even tailored to the needs of an individual.

Digital Tools to Support Users

The benefits of using smart devices go beyond

training. Sensors enable the recording of usage data, which can be shared with HCPs to ensure patients are adhering to their treatment, or with device manufacturers to make improvements to their product offering. Patients can also access more general information and support around managing their condition.

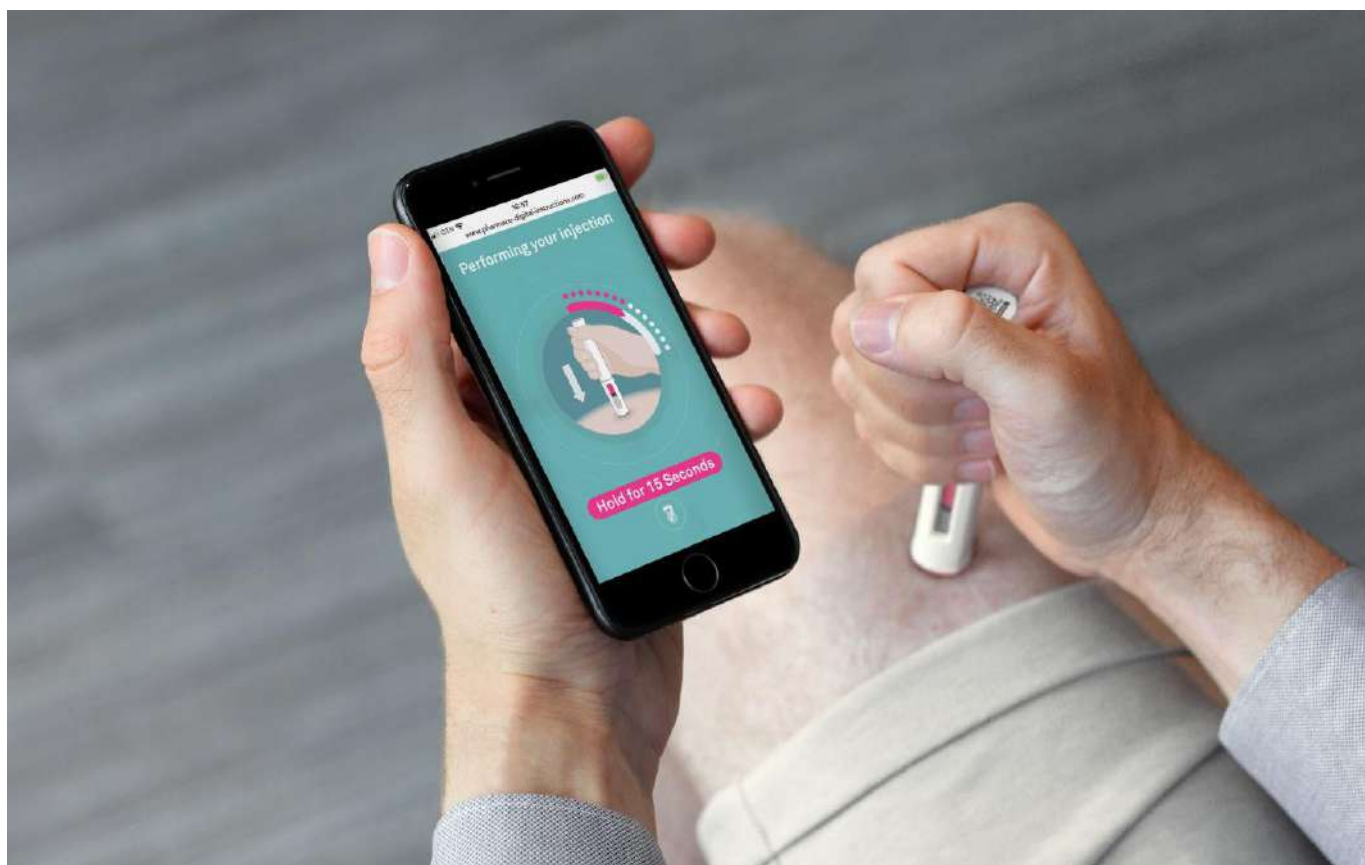
Another area where smart devices are proving to be useful is in the decentralisation of clinical trials. As the name suggests these would typically be conducted in a clinical setting which may therefore limit the number and type of participants that pharma companies can engage with. Additionally, a clinical setting can influence the behaviour of a participant.

Smart devices are now enabling clinical trials to be conducted over longer periods of time, in the participant's home environment. This gives pharma companies much greater access to patients – especially more vulnerable cohorts who would previously have been excluded from attending clinical settings, such as cystic fibrosis patients. It also provides more confidence that the data collected is representative of reality. In short, smart devices in clinical trials allow for higher quantities of more targeted data, which can help to promote safer and more effective treatments.

While these digital solutions may seem like an obvious benefit for both users and pharma companies, the system design needs to work hard to engage and motivate patients, particularly if additional user steps are required such as downloading an app or sharing personal data. Designing solutions to prompt and motivate users to adopt a digital solution requires a deep understand of their desires and un-met needs. This comes down to performing good contextual research from the outset and testing ideas often with the target user group.

Ensuring User-centred Design in a Development

Taking healthcare out of the hospital and clinical settings has the potential to improve access, enable faster, more accurate diagnosis, reduce burden on the healthcare system and ultimately create better health outcomes. However, doing so places greater burden on both the devices enabling this and the users themselves. It is therefore important to think carefully about what is being lost by taking a healthcare application out of the hands of an experienced HCP. Achieving the right balance involves developing devices which people can and want to use, which are simple, intuitive and safe. This is easier said than done. The following are some of the key steps that can be employed in a device's development to achieve successful, user-centred design.





Contextual Research

The key to effective design is understanding the underlying behaviours, beliefs and unmet needs of your users, followed by a cycle of developing and prototyping solutions and testing them frequently with stakeholders along the way. This process should ideally begin with conducting contextual research. When developing a diagnostics device for example, it can be useful to visit labs, GP surgeries, hospitals and pharmacies, ideally in different locations. This ensures that regional differences are captured and insights gathered from a sample of relevant stakeholders, which may include patients, carers, HCPs, buyers and regulators.

User Journey Mapping

Once a contextual understanding of the user and environment of use has been developed, a useful next step is creating a user journey map. The aim is to map the different use steps and highlight pain points in a user's journey – the areas of friction where improvements can be made. If there are multiple stakeholders involved, this is also where device manufacturers can identify conflicting requirements for the device.

From here, key design challenges can be identified and prioritised, which can then be expressed as “how might we?” statements, such as “how might we reduce the number of use steps required to set up a test?”. These insights can then be used to inform the concept generation phase.

Concept Generation

Getting something into the hands of the target users early and often is essential to allow effective testing and iteration of device

designs. This can range from simple foam handling models to functional demonstrators. Creating something physical is a valuable way of identifying potential usability issues and design flaws that are often difficult to foresee. This may involve simple ergonomic issues such as how a user naturally holds the device, or functional problems involving the position of different features. By creating quick and dirty prototypes, device manufacturers can work through a cycle of prototyping, testing and iterating the design, until converging on a few suitable options to take forward.

Human Factors Studies

As the development team begins to converge on a suitable design, it is a good idea to start conducting more formal human factors observational studies. This provides the opportunity to explore specific aspects of the device's use in more detail, to understand the root causes of any issues. It is again important to consider these usability challenges early on in the project, before beginning the physical development of the device. This can be particularly useful for understanding how a user interacts with a digital user interface (UI). For example, there are a number of UI prototyping tools available for smartphones and tablets that allow development teams to quickly and cheaply prototype a workflow for a user study. Recording these interactions allows a review of what the user focuses on at different moments of time, if they are experiencing an issue.

In medical device development, the process of learning from target users is often continuous and should occur throughout the development. The above steps should come together to provide a rich picture of user

expectations and their comprehension of the system. This allows design decisions to be based on first-hand evidence.

The Design Ecosystem

Sometimes a complicated challenge can't be solved through device design alone and requires looking at the packaging and information design, digital design and even service design to achieve a desired outcome.

One of the common challenges with designing medical devices is how to deal with the existing mental models of a user. This might range from perceived ways to administer an injection dose, to applying a sample off-instrument for a diagnostic device. To tackle any preconceived mental models, designers can utilise the various parts of the design ecosystem to nudge and guide the user towards a desired behaviour, from the packaging and instructions for use, to the design of the device itself.

Conclusion

As the industry continues to move towards providing more healthcare outside of the hospital, it is essential to ensure that the medical devices needed to enable this are safe, effective and easy to use. Achieving this requires device manufacturers to build a strong understanding of their users, including their challenges, motivations and unmet needs. In doing so, they can continue to create medical devices that empower users to take on tasks previously limited to trained HCPs.



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