A PATIENT-CENTRIC APPROACH TO THERAPY MANAGEMENT

Life after being diagnosed with a chronic illness is difficult. Here, Karl Hewson, User-Centred Design Engineer, and Uri Baruch, Head of Drug Delivery, both of Cambridge Design Partnership, discuss the challenges presented by chronic illness, and look ahead to a better future of patient-centric treatment, personalised to each individual's needs.

Average life expectancy is longer than ever before. However, this increased longevity often goes hand in hand with an increase in health issues. We're more likely to fall prey to the so-called diseases of ageing – problems such as cancer, diabetes and heart disease. In a similar vein, younger patients suffering from chronic conditions, such as rheumatoid arthritis, face the burden of living with their illness for many more years than previous generations. Add to that the effect on their families and the increased workload for healthcare professionals and the scale of the problem becomes clear.

The patient "journey" is tough. Going from the initial identification of symptoms, through consultations with various medical professionals to reach a diagnosis is often a traumatic experience. But, in many ways, that is only the start of the journey. Once treatment has been prescribed, a patient with a chronic condition suddenly has to take on the burden of the day-to-day responsibility of managing their disease – sometimes with little or no support system to fall back on. The symptoms of their disease also often exacerbate the problem, causing significant physical or cognitive difficulties, as well as the emotional challenges of coping with the life-changing diagnosis.

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A patient's age also presents its own challenges. A diagnosis later in life often requires patients to relearn, adapt or even sacrifice many of the activities and routines which have become a key part of their daily lives. In addition to the symptoms and physical challenges arising from the illness, the patient may also have to face the added complexity of a mental health issue. A diagnosis during childhood, on the other hand, can be easier for the patient – but may be more challenging for the parent who is responsible for initially managing the condition, administering therapy and eventually training their child to manage the condition themselves.

Pharmaceutical therapy regimens can vary significantly in frequency and complexity but even the simplest routine, such as swallowing a tablet at the right time, can prove difficult for some patients. Memory problems, for example, might make it difficult for an elderly patient to reliably take their medication at the right time, thus leaving them at risk of accidentally under- or overdosing.

When a drug delivery device is involved, technical complexities are added to the cognitive burden. Inhalation devices often require conflicting techniques – the use of a dry-powder inhaler, for example, requires a vastly different technique from a pressurised metered-dose inhaler. The correct inhalation rate might be fast or slow, and the device may or may not need to be shaken prior

Karl Hewson
User-Centred Design Engineer
T: +44 1223 264 428
E: kjh@cambridge-design.co.uk

Uri Baruch
Head of Drug Delivery
T: +44 1223 264 428
E: ueb@cambridge-design.co.uk

Cambridge Design Partnership
Church Road
Toft
Cambridge
United Kingdom

www.cambridge-design.co.uk

to use. Similarly, injection devices often require careful preparation and an understanding of where and how to inject, whilst avoiding accidental needlestick injury. For more complex treatments, such as those for HIV or cancer, multiples of different drug therapies and devices may be required, in addition to treatments being received for comorbidities.

A PATIENT-CENTRIC APPROACH

In other sectors, such as transport and the consumer industry, we're seeing technologies emerge which greatly simplify our daily routines. Smart homes can now detect whether or not a person is at home and switch the central heating and lighting on or off accordingly. We can remotely switch on our smart ovens or record our favourite TV programme from the office so everything is ready for when we get home. We're even able to get our sound system to play our favourite track using a simple spoken request. Our cars have evolved to keep us safer on the road, systems ranging from anti-lock brakes and self-dipping headlights through to corrective steering to prevent lane drift and automated speed and breaking control reduce our physical and cognitive burden when driving, thereby decreasing the risk of human error.

So how could assistive technologies help patients with chronic illnesses and complex therapy regimens? One approach is to look at the areas where patients are commonly making mistakes, leading to harm or poorly controlled symptoms. Medical device manufacturers today follow a risk-based approach to design laid down by regulatory bodies such as the US FDA and the MHRA. This approach helps to ensure patient safety, within the context of administering a drug. It looks at the design of the therapy administration and tries to simplify it to ensure patients or carers are informed through an ever-growing list of information sources – ranging from standard "Instructions for Use" to online therapy websites offering training videos and detailed instructions. Some new devices even offer phone apps and augmented reality features.

There is also growing pressure for device functionality to be as simple as possible – sometimes down to just two steps for device operation. But, at the same time, there is a demand for more and more complex features: more elaborate patient injection prompts on the device and automated functions such as needle insertion, reconstitution and connectivity. It's a delicate balancing act, even before you take into account the fact that patients really just want to forget about their illness and get on with their busy lives.

That's why a patient-centric approach is crucial: one size does not fit all. Diagnoses and treatments need to be designed, or at least customised within safe limits, for each patient and their lifestyle. Diagnosis is already moving towards point-of-care diagnostics, as well as at-home diagnostics. In Japan, for example, where there is already a high prevalence of electronic toilets, companies are working on the automated collection and analysis of urine samples. Imagine the potential benefits from early detection of a variety of medical conditions.

On the therapy side, personalised therapy has made headlines; CAR-T cell therapy from Novartis has achieved approval and further developments are in the pipeline for Roche and others. These go hand in hand with cheaper, faster DNA sequencing, which companies such as 23&Me are using to offer DNA insights, whilst also building a large pool of human DNA metadata that can help customise the therapies of tomorrow.

LIMITING FACTOR

So, we are well on the way to detecting diseases earlier and understanding their make-up better, as well as having keener insight into patients themselves. In the near future, this will allow us to really personalise therapies, not just to specific diseases but to individual patients. The limiting factor is the manufacturing and delivery of these personalised therapies. Manufacturing is currently geared towards large-scale production and can't cope with a complete shift to individually personalised "therapy on demand". Several organisations are working on solutions to tackle this issue, moving away from large-scale manufacturing of identical therapies into a situation where each batch is patient specific. The aim is to be able to manufacture, on demand, a batch of medication for a specific patient based on their disease state and genomic make-up.

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That future is still some way off – but the technology is already here to transform the lives of patients juggling complicated treatment regimens and bring down costs for healthcare providers. A radically new approach is possible by combining state-of-the-art technology with user experience and human factors expertise, all within the framework of current medical device regulation.

A NOVEL APPROACH TO DRUG DELIVERY

This new generation of treatment could, for example, transform the world of autoinjectors. We could do away with the need for rheumatoid arthritis patients to worry about storing their drugs in the fridge, warming them up to the correct temperature for injection, preparing their autoinjector for use, and disposing of the device safely. A smart base station could reduce the patient's task to the simple action of picking up a reusable autoinjector from the base station when prompted to do so, injecting themselves and then returning the device to its cradle. After injection, the base station could automatically collect the needle and cartridge ready for safe disposal, also alerting the patient when supplies are running low, and possibly even automatically reordering if required. Such technology could be adapted to cope with multiple users and different medications, either in the home or at a small clinic, for example. Fingerprint recognition technology could be used to identify the correct user each time, with a childproof lock to prevent accidental use.

The technology is here now – all it takes is a little imagination.