THE LATEST DIGITAL TOOLS REVEAL ACTUAL PATIENT BEHAVIOUR

In this piece, Ryan Noble, Senior Drug Delivery Specialist, and Tom Lawrie-Fussey, Healthcare Digital Strategist, Cambridge Design Partnership, discuss the potential of digital innovations to improve understanding of real patient behaviour and consequently increase adherence.

The digital world is increasingly affecting our interactions with information and with each other. Value is no longer restricted to physical products – it's now also linked to the information a product creates or gives us access to. Inhalation device development very much aligns with this strategy, with many new connected devices and service organisations now established to help quantify patient adherence, and ultimately improve patient outcomes, for diseases such as chronic obstructive pulmonary disease (COPD). But is this going far enough? Is it truly patient centric? The problem is particularly acute for patient groups that typically don't shout loudly about their concerns, children and the elderly for example, from whom it's particularly hard to elicit opinions.

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EFFICACY OF THERAPY DUE TO LOW ADHERENCE

We all hear a lot about adherence. But although this term is now common parlance across the industry, successful system-level implementation of product-enabled services, beyond the concept, remains far from established. We know that poor adherence leads to poor disease control and increased healthcare costs, so how are we assisting patients in optimising their therapy? Do we understand how to help them push through the barriers of remembering to take their prescription on time and in the right way? Do we enable patients to persevere and receive the clinical benefits they need?

Adherence is far from a new topic. It has been written about in the context of using technology to monitor dosing since Cramer's 1995 article on "Microelectronic systems for monitoring and enhancing patient compliance with medication regimens", in which a method of understanding how patients were taking their tablets is described, using special containers with a microprocessor that records the time when each dose is removed.[1]

Jump forward 20 years and the EU's myAirCoach project is looking into multiple factors around asthma sufferers' daily management of their therapy,[2] including fluctuations in disease state and improved lung models. A key aspect of this study is how it hopes to understand aspects of adherence better by using on-inhaler sensors to monitor the time of use of products. It then sends this usage data up to a cloud-based analytics service for assesment, using the insights gleaned to help tailor personalised asthma treatment plans in the future. Whilst a fantastic step forward – and one that will surely uncover a wealth of opportunities – we should consider it as just a part of the journey, not the endpoint. There are still many other innovative ways of enhancing (and simplifying) the actual inhalation process.

WILL BETTER DEVICE DESIGN SOLVE THE ADHERENCE PROBLEM?

But surely we can solve the adherence problem by improving the real-world patient experience? Are there established links that relate adherence to inhaler design, perhaps?

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Certainly, there are many devices already on the market, such as dry-powder inhalers (DPIs) and pressurised metered-dose inhalers (pMDIs), that aim to improve quality of life in routine treatment. With design features such as multi-dose capabilities and counters, better device design improves adherence – on paper, at least. However, a recent study looked at the impact of multiple-dose versus single-dose inhaler devices on treatment via persistence.[3] The study indicated that, in fact, inhaler type seems to make no difference to adherence. It is perhaps worth highlighting that these more sophisticated devices, whilst potentially superior, are still inherently disliked by patients – often not due to any design flaw but simply because the patient doesn't want to use the device in the first place.

The current industry realisation is that the true therapeutic benefits of long-term inhaled medicine may never be fully realised, due to patients failing to take their medication on time and not persevering with the right technique to get the effect they need. Indeed, in a study published earlier this year, the pMDI inhalation technique of more than 200 adults was observed, and only 23.1% were found to use their inhaler correctly.[4]

This is particularly true of those patient populations that perhaps require the greatest support but don't necessarily represent the majority – and therefore lack the loudest voice. Understanding the behaviour of the young and old may well unlock the most significant innovation opportunities. Further, these behavioural observations shouldn't be restricted to the inhalation process – better understanding the day-to-day situational context is crucial to providing an improved patient experience, and ultimately better outcomes.

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REGULATED INNOVATION

If we look at other regulated sectors, such as automotive, aerospace and nuclear, they have all successfully innovated without impacting on safety – indeed, they've markedly enhanced it. In those instances where safe consumer interaction is paramount (e.g. interfacing with the driver whilst they're at the wheel) innovations have rapidly evolved, with a typical dashboard now providing a plethora of safety, convenience and infotainment feedback, often controlled by gesture alone. How has the automotive sector managed an increased adherence to safety and better driving practices, whilst providing substantial interaction gains to the consumer, whereas adherence to inhalation methods remains stubbornly low?

The route to innovation has not been driven by regulation but by competition, and also a tier-1 supplier base that is a very active development partner. Such an industry dynamic creates a never-ending rush to democratise new technology, and there is a convenient spread of product/cost to accommodate the roll-out. Whatever appears on the luxury (higher margin) fleet will typically appear on all vehicle variants within 10 years. So how can this staged roll-out and development partner ecosystem be adopted and adapted to better serve medical devices?

FOCUS ON SPECIFIC DEMOGRAPHICS

Should we start with specific demographics, where overall production volumes are low and margins high? Whilst they provide a credible commercial launchpad, asking children or the elderly what they look for in an inhalation device rarely leads to success. Similarly, monitoring them in user trials, equipped with the usual myriad of cameras, microphones and one-way glass hiding review teams, often causes the Hawthorne effect – our behaviour changes when we know we're being watched. This is true for us all but often manifests itself even

more strongly with those demographics that are more intimidated by such a facility, don't fully grasp the fundamental aim of such work, and worry instead about what they're expected to do.

What if we could leverage development partners and access the latest remote observation technologies, so that we can observe users in their homes – without affecting their behaviour? What if we could also quantify their exact behaviour and usage interactions? With this quantitative truth, surely we'd be better placed to make informed product development decisions, where we could aim innovations squarely at those user sequences that a particular demographic most struggles with?

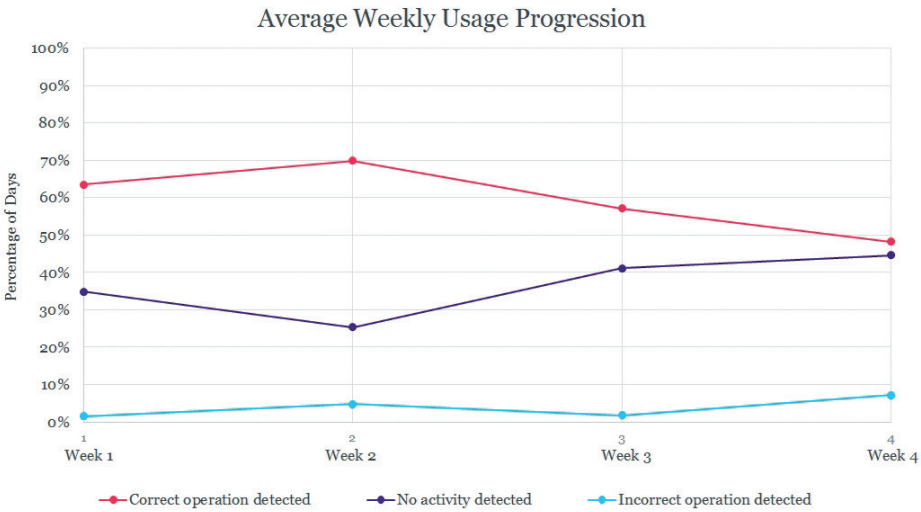

Figure 1: User trial results.

USER TRIAL RESULTS

Results from our recent at-home monitoring study of the use of a product over a one-month period have shown a significant drop in use after just two weeks. Whilst the logging technology was hidden from view, users were informed of the capabilities of this approach – yet still we saw clear drop-off in adherence during the study. We used miniature bolt-on logging "pucks" which are able to capture a range of user behaviours, without impacting the very use they're assessing.

Our data scientists decoded and translated this raw usage data into tangible user insights (see Figure 1). Behind the seemingly simple challenge statement lies a vast array of tasks, including initial hackspace challenge scoping, development of new caseworks, modifications of our electronic modules and, most crucially, the development and iteration of the back-end analytics service. In this instance it had to learn what "normal" looked like for each user. Once these individual characteristics were categorised, the usage classifier was then able to suggest what was normal or abnormal – or non-usage.

This trial confirmed two things – firstly, even though the respondents insisted they had continued to use the device each day, their own usage data disputed this. Secondly, after an initial increase in usage, soon after week two many respondents clearly found the immediate gains to be insufficient and usage quickly dropped off.

So what insights can we take from this? Probably most critical is that it clearly shows there is a defined point in time where users are about to reduce their adherence – in this case, soon after two weeks but likely to be different for different treatments. If this inflexion point could be known, relative to when a patient started to take the treatment, additional measures could be taken (e.g. personalised incentives) to attempt to bridge the gap between initial interest and longer-term verifiable gains/results.

In the world of inhalation, for example, it may be possible to act when a patient is inhaling too quickly or storing the device the wrong way. Such actions could be measured and the user provided with the appropriate feedback, either in real time or as a reminder on a connected application. If we use technology to understand the behaviour of patients – not just in the market but during the development of the product – then we may gain access to previously unknown information that can be used to help users achieve the clinical effect of their medication.

CONCLUSION

It is understood that a certain amount of success can be achieved purely through patient engagement software such as HealthPrize, which has focused on the human psychology element in aiming to create the optimal carrot/stick incentivisation regime. It remains a difficult path to tread, however, as the aspirations of the sector continue to mature beyond monitoring to include assisting in treatment or diagnosis.

What is clear is that the base technology already exists to enable designers to improve their understanding of the needs of their patients and, in doing so, it empowers them to make the required design changes to inhalers to provide a beneficial user experience. Translating such raw usage data into quantifiable user insights is hard, requiring large high-quality datasets, a sound grasp of the fundamentals of classic data science and (then and only then) vast amounts of computing power to drive artificial intelligence and machine learning.

So what is really stopping us? Is it the cost? Is it the regulations? Or is it simply not understanding the patient well enough?

REFERENCES

1. *Cramer JA, "Microelectronic Systems for Monitoring and Enhancing Patient Compliance With Medication Regimens". Drugs, March 1995, Vol 49(3), pp 321-327. (link.springer.com/article/10.2165/00003495-199549030-00001)*
2. *www.myaircoach.eu/myaircoach/ (Accessed October 30th, 2017)*
3. *van Boven JFM, van Raaij JJ, van der Galiën R, Postma MJ, van der Molen T, Dekhuijzen PNR, Vegter S, "Impact of Multiple-Dose Versus Single-Dose Inhaler Devices on CODP Patients' Persistence With Long-Acting β_2-agonists: A Dispensing Database Analysis". npj Primary Care Resp Med, www.nature.com/articles/npjpcrm 201469.pdf (Published October 2nd, 2014; Accessed October 30th, 2017).*
4. *Bartolo K, Balzan M, Schembri EL, Asciak R, Balbi DM, Bardon MP, Montefort S, "Predictors of Correct Technique in Patients Using Pressurized Metered Dose Inhalers". BMC Pulm Med, bmcpulmmed. biomedcentral.com/articles/10.1186/s12890-017-0386-6 (Published February 28th, 2017; Accessed October 30th 2017).*