INSULCHECK CONNECT: ADDRESSING ADHERENCE WITH A CLOSED-LOOP SOLUTION

In this article, John Hughes, Chief Executive Officer, Innovation Zed, and Alina Smotrova, Business Development Manager, SHL, discuss the success of the InsulCheck Classic, an add-on device to help patients with diabetes improve adherence to their medication, and how user feedback and modern technology has led to the development of its second generation, InsulCheck Connect.

It is well documented that non-adherence to medication is a public health problem worldwide. With the increasing prevalence of chronic diseases and the growing list of conditions that require self-injection, such as diabetes, Parkinson's disease, multiple sclerosis, rheumatoid arthritis and migraine, ever more patients are demanding a simple solution that can help them manage their conditions more efficiently without disrupting their daily routines.

Having been diagnosed with diabetes more than 25 years ago, John Hughes, Chief Executive Officer of Innovation Zed, is no stranger to the complexities associated with the management of chronic conditions. When he noticed his own behaviour falling short of optimal, he saw a need for a technology that could help him close this gap. That is why John and his colleagues at Innovation Zed, an SHL partner company, officially launched InsulCheck Classic in 2016, an add-on device for existing insulin pens. Since then, thanks to its intuitive features and compatibility with the majority of insulin pens on the market, the device has benefited a number of users across the globe.

Now in 2018, on the eve of the next generation, InsulCheck Connect, hitting the market, the team behind this patient-proven product takes a look back at its journey, discusses the key learnings that led to InsulCheck Connect, and talks about what lies ahead for the platform.

THE CHALLENGE OF NON-ADHERENCE

The impact poor adherence has on diabetes treatment can range from below optimal health outcomes to extremely dire consequences, such as heart disease, stroke, kidney failure, lower limb amputations and blindness.[1] Poor outcomes can, in turn, lead to increased healthcare service usage, ultimately resulting in the escalation of healthcare costs. The financial pressure is sometimes even passed onto patients by payers through higher co-payments or via higher costs of coverage per employee.[2]

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In light of these challenges, a multitude of studies have been carried out to understand the determinants of non-adherence and identify methods of improvement. When studying diabetes, for example, one common method is to have patients keep what is known as a

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"diabetes diary", where patients produce a written account of when they took their medication and what their glucose levels were like every few hours. This type of subjective approach where patients are asked to define their own adherence, either using pen and paper or through personal interviews with healthcare providers, is often time-consuming and can result in unreliable reports. For example, a study where patients were asked to provide their subjective ratings of adherence found that those admitting to non-adherence were able to describe their behaviour accurately,[3] whereas patients who denied non-adherence were unable to accurately recount their activities.

On the other hand, traditional objective strategies, such as counting remaining dosage units (e.g. tablets) during clinic visits or using pharmacy databases to track when prescriptions are filled, have their own set of limitations. This is in part because obtaining medicine by itself does not ensure its use. Such information can also be incomplete because patients may use more than one pharmacy, or data may not be routinely captured. In addition, implementing a comprehensive information technology infrastructure involving multiple parties can be complicated, time-consuming and potentially very costly.

ADDRESSING ADHERENCE WITH TECHNOLOGY

Recent developments in modern technology have made it possible to monitor adherence more easily and objectively, without adding burden to the patient. For example, the creation of devices that automatically record details about oral and inhalation therapy can provide evidence-based records of the patient's behaviour. Yet when it comes to combination products, introducing a new feature is often a lengthy process, complicated by regulatory hurdles, costs and time-to-market considerations.

First introduced to the market in 2016, InsulCheck is a snap-on accessory for a wide range of existing insulin pens (Figure 1). Providing patients with the benefits of technology, the device enables straightforward insulin management for diabetics. Its first generation, the Classic, reliably displays the time since the last injection on a large and easy-to-read display panel that ensures the information is easily accessible to the user.

Figure 1: InsulCheck can be easily mounted onto a majority of existing insulin pens.

Since its launch, users of this intuitive device have first and foremost praised its ease of use – there is no need to adapt to new regimens as the device can be used with existing pens. They have also reported significantly improved confidence in managing their injections, no longer needing to worry about double injections and opportunities to catch up on forgotten injections, which in turn leads to improved safety and better health outcomes. More importantly, reports have suggested that many patients now see the device as an essential, even indispensable, complement of their pens, adding that they will continue to use it when they move to new pens.

LEARNING FROM EXPERIENCE

Whilst InsulCheck Classic was widely praised among its users for its ability to support adherence, user feedback, gathered by telephone, surveys, traditional mail and online, revealed that patients wanted more information that could help them save time and effort. This could be achieved through the automatic recording of injection data, which could be logged in digital diaries and passed to clinicians for evidence of treatment. Users also wanted the ability to enable auto-correlation via intuitive pictorial representations where data related to glucose readings and insulin intake is presented on their mobile devices.

This user feedback led to the creation of InsulCheck Connect, the second-generation iteration where data recording and connection capabilities have been implemented to support the analysis of injection behaviour. The connected device can record the time and frequency of injection and send this data to the patient's mobile device. From there, the data can be integrated into diabetes management algorithms to support condition management.

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In order to capture a more accurate account of device acceptance and functionality, the team created a connected version of the add-on device to undergo intensive trials in the UK NHS. Initial findings revealed that not only is the collection of data important, but the presentation and format for user and clinician interpretation is also key. The trial also reinforced the premise that there is value in having a one-size-fits-all solution readily accessible across a range of existing injection pens, covering over 100 million users worldwide.

ENHANCED FEATURES FOR BETTER CONNECTIVITY

Since the NHS trial, InsulCheck Connect has undergone a series of design enhancements to improve its usability and capabilities. For example, besides recording injection time and frequency, a sensor that detects device mounting and dismounting activities was added so as to track pen usage and potentially highlight anomalous behaviour – crucial information which can be used to give feedback on best practices. Because insulin needs to be stored under certain temperatures to maintain safety and efficacy, the device can now also measure and track ambient temperature, giving warnings when necessary. The industrial design was also improved to support a larger display area and to make space for an upgrade to the battery component, which can now be recharged via a USB cable.

With InsulCheck Connect, each and every data point is automatically recorded and sent to the user's mobile device wirelessly via Bluetooth. Paired with a mobile application, the data becomes an invaluable asset for clinicians and health professionals who need accurate evidence of user behaviour, to support treatment adjustments.

Understanding that quality and safety are at the core of any medical treatment, the InsulCheck Connect has attained a CE marking approval in Europe and has been certified by the US FDA as a Class I medical device.

CLOSING THE LOOP FOR THE VALUE CHAIN

Once InsulCheck is attached to a pen and connected to a mobile phone, patients can enjoy the benefits of data monitoring and condition management without the need to change their routines, an important characteristic that is at the heart of InsulCheck's add-on approach.

With reliable injection data at hand, patients know the exact details of their previous injection, which helps them avoid dose miscalculations and miss fewer injections. Caregivers are also provided with peace of mind by the integration of functions such as remote monitoring and instantaneous alerts.

For healthcare professionals, including nurses and physicians, a significant amount of time can be saved over manually gathering and logging adherence data, with the added benefit of improved reliability over traditional manual methods. The time saved can then be focused on addressing the situations at hand, whether it is on improving adherence or laying out plans for optimal treatments.

For pharmaceutical companies seeking to utilise connectivity to support adherence and create market differentiation for their products, InsulCheck's add-on approach lowers the barriers to entry. This is because integrated pens are expensive to create and require extra time to attain regulatory approvals. In addition, patients will be required to adapt to new practices and habits, thereby increasing the potential for resistance.

For pharmacies, the collected data can be incorporated with a customer database to provide personalised services, which can help enhance user experience, drive loyalty and also improve customer retention and penetration.

Last but not least, payers can gain real-world insight into understanding if prescriptions are not only filled, but properly adhered to. These insights help payers identify the patients who achieve optimal treatment and the best health outcomes, which in turn can translate into lower healthcare costs that can go back into rewarding the patient. The data also allows payers to more effectively help patients who have not achieved optimal treatment.

Figure 2: InsulCheck Connect's closed-loop system.

In summary, with each member of the value chain benefiting from the data captured, the Connect presents a closed-loop solution that helps patients achieve better health outcomes (Figure 2).

BEYOND ADHERENCE

When recommending strategies to improve adherence, the WHO advises using a multi-disciplinary approach that combines feasible self-reporting and reasonable objective measures.[4] InsulCheck Connect supports this multi-disciplinary approach by making the sharing of objective, real-world data possible across multiple conditions, devices and platforms.

To support this aim further, Innovation Zed has launched a number of initiatives within the digital space to provide its software partners with market-tested expertise and knowledge in the form of a certified medical device with an open application programming interface (API), through which data is easily available for integration. The data, which can be

Figure 3: InsulCheck Connect is an example of how the ENYA platform can be easily extended to other health conditions and sectors.

used for condition insight and analysis, can be transformed into invaluable statistics that will enhance their existing offerings.

With the ongoing increase in injectable therapies for the treatment of chronic conditions, Innovation Zed is expanding this approach to be easily extended to other health conditions and sectors in the form of a condition-agnostic hardware platform – ENYA. The ENYA Platform is completely injection-device independent and can work across multiple injectable conditions. This makes it possible for pharmaceutical companies to support their patients with the benefits of connectivity without recertifying their injection devices (Figure 3).

As the industry is focusing more and more on patient-centricity, the add-on platform provides an excellent opportunity to improve patients' user experience. This can be done without changing the injection process that they are accustomed to. The data captured by the add-on device can be used to introduce a focus on adherence, which will help the patient manage their therapy and, with their consent, be shared with caregivers, doctors, payers and pharma companies.

ABOUT THE PARTNERSHIP

SHL is a world-leading solutions provider in advanced drug delivery systems, such as autoinjectors and pen injectors. Its pioneering products for major pharmaceutical customers are based on human-centric designs and market-proven functionalities. Combining SHL's broad knowledge base with Innovation Zed's condition management expertise, the partnership offers a flexible, robust and risk-proof approach to supporting pharma's first steps into connected devices and digital health.

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ABOUT THE AUTHORS

John Hughes is the Co-Founder and Managing Director of Innovation Zed. As a computer scientist and entrepreneur with over 30 years of experience in business development, Mr Hughes dedicated his career to developing digital solutions that create better health outcomes for patients.

Alina Smotrova is a Business Development Manager at SHL Group responsible for the expansion into new markets and exploration of new technologies and business models. She works with SHL's customers and partners to provide advice on business model innovation, market insight and growth strategies with a particularly focus on digital health.

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