THE ADD-ON APPROACH TO CONNECTIVITY

Digitalisation is playing an increasing role in the way healthcare is delivered, particularly in terms of compliance with treatment. However, the lengthy time taken in getting digital delivery devices to market can mean that patients are being denied the benefits of these advances. One solution is the use of simple add-on platforms that can work with an existing device. William Cirillo, Head of Product Development at Innovation Zed, and Christian Keller, Director for Engineering Solutions at SHL Group, describe one such platform developed by their companies.

Digital health is an umbrella term that covers a lot of different applications of technology in the health industry. From wearable sensors and electronic health records to health apps, connected and digital solutions are becoming more accepted. With almost three-quarters of the world's population having access to mobile technology, usage is increasing among all age groups; already up to 75% of people in the UK are going online for health information.[1,2]

WHY DIGITAL HEALTH?

Digitalisation of healthcare is happening and connected solutions will continue to play an increasing role for patients, healthcare providers, payers and pharmaceutical companies. These advances are supported not just by the availability of technology. A new generation of patients has grown up and they approach their own and their families' healthcare differently today. They want to be informed, engaged and in control of their treatment process more than any previous generation.[3] From the point of view of governments and insurers, longer life expectancy and increasing prevalence of chronic diseases mean that healthcare costs are growing unsustainably. According to the OECD, health spending has been rising faster than economic growth in the developed world and will reach 14% of GDP by 2060 unless reforms are implemented.[4] Wider implementation of digital technologies can save healthcare systems 7-11% of spending by improving hospital efficiency and encouraging home care and self-management.[5] One major area in which new technology can be used to curb costs is outcome-based healthcare. To ensure that therapies benefit patients and reward outcomes, it is crucial for health agencies to be able to monitor adherence; and connected technologies are an excellent solution for this.

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ADHERENCE TRACKING AND CONDITION MANAGEMENT

The World Health Organization agrees that "increasing adherence may have a greater effect on health than improvements in specific medical therapy".[6]

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Yet an average compliance rate is only 50% in the developed world and even lower in the developing.[1] Non-compliance is damaging for everyone. Patients have their health deteriorating; doctors and pharmaceutical companies cannot properly assess the effectiveness of the treatment; and both pharma and payers suffer avoidable costs.

The pharma industry understands the importance of digital solutions in dealing with this challenge. This is evidenced by the fact that the number of unique proprietary health apps by pharmaceutical companies has grown by 63% in 2013-2014.[2] Sensors and smart technologies are being introduced for various stages and indications, including:

- Monitoring real-time patient experience in clinical trials in order to improve adherence to COPD treatment[7]
- Branded drug apps to help manage the treatment of type-2 diabetes[8]
- Comprehensive cloud-based device/software solutions for sleep and respiratory patients.[9]

THE ENYA PLATFORM

Now that data from already introduced tools is becoming available, it is clear that they can bring about real improvements in outcomes and are highly accepted by patients and healthcare professionals.[2] However, introducing connectivity for combination products is often a lengthy process complicated by regulatory hurdles, costs and time-to-market considerations. Therefore, while pharma companies are still considering, or are in the process of developing, a delivery device with integrated connectivity, a gap appears between patients' expectations and available solutions. One way to narrow this gap is to use an add-on platform that can work with an existing device.

SHL, in partnership with Innovation Zed, has developed such a solution for pen injectors – the ENYA Platform. It allows connectivity to be added to any multiple dose injection pen in a fast and easy way without any modifications to the existing device (Figure 1). The cross-platform solution can track injections "on the go" and connect via Bluetooth to a custom-made or third-party condition management application.

The beauty of ENYA is that it is completely injection device independent. Therefore, a pharma company can connect an existing product for any indication within a 12-month timeline. There is no need to recertify the injection device, no extra regulation and no change to the manufacturing process.

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

Figure 1: The ENYA platform can work with existing devices.

BENEFITS OF THE ADD-ON APPROACH

What are the key benefits of the add-on approach? For pharma companies, it is an opportunity to present an innovative offer at lower cost and faster time to market. In addition, as the platform is completely customisable and entails incremental functionality for different markets and indications, the ENYA Platform can be effectively used to differentiate across devices and conditions.

For patients, it is the peace of mind. They don't have to worry anymore about remembering or manually inputting their injection data. The connectivity empowers them to interact directly with various stakeholders in real time, providing what many advocacy groups are emphasising – confidence, engagement and feeling in control of their health. And, of course, with improved adherence their long- and short-term health outcomes will improve.

For healthcare professionals, the recording of injection behaviour "on the go", eliminates conjecture by lending factual evidence to the data. This enhances the professional's ability to have more meaningful interactions with their patients with a view to improving therapies and achieving better health outcomes.

For health agencies and payers, these improvements in health outcomes will significantly lower their chronic condition-related spending. Moreover, the availability of real-time evidenced data on adherence and outcomes will make reimbursement decisions more informed. It will also reduce emergency admissions and make hospital visits more effective.

Figure 2: Patients can continue using their chosen insulin pens.

Figure 3: The connected device is designed to integrate with any diabetes management system.

CASE IN POINT – INSULCHECK

An example of the ENYA Platform that has already proven itself on the market is InsulCheck – an add-on device for insulin pens. With over 100 million diabetic insulin pen users globally, it provides a powerful solution that does not require them to change their injection habits in any way. InsulCheck works with any existing pen through the customised sleeve interface (Figure 2). The connected device records injection behaviour and sends this data to the patient's mobile device, where it can be integrated into diabetes management algorithms (Figure 3). Research shows that using the InsulCheck device provides better clinical outcomes. A study by Minnock[10] has shown that the effects of using the device included improved HbA1c readings (average long-term blood sugar level indicator), fewer hypoglycaemic events (blood glucose below 3.9 mM) and fewer hyperglycaemic events (blood glucose over 11.1 mM).

What does it mean for patients using the device? If they know exactly the details of their previous injection, they will avoid dose miscalculations and miss fewer injections. That means they will suffer fewer hypoglycaemic events, have greater control of their glucose levels and minimise the time spent in hyperglycaemic states. Less injection mistakes also mean less hospital emergency admissions to treat the short and long-term problems connected to hypoglycaemic events. In short, it means that diabetes patients are able to lead a safer life without worrying constantly about missed injections – they are in control of their treatment.

All of which helps to reduce HbA1c readings and the long-term complications of diabetes. According to the research,[11] reducing HbA1c levels by just 1% will:

- Decrease risk of heart failure by 16%
- Decrease risk of heart attack by 14%
- Decrease the risk of stroke by 12%
- Decrease risk of diabetes-related death by 21%
- Decrease risk of amputation by 43%
- Decrease risk of small blood vessel disease by 37%
- Decrease risk of death from all causes by 14%.

Using InsulCheck device over a one-year period can improve HbA1c by more than 1.0%. Thus, by using this simple device that does not require any extra steps during the regular process of injections, people living with diabetes will enjoy greatly improved health outcomes. At the same time, it will help their clinicians to adjust and modify their treatment based on consistent data monitoring and reduced number of complications resulting from non-adherence. Finally, it will significantly reduce the healthcare costs of hypo- and hyperglycaemic events and other diabetes-related conditions.

> "...a simple add-on solution recording and transmitting the data about injection time and dose can create long-term health benefits, lower the costs of health care and introduce a new interface with the patient."

BEYOND THE INJECTION

In conclusion, a simple add-on solution recording and transmitting the data about injection behaviour can create long-term health benefits, lower the costs of health care and introduce a new interface with the patient. The resulting increased adherence leads to better outcomes. Pharma companies can achieve better positioning in their markets as they differentiate their offer and manage an improved product lifespan.

But compliance tracking is about more than just injection; it is about a range of behaviours. Therefore, it is important to look deeper into the therapy practices. Drug temperature tracking, needle withdrawal duration, training tips, preparation confirmation – all of this information can be vital to condition management. Thanks to the variety of customisation and functionality options available, the ENYA Platform can accommodate a variety of requirements from pharma and biotech industries.

SHL's vast experience in developing, designing and manufacturing injection devices for a number of major pharma customers means that the ENYA platform has the support of SHL's broad knowledge base and comprehensive capabilities. Combining longstanding

reliability and visionary innovation, SHL and Innovation Zed offer a flexible, robust and risk-proof approach to adding connectivity and jump-starting your entrance into the digital health era.

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ABOUT THE AUTHORS

Christian Keller is working for SHL Group in Taiwan, where he leads an engineering team which is dedicated to creating new customer value in health and medical applications through the latest developments in IoT, connectivity and digital health. SHL is one of the world's largest solution providers in design, development and manufacturing of advanced drug delivery systems. Mr Keller graduated in 2005 from prestigious Swiss Federal Institute of Technology in Zurich (ETHZ) with a Master's degree in Electrical Engineering, and since then has been working in different engineering and project management positions. He has been involved in product developments from early-stage concepts to design for manufacturing and production.

William Cirillo is the co-founder and Head of Product Development of Innovation Zed, a company focusing on research and development in the area of connected solutions and services in drug adherence and condition management. A diverse technical background and experience enables Mr Cirillo to work on developing new and interesting products in many different areas to help make people's lives better. Graduating from the University of South Australia with a Bachelor of Applied Sciences degree in Physics in 1986, Mr Cirillo has been working in various engineering and scientific fields for 30 years, with areas of expertise ranging from manufacturing to pure research and from hardware to software.

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