



ENABLE CONNECTIONS: A BLUETOOTH-CONNECTED WEARABLE, ON-BODY INJECTOR

Last year, Enable Injections announced the development of a Bluetooth-connected Enable Wearable Injector. In this article, we explore the vast potential for improving patient care that comes from adding connectivity to devices that deliver biotherapeutics for the treatment of chronic conditions and, in particular, the synergy that exists when wearable on-body injectors are combined with connectivity technology.

Written by ONdrugDelivery Magazine, for and on behalf of Enable Injections.

The steady uptake of digital technologies within healthcare continues to improve diagnosis, treatment and patient management in the clinical setting. It produces a large amount of data – the manifold uses and value of which industry stakeholders are just coming to terms with. An opportunity exists to produce far more, increasingly valuable data from digital

technologies if the healthcare sector is able to direct the necessary resources towards building the infrastructure to connect digital health technology to the cloud, for true connected health (CH).

The area of consumer health is moving ahead on this, with connected biometric devices already becoming widespread. The growth of the smartphone industry has clearly been a key enabler and monitoring our own health outside the clinical setting with mobile and wearable clinical and fitness devices has become popular. For consumers, this represents a powerful tool, providing the ability to access, analyse and share their data from connected devices and apps.

The medical and pharmaceutical segments of the healthcare industry are on the verge of harnessing these developments and taking advantage of the benefits CH can bring. The potential to create a better, more efficient and cost-effective healthcare system is substantial.

CONNECTED HEALTH IN BIOLOGICS DELIVERY

Biologic-based therapeutics have been reaching the market in steadily increasing numbers, with biologics-rich pharma

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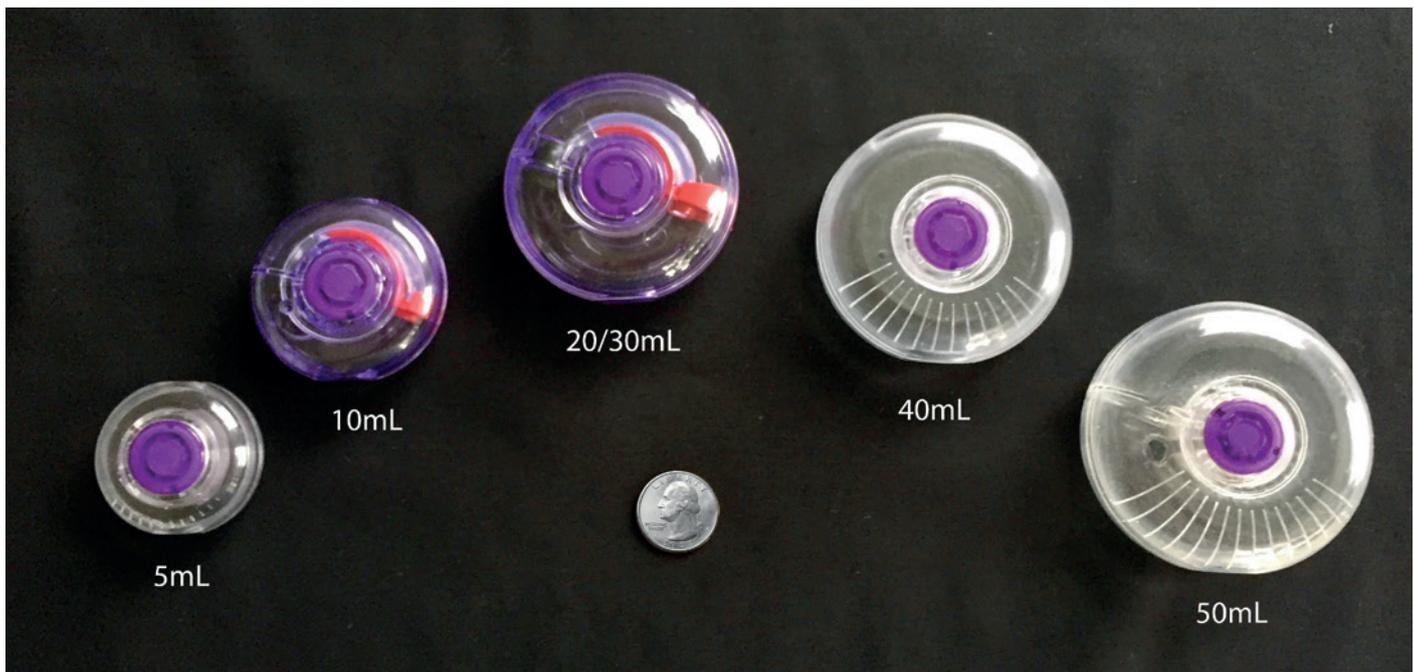


Figure 1: The Enable Wearable Injector can deliver volumes from 5 mL up to 50 mL.

company R&D pipelines promising more to come in the medium and longer term. Biologics typically treat chronic conditions requiring a long (often life-long) treatment regimen, and such indications are on the rise due to advances in medicine and people living longer. What were once fatal diseases have become chronic diseases. The underlying growth in global population is also a factor. The rampant growth in the development of biologics has been driven by the need to meet this rise in chronic conditions.

medications introduces further complexities most notably: the high viscosities arising from high protein concentrations, giving rise to large injection volumes; the frequency of required dosing can be inconvenient; there are larger volumes of drug to monitor and, due to their high price, reducing excess and waste is important. The burden and inconvenience of complex treatment regimens threaten patient compliance/adherence, with consequent negative impact on clinical outcomes.

administration simple, intuitive and safe enough for self-injection at home.

For the more complex, viscous formulations with high dose-volumes, which are often the biotherapeutics that are effective in difficult-to-treat indications, auto-injectors are not usually suitable delivery devices. However, wearable, on-body injectors like that under development by Enable Injections do overcome the technical restraints that previously inhibited use of these difficult-to-deliver biologics outside the hospital setting in the past.

A principle advantage of wearable bolus large-volume injection devices is essentially that they take the time pressure off the administration procedure. With a syringe or an auto injector, the injection needs to be completed quickly – seconds rather than minutes. Whereas once you move to a device that is worn on the body, the process can take a few minutes, or more, without any problems.

The very significant advantages and possibilities that open up if you can take more time, slow down the rate of injection, and allow a higher dose volume are summarised in the boxed text at the end of this article. The specific advantages of Enable Injections' wearable device, which can now deliver volumes from 5 mL right up to 50 mL (see Figure 1) were discussed in greater detail in Enable's article, "People Power: Inspiring & Delivering a Unique Wearable Bolus Injector", which appeared in ONdrugDelivery Magazine, Issue 51, July 2014, pp 31-33.

"The connected Enable Wearable Injector features passive monitoring. The monitoring software is integrated with the device to deliver a fully automated monitoring process. This removes all requirement for user input and for the user to carry out process steps with applications as far as recording the data is concerned, avoiding the user retention issues that have caused other mobile monitoring projects and therapy adherence apps to fail in the past."

Almost all biologics require delivery via infusion or injection and traditionally the hospital setting was the location for their administration, by healthcare professionals. On one hand, these sophisticated medications are highly effective in treating difficult diseases. But on the other hand the nature of many of these

Self-administration at home is clearly a highly favourable means to increase convenience, and over recent years we have seen the emergence of enabling technology capable of taking treatment out of the hospital and into the home. For small volumes of less viscous formulation, pens and auto injectors often suffice, making

The cost savings that wearable large-volume injectors bring are not limited to those arising from enabling self-injection compared with the more expensive clinic- and hospital-based treatments. “The benefit for biopharma companies is they can get their product into clinical evaluation quicker as there is no need to spend time on additional formulation to achieve low volumes,” explained company Chief Executive Officer, Mike Hooven.

Nevertheless, whilst huge benefits stem from moving injected therapeutics, even those requiring large volumes or highly viscous formulations, out of the clinic and into the home setting for self-injection, there is one element of compromise – because of course moving treatment home and out of the clinical setting also means moving the patient and their treatment away from the close oversight and monitoring that healthcare professionals provide in the clinic where they are present.

“In connecting the Enable Wearable Injector via mobile devices to the cloud, Enable Injections is demonstrating that its founding principles of patient-centric innovation, promoting adherence, technology-enabled therapeutics and cost reduction endure.”

As more biologics reach the market, and the trend for their self-administration as injectable therapeutics in combination with drug delivery devices accelerates, this presents an obstacle: self-administration at home diminishes the ability of healthcare providers to track and monitor the use of ever larger amounts of therapies being prescribed to a large and growing number of patients.

It is this undesirable compromise that connecting delivery devices to the cloud can really help to avoid – CH allows the patient and other stakeholders to enjoy all of the benefits of self-administration without it having to be

at the expense of the benefits of clinical oversight and monitoring. Having the best of both worlds – convenient, intuitive administration at home and clinical monitoring – becomes an achievable goal.

In addition to allowing clinicians to monitor and oversee treatment at home, CH has the potential to aid in patients’ accountability for their own home treatment. A connected drug delivery system increases patients’ engagement with their treatment since: 1) they know they’re being checked and 2) there is a sense of gratification from meeting the marks required of them.

The same human psychology applies with treatment adherence goals as with mHealth products such as Fitbit, which works because we want to meet our target of, for example, taking a certain amount of steps a day, and to see our achievements displayed visually on our phone screens via the app. It is well understood that patients who engage in their healthcare decision-making process tend to have healthier outcomes.

Self-managed health and wellbeing using a connected delivery device brings with it numerous additional benefits including: the sharing of essential data with doctors/physicians; the ability to alert healthcare providers to potential problems; using the data to facilitate more informed clinical decisions and efficiently manage populations. Connected devices can help accommodate different patient populations and instil confidence with self-administration – for example patients with different disease states; patients experienced with using injections *versus* self-injection-naïve patients; variable cognitive abilities; differing physical dexterities; and patients of different ages.

CONNECTING THE ENABLE INJECTION DEVICE

In 2015, recognising the enormous potential that the synergy of CH and wearable on-body injectors holds, and the rising need for compliance monitoring and data capture with a mobile app, Enable Injections announced a Bluetooth-connected Enable Wearable Injector. Mike Hooven said: “Now pharmaceutical companies, physicians and patients can each have the tracking data they need by using a mobile app or Bluetooth-connected device. The ultimate goal is that the new drug delivery technology will not

only benefit patients by improving their health outcomes, but also lower costs by streamlining drug development and replacing costly hospital-based infusions.”

The connectivity hardware (chipset), which is developed in partnership with Flextronics International Ltd (“Flex”), is conveniently packaged inside the Enable Wearable Injector’s button (see Figure 2). The operation of the drug delivery device function remains wholly mechanical and independent from the electronic components used to capture data. Therefore the connectivity aspect is optional and if, for example, the chipset malfunctioned, the drug delivery device would still function completely normally.

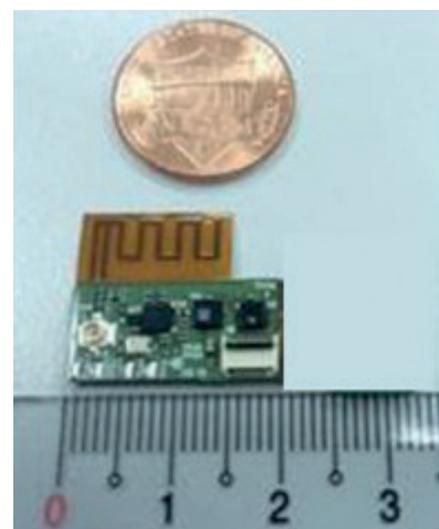


Figure 2: The chipset for the Bluetooth-connected Enable Wearable Injector, which will be packaged conveniently inside the injector’s button.

Whilst the delivery device functions mechanically and independently of the connectivity electronics in the button, the connected Enable Wearable Injector features passive monitoring. The monitoring software is integrated with the device to deliver a fully automated monitoring process. This removes all requirement for user input and for the user to carry out process steps with applications as far as recording the data is concerned, avoiding the user retention issues that have caused other mobile monitoring projects and therapy adherence apps to fail in the past due to the need for active user input. But at the same time, once the data has been collected automatically, it can be processed and actively delivered in a useful format to the patient via mobile app notifications and alerts, driving incentive, engagement,

and patient accountability when using wearable on-body delivery devices.

The possibilities for improving treatment outcomes arising from having the ability to collect real-time and historic data from the Enable Wearable Injector are breathtaking and do not stop at promoting patient engagement, accountability and increasing adherence. For example, in many diseases there is no “one-size-fits-all” care management approach. A variety of nuances related to the disease treatment such as disease progression, genotype, comorbidities, and/or other risk factors drive the need for an optimal, individual approach. Based on data feedback from the Enable Wearable Injector, dosing regimens can be tailored to real individuals’ needs.

CONCLUSION

The original, founding principles of Enable Injections were around patient-centric innovation, carrying out detailed user preference and usability studies, and using the insights from these to incorporate innovative device design features that promote adherence. The concept of technology-enabled therapeutics was also crucial, whereby the provision of a wearable, on-body injector capable of delivering high volumes of viscous formulations could transform active biologics into convenient, effective successful therapeutics on the market. These were previously so complex and difficult to deliver that they were not viable as pharmaceutical products. Additionally, as explained previously, the Enable Wearable Injector provides an efficient means to reduce and manage the growing expense associated with the rising incidence of chronic conditions. The over-riding objective is always to improve treatment outcomes from biological therapeutics.

In connecting the Enable Wearable Injector via mobile devices to the cloud, Enable Injections is demonstrating that its founding principles of patient-centric innovation, promoting adherence, technology-enabled therapeutics and cost reduction endure and with it the promise of significant, life-enhancing treatment outcomes for patients suffering from chronic conditions.

SUMMARY OF ENABLE WEARABLE INJECTOR ADVANTAGES

The Enable Wearable Injector provides numerous advantages, including:

- Subcutaneous delivery of up to 50 mL doses of high volume and/or viscous biologics
- Passive warming of drug product, eliminating the 30-minute wait for refrigerated vials to reach room temperature
- Automated mixing and reconstitution, reducing formulation time and drug development costs
- Use of standard vials, cartridges and syringes, and existing container closures
- Facilitation of in-home therapy, reducing healthcare system costs
- Ability to monitor compliance and capture data utilising optional Bluetooth connectivity and a mobile app to provide a connected healthcare solution.

Treatment developed by you. The future delivered by us.

 enable injections



10mL
*OBDS

Enable their day!

*OBDS - ON BODY DELIVERY SYSTEM
FOR INVESTIGATIONAL USE ONLY