



ADDRESSING EVOLVING HEALTHCARE NEEDS WITH DIGITAL HEALTH: CONNECTING DRUG DELIVERY

Sundeep Kankanala, PhD, MBA, Vice-President, Research & Development at BD Medical - Pharmaceutical Systems, and Chris Franzese, Lead Clinical Analyst at Matchstick, explain how BD is increasingly moving towards providing solutions rather than products, particularly in the field of diabetes. Two frameworks have been created to improve the impact of the connected solutions now available for dealing with chronic disease – “Duality of Smart” and “Collect, Understand, Act”.

Over the last several decades, advances in medical science have extended life expectancy substantially. However, the implications of increased longevity in an ageing population have placed chronic diseases among the most common causes of mortality worldwide. According to the Centers for Disease Control and Prevention (CDC), seven of the top 10 leading causes of death in the USA can be attributed to chronic diseases, and about half of all adults have at least one chronic condition.¹

To accommodate this growing trend, clinical practice and the pharmaceutical industry have shifted their therapeutic focus towards managing persistent disease long-term, significantly extending the duration of care across the healthcare continuum.²

Simultaneously, the advent of biologic therapies has revolutionised chronic disease treatment. These novel therapies have not only unlocked the ability to manage intractable diseases, but in many cases, also offer safer alternatives to historically toxic medicines.³

As a result, drug development is largely centered around these high-cost, specialty medications. In 2016, eight of the top 10

best-selling drugs were biologics, and similar drugs will comprise up to 30% of the pharmaceutical pipeline by the end of this year.^{4,5}

Although the benefits of biologics are profound, they do come at a price. The annual costs per patient for these treatments may range from US\$10,000 to more than \$150,000.⁶

The costs also extend beyond the financial. Nearly all biologics are far too large, complex and polar to be administered orally.⁷ Thus, they must be injected via one of three routes: intravenous (IV), intramuscular (IM) or subcutaneous (SC). Traditionally, trained professionals delivered medicines via these delivery modes in a healthcare setting. Due to significant pressures to reduce the growing costs of healthcare, patient care is increasingly shifting to the home,⁸ where patients are being asked to administer these medicines themselves.

“To date, there are over 50 self-injected medications being used to treat a variety of diseases,⁹ and the demand for delivery devices will continue to increase alongside drug development.”



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“Through their ability to collect a variety of information, smart devices have the potential to impact stakeholders positively across the healthcare continuum.”

ENABLING SELF ADMINISTRATION

Innovation in drug delivery devices has empowered patients to self-administer injectable medications safely and cost-effectively in the comfort of their own homes. Devices range from prefilled syringes (PFS), safety syringes and pen injectors, to auto-injectors (AIs) and large-volume wearable injectors (LVIs).

To date, there are over 50 self-injected medications being used to treat a variety of diseases,⁹ and the demand for delivery devices will continue to increase alongside drug development. Nonetheless, as therapies continue to evolve, delivery devices must as well.

One strategy is to develop smart devices that support a better patient experience and provide critical information to other stakeholders.

BENEFITS OF SMART DEVICES

Through their ability to collect a variety of information, smart devices have the potential to impact stakeholders positively across the healthcare continuum:

Patients

These devices can increase patients' confidence in managing their disease by:

- Confirming the drug is at room temperature and ready to inject
- Confirming that the injection was correctly performed
- Providing feedback that the injection has initiated, is proceeding, and the dose volume has been delivered
- Utilising a personalised engagement model to encourage adherence and reduce anxiety.

Healthcare Providers

Healthcare providers (HCPs) can make better treatment decisions for their patients because the devices:

- Provide medication adherence data-based analytics to guide therapeutic decisions and assess efficacy of treatment
- Confirm effectiveness in patients' training and injection management.

Payers

Devices can provide population health data to evaluate outcomes and cost-effectiveness of therapies by:

- Providing aggregated adherence data for different therapy regimens.

Pharma

Pharmaceutical companies can know that patients are taking their medications, that their devices are usable, safe and effective, and that they are offering differentiated value in the market because the devices:

- Provide aggregated confirmation of adherence to therapies
- Provide feedback on dose delivery
- “Accelerate clinical trials”
- Create a more inviting user experience, reducing patient anxiety, and driving medication adherence.

CONNECTED SOLUTIONS

As a leader in drug delivery, BD is uniquely positioned to meet the growing need for connected solutions. BD products touch patients billions of times each year, enabling the company to understand the needs of patients and caregivers.

As care delivery transitions from clinic to home, BD is taking our expertise in the acute care environment, and translating that to address the needs of patients and caregivers at home.

BD has been working on digital solutions in various business units across the company. Recognising that truly meeting patient needs requires transitioning from a drug delivery provider to providing interconnected disease management systems, BD has invested in consolidating its digital expertise to develop fully-integrated, drug delivery solutions.

“The creation of BD Digital Health demonstrates leadership recognition that digital health is here to stay, and BD must build a strong capability in this area to provide direction and growth for the future,” says Dave Icke, Vice-President and General Manager, BD Digital Health. “The new business unit provides a centre of innovation that expands upon BD's base of software expertise, to create technologies,

capabilities and platforms that can help make existing BD technologies smart to increase value to the system and establish new services, capabilities, and solutions that address unmet needs in healthcare.”

BD's connected solutions are built on a foundation of expertise in primary containers, clinical injection, and drug delivery. The result is improved overall device performance, ensured drug compatibility, minimised risk of system failures, and enhanced patient experience. To achieve this, BD applies two unique frameworks for their connected systems.

Duality of Smart

BD's “Duality of Smart” approach considers that features need to fit specific market needs – not every patient or situation requires the same degree of connectivity.

BD approaches smart technology on a continuum ranging from “local” to “connected” solutions.

A local smart delivery device provides information only to the patient, based on what the device senses. Because communication occurs directly from device to patient, connectivity to external devices is not needed.

A connected smart device allows data to flow off the device wirelessly (e.g. via Bluetooth or RFID) to a receiving unit, namely a patient's phone or cloud server.

Information sent to a patient's phone may be used solely by that patient, such as contextual instructions for use, which would enable patients to move through the injection steps displayed on the phone's interface as they progress through the injection. Data sent to a cloud server may be used to aggregate information for other stakeholders, such as caregivers, healthcare providers, payers or manufacturers.

The Duality of Smart approach supports scalability of smart solutions, allowing pharmaceutical brands to choose which option to pursue aligned to their unique patient needs.

Collect, Understand, Act

BD's “Collect, Understand, Act” framework ensures that connected solutions provide the greatest benefit to the target patient population. This three-phase approach centres around gathering the right information, translating it into an actionable form and presenting it in ways that engage patients when they need it, wherever they are.

“This modular approach provides pharmaceutical companies with a viable platform technology option, which can offer smart features or not, depending on the needs of different patient populations and therapies.”



Figure 1: BD Vystra™ disposable liquid pen (below) with smart pen technology (above).

Collect: The Collect phase focuses on accumulating data, whether actively from the patient or passively from the smart delivery device. Collected data could include drug administration metrics, information logged by patients themselves, and data sent from other connected devices. Regardless of data type, it requires normalisation to be useful.

Understand: In Understand, algorithms and analytics help transform data into useful insights for patients or other stakeholders.

“What we’re trying to deliver are actionable, personalised insights, captured through smart devices,” says Icke.

Act: The final phase, Act turns insights into solutions, and delivers them to patients in the moment that they need them, wherever they are. This is where creating a positive patient experience and rich data sets, combined with BD’s expertise in healthcare, delivers a patient engagement engine that could result in better clinical outcomes.

“Chronic disease patients are rarely afflicted with a single disease. They typically manage a variety of co-morbidities simultaneously. To be successful, solutions must consider the entire patient.”

By applying these frameworks, BD is already building patient experiences, capabilities and platforms that have applicability across disease states.

EXAMPLES OF CONNECTED DEVICES

BD is developing solutions that offer ways to manage conditions that fit with patients’ lifestyles and needs, starting with smart pen technology and BD’s on-body injector.

BD Vystra™ Disposable Pen and Smart Pen Technology

BD’s smart pen technology captures irrefutable dose data via a wireless-enabled attachment that allows for communication and integration with other data in a fashion that is compliant with cybersecurity standards.

This innovative attachment converts traditional pen injectors like BD’s Vystra pen injector into a smart pen injector. BD Vystra is an intuitive, high-quality and customisable disposable pen injector, which has been validated by rigorous ergonomic and quality assessments to ensure ease of use, comfort, and reliability (Figure 1).

BD’s smart pen technology is flexible across other products – it is compatible with all

leading diabetes pen injectors in addition to Vystra and offers open application program interface (API) protocols to accommodate multiple data integration approaches. However, BD isn’t stopping there to make interconnected diabetes management accessible for all diabetes injectors.

BD On-Body Injector

BD is developing an elegant solution to simplify the lives of patients with an on-body injector designed to deliver time-delayed subcutaneous injections.

The device is comprised of two components: a programmable, body-worn delivery device that can accommodate a total dose of up to 3 mL, in single bolus or multiple doses, and a durable wireless controller that will last for two years (Figure 2).

The design of the device is small and discreet, which affords patient comfort and concealability during wear and injections. In addition, the injector is backed by a new drug administration Current Procedural Terminology (CPT) code to support proper reimbursement.

Unlike BD’s Vystra, the on-body injector has inherent smart capabilities, including programmable delayed dosing, (which offers the possibility of fewer doctor visits), secure wireless communication of dosing information, and seamless integration of data with other connected systems.

BD is considering options for applying these technologies beyond diabetes to meet the needs of other patients taking injectable biologics.



Figure 2: BD’s programmable on-body injector.

FULLY-INTEGRATED AND PLATFORM SMART TECHNOLOGIES

BD is leveraging the digital capabilities built for diabetes management together with their extensive expertise in providing prefilled primary containers and combination product devices to serve its pharmaceutical customers better.

BD's range of devices can accommodate changing formulation requirements and patient requirements across many disease states, while enhancing the patient experience and delivering information beneficial for a variety of chronic diseases.

BD Libertas™ Wearable Injector

After extensive preclinical and clinical research characterising the injection experience with large-volume SC injections, BD developed the BD Libertas wearable injector to deliver large-volume and/or high-viscosity biologics. BD Libertas, a single-use, disposable, hands-free, prefilled syringe-based delivery system, is flexible and customisable to industry needs, and leverages Neopak™ technology for delivering doses of 2-10 mL (Figure 3).

BD Libertas features a fully-integrated prefilled syringe design that uniquely enables aseptic transfer of drug from the container into the body of the device without user assembly. BD conducted extensive generative research to inform an intuitive, ergonomic design. The injector's two-step "slide-push" button activation is designed to prevent inadvertent activation of drug delivery, enhancing patient experience and preventing high-value drug loss. The device interface features visual, tactile and audible indicators to inform patients about their injection state and provide assurance throughout the injection process, including dose progression and confirmation.

BD Libertas' smart technology utilises a modular approach through a customisable top case that incorporates sensors and electronics. This modular approach provides pharmaceutical companies with a viable platform technology option, which can offer smart features or not, depending on the needs of different patient populations and therapies.

The smart option has the capability to detect data on drug temperature, dose progression, dose confirmation and device errors, provide feedback to patients on these device states and transmit this information via Bluetooth to an app on the patient's smartphone.



Figure 3: BD Intevia™ disposable auto-injector.



Figure 4 : BD Libertas™ wearable injector with Smart option.

Additional developments underway include such a user-friendly app for patient engagement and healthcare provider interaction.

BD Intevia™ Auto-Injector

BD Intevia is an auto-injector platform technology specifically designed for high-viscosity drug delivery. Like BD's other delivery devices, Intevia's development has been rigorously informed by human factors studies, resulting in

a slim, intuitive, and ergonomic design with multiple visual and audible indicators to enhance patient experience (Figure 4).

The device also features two-step, push-on-skin activation to avoid accidental or premature injection initiation. Intevia can include a smart option for the auto-injector platform. This will allow for a scaled, cost-effective approach to smart technology, that is flexible to industry needs.

MOVING FROM PRODUCTS TO SOLUTIONS

BD has long been a leader in drug delivery devices. As the market needs evolve, BD is moving from providing products to providing solutions that address the needs of the multiple stakeholders involved in the healthcare ecosystem.

By investing in a digital health business unit that can create platforms to address individual business unit needs, BD is constructing a system that leverages expertise across the company to deliver smart solutions to the market.

BD's ultimate vision for an interconnected disease management system will encompass the entirety of a patient's disease, including all therapies. Chronic disease patients are rarely afflicted with a single disease. They typically manage a variety of co-morbidities simultaneously. To be successful, solutions must consider the entire patient experience.

Collaboration across industry stakeholders provides the path to patient-centered, fully integrated solutions. BD recognises this need and is engaging to build the coalitions required to deliver this vision.

BD Libertas, BD Intevia, BD on-body injector, and BD smart pen technology are products in development; some statements made are subject to a variety of risks and uncertainties.

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ABOUT THE COMPANY

BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. BD leads in patient and healthcare worker safety and the technologies

that enable medical research and clinical laboratories. BD provides innovative solutions that help advance medical research and genomics, enhance the diagnosis of infectious disease and cancer, improve medication management, promote infection prevention, equip surgical and interventional procedures, and support the management of diabetes. The company partners with organisations around the world to address some of the most challenging global health issues. BD has nearly 50,000 associates across 50 countries who work in close collaboration with customers and partners to help enhance outcomes, lower healthcare delivery costs, increase efficiencies, improve healthcare safety and expand access to health.

ABOUT THE AUTHORS & CONTRIBUTORS

Sundeep (Sunny) Kankanala is Vice-President of R&D for the BD Medical – Pharmaceutical Systems (PS) business. His responsibilities include leading product and technology development across the PS project portfolio. Previously as the Director of Smart Device and Data Sciences focus area at BD Technologies, Dr Kankanala lead the development of IT enabled medical device technologies to capture and make meaning – e.g. through patient and clinician decision support – of diagnostic and therapeutic data, to improve outcomes in chronic disease management. He also spent three years in BD's Infusion Therapy business leading the product development of new IV catheters. For his contributions to this program, he was recognised with BD's Wesley J. Howe Award for Technical Innovation in 2016. Prior to joining BD, Dr Kankanala was a Subject Matter Expert in Smart Materials and Advanced Safety Systems at Ford Motor Company (Dearborn, MI, US). His fifteen years at Ford spanned a range of assignments across biomechanics and smart materials to advanced occupant safety systems. He has several peer-reviewed scientific journal papers in smart materials and automotive engineering fields. Dr Kankanala received a PhD in Aerospace Engineering from the University of Michigan (Ann Arbor, MI, US) for his theoretical and experimental work in magnetoelasticity. He also earned an MBA from MIT's Sloan School of Management (Cambridge, MA, US).

Chris Franzese is the Lead Clinical Analyst for Matchstick. In this role, he is responsible for leading a team of clinicians supporting client projects related to combination product and medical device development and usability testing. He also has responsibility for teaching clinical content to the broader Matchstick team and making clinical knowledge relevant to client projects. Mr Franzese is an experienced clinical trial researcher, with 11 peer-reviewed papers on a variety of topics related to usability research for connected medical devices, anticoagulation and clinical laboratory testing. He has a BS in Biology from Loyola University, and is pursuing a concurrent PharmD and MS in Health Informatics from Fairleigh Dickinson University.

Dave Icke joined BD in 2016 to lead the Digital Health Business Unit, supporting the Medical Segment. Prior to BD, he served as a consultant to multiple private and public companies (such as Profusa, Twine Health, Qualcomm and Flextronics) to launch new initiatives in digital health. Until 2014, Icke served as the founding Chief Executive Officer of MC10 – a pioneer in patch-based biometric wearables for digital health, fitness, and medical devices. Earlier in his career he had experience scaling IoT businesses and running P&Ls in semiconductor equipment companies. Icke has a BS in Chemical Engineering from Stanford University, and an MBA from Harvard Business School.



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FOR BETTER TREATMENT OF CHRONIC DISEASES. Across the healthcare continuum, BD is the industry leader in parenteral delivery devices that help health systems treat chronic diseases. We not only continually advance clinically proven, prefillable drug delivery systems, we do so with a vision to help healthcare providers gain better understanding of how patients self-inject their chronic disease therapies outside the healthcare setting. This is why we partner with leading pharmaceutical and biotech companies worldwide to develop digitally-connected self-injection devices—including wearable injectors and autoinjectors—to capture valuable data that can be shared with caregivers. Discover how BD brings new ideas and solutions to customers, and new ways to help patients be healthy and safe. **Discover the new BD.**



BD Libertas™ wearable injector



BD Libertas™ wearable injector
with Smart option



BD Intevia™ autoinjector

Learn more at bd.com/Discover-BD1

BD Libertas™ wearable injector, BD Libertas™ wearable injector with Smart option and BD Intevia™ autoinjector are products in development; some statements made are subject to a variety of risks and uncertainty.

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