Finding Common Ground: Bringing Together Perspectives On Connected Drug Delivery Devices

Health services around the world were already under pressure before the COVID pandemic, due to aging populations and the growth in chronic diseases. If more patients were able to self-administer treatments and manage their own conditions in the home setting, some of the pressure on health care systems would be eased. Digital transformation in health care plays a critical role in remote patient management, by enabling access to clinicians when a physical consultation is not possible or necessary, and by helping to ensure that prescribed therapies are administered using the correct dosage and frequency. Drug delivery devices with connectivity features to enable information transfer help to deliver these patient data to clinicians or even other health care players. Strides are being made in this area of device manufacturing. In fact, the global connected drug delivery device market (injectables and inhalation devices specifically) is projected to grow at over 25% CAGR to reach more than $700m in 2025.[1]

However, introducing such devices into the health care system is not straightforward. The potential of any device cannot be realized if regulations are not met, if designs are not user-friendly, or if hospitals and clinicians are slow to adopt. Moreover, there are multiple key stakeholders involved in the adoption of medical devices: patients, governments, payers, health care providers, and pharmaceutical companies. It is essential for these actors to work together to ensure effective implementation, especially as digitalization introduces a particular set of challenges. For instance, connected devices may be vulnerable to cybersecurity threats, so it is critical that electronic health records containing patient data are properly secured. This article explores the respective attitudes and approaches of health care stakeholders toward greater connectivity, and the value that digitalization will bring to their function.

UNDERSTANDING STAKEHOLDER PERSPECTIVES

The overarching goal of expanded connectivity is to increase patient adherence to treatments and therefore ultimately improve outcomes, but this cannot be achieved if the patient is not properly understood from the beginning. Human Factors research shows that digital capabilities are not currently uppermost in the patient's mind.[2] Instead, comfort and ease-of-use rank highest for injection devices such as auto-injectors. It is therefore critical that device designers prioritize these factors via thorough testing to ensure acceptance, avoiding the introduction of new challenges for both patients and clinicians. Tasks such as Bluetooth pairing and downloading and using apps can be confusing for some patient groups even though they may provide functional benefits. Pharmaceutical companies will also need to consider the impact of making treatment data available to patients, and this will need to be carefully managed. Though access to these data is empowering and can encourage greater adherence, regular data feeds may be overwhelming, or even distressing for some patients. Additionally, it is recommended that health care systems carry out programs for patients, caregivers and health care professionals to raise awareness of the benefits of drug delivery device digitalization, with the aim of encouraging adoption and use.

It is clear then that connected devices in their own right do not ensure patient adherence. However, with the help of embedded electronics and sensors, they can generate data on the time, volume and site of a self-administered medication, allowing clinicians to remotely track adherence where it would not otherwise be possible and in turn plan interventions to improve it. Clinicians' interest in connected devices is primarily from a patient benefit perspective, and further advances will enable more sophisticated monitoring capabilities than what is currently available. In the medium-term, devices are likely to go beyond dose reporting and reminders, and enable monitoring for side effects or evaluation of regimen changes. One such example is a closed-loop system that monitors a diabetic's blood glucose, and regulates insulin delivery accordingly to maintain target blood sugar levels. Records of these adjustments are then fed directly into a clinical database. A more distant possibility is remote dosage setting by clinicians, based on remotely monitored patient indicators, which would allow greater interactivity with the data generated.

Payers are increasingly seeing the valuable role that connectivity can play in reducing health care costs. For instance, in the US, the Centers for Medicare and Medicaid Services (CMS) – the single largest payer for seniors and chronically ill patients – has now widened health care provider access to payment for remote patient monitoring.[3] This followed a 2017 study of the organization's non-face-to-face Chronic Care Management program, which cited among the positive outcomes improved patient satisfaction and adherence to recommended therapies, improved clinician efficiency, and decreased hospitalizations and emergency department visits.[4] These benefits may be especially important for biological therapies, which are highly effective and help to prevent future escalation of co-morbidities, but can come with a considerable initial cost. From a payer point of view, connected devices are a

critical tool for helping to ensure that patients adhere to treatment regimens and therefore gain the maximum benefit from expensive medication, and they also help to prevent waste.

Pharmaceutical companies also welcome any means of reducing waste or misdosage, because inefficient use of a drug may ultimately affect its efficacy. From a commercial perspective, over time companies may lose competitive advantage if they do not offer digital capabilities, in light of the increase in self-administration and remote patient management, now given greater impetus by the pandemic. A number of pharmaceutical and medical device companies now offer a holistic patient service package alongside a drug, to support training, adoption and adherence monitoring of the therapy. Digital connectivity – especially through drug delivery mechanisms – would help to deliver such services more efficiently and economically, and produce data that build a more detailed picture of the complete patient treatment regimen. As governments and health insurers now require clear evidence on the efficacy as well as adoption and adherence of the drugs they procure, these data are invaluable in both demonstrating value for money and supporting economic outcomes in health care.

RESOLVING COMPLEXITIES

One obstacle to implementing digital devices and gaining all the benefits outlined above is clearing regulatory approval processes. Organizations such as the Food and Drug Administration (FDA)[5] in the US and the National Institute for Health and Care Excellence (NICE)[6] in the UK have established evidence-based standards for digital health technologies. However, this hard evidence is difficult to obtain without deploying connected drug delivery devices in the field. In a survey[7] of almost 200 pharmaceutical executives, just over half (59%) said that the primary challenge in developing smart drug delivery devices is winning regulatory clearance. Device electronic elements also make compliance more complex and introduce further regulatory requirements, such as compliance with WEEE (Waste Electrical and Electronic Equipment Regulation). Among other concerns cited by respondents are maintaining ease of use, utilizing appropriate technology, and managing costs. Developing new connected technologies comes with its own challenges, including ensuring accurate dose delivery and that the drug is compatible with device components, especially for combination injection products involving biologics. It is therefore crucial to invest in specialist knowledge and support as needed, to proactively resolve concerns, overcome technical issues and provide sufficient information to avoid a failed regulatory submission.

An important consideration in our more environmentally conscious world is the sustainability of digital devices and their electronic components. When implemented effectively, digital solutions can reduce a therapy's environmental impact. If patients are better able to manage their own conditions, this may reduce the frequency of consultations and interventions, and the associated consumption of energy, pharmaceutical products and equipment. One study found that overall, greenhouse gas (GHG) emissions were reduced by around 50% where a patient with poorly controlled asthma improved adherence using a smart inhaler.[8] However, limiting environmental impact can be a challenge when working with devices that are designed usually for single use. Creating entirely disposable connected devices would not be sustainable or financially viable, and embedded electronics within these devices use rare earth metals that are largely not recycled properly. These concerns are being addressed in some cases by taking a hybrid approach, where the product has two components: electronics are embedded in a re-usable, connected "shell" device, while the traditional auto-injector or pre-filled syringe sits within the shell and can be disposed of and replaced.

Lastly, greater digitalization in health care raises new challenges relating to data management. To ensure smooth implementation across different health care providers, data transfer protocols must be standardized so that devices are interoperable with standard clinical systems, and it is critical to put robust data protection measures into place from the outset. Industry stakeholders must decide which entities are responsible for data storage and clarify who owns the data collected. Each stakeholder will need to be a part of this dialogue, and collaborate to establish standards and procedures. Without this collective effort to address obstacles to implementation, it will take much longer for the health care industry to realize the full benefits of connected drug delivery devices.

REFERENCES

1. Owen Mumford Pharmaceutical Services, *Well Connected: An Update on the Connected Drug Delivery Device Market*, May 2020.
2. Owen Mumford Human Factors qualitative research conducted among a 120+ strong focus group.
3. Samsung Insights, *The New Rules for Remote Patient Monitoring Reimbursement*, September 2, 2020, https://insights.samsung.com/2020/09/02/the-new-rules-for-remote-patient-monitoring-reimbursement-2/
4. J. Schurrer, A. O'Malley, et al., *Evaluation of the Diffusion and Impact of the Chronic Care Management (CCM) Services: Final Report*, November 2, 2017, https://www.mathematica.org/our-publications-and-findings/publications/evaluation-of-the-diffusion-and-impact-of-the-chronic-care-management-ccm-services-final-report
5. See https://www.fda.gov/medical-devices/digital-health/guidances-digital-health-content for a list of guidance documents relating to digital health content.
6. See https://www.nice.org.uk/Media/Default/About/what-we-do/our-programmes/evidence-standards-framework/user-guide.pdf for evidence standards framework for digital health technologies
7. Owen Mumford Pharmaceutical Services, in partnership with Pharma Intelligence, *INJECTABLE COMBINATION PRODUCTS: Industry Insights On The Challenges Of Meeting A Growing Global Need*, August 2020.
8. AstraZeneca, Sustainable Healthcare Coalition, *Digital Adherence Monitoring in Poorly Controlled Paediatric Asthma Care Pathway Case Study*, 2017, https://shcoalition.org/wp-content/uploads/2019/12/Digital-Adherence-Monitoring-in-Poorly-Controlled-Paediatric-Asthma-Final.pdf.