Well Connected

An update on the connected drug delivery device market

Owen Mumford Pharmaceutical Services

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Summary

- The global connected drug delivery device market is projected to grow at over 25% CAGR to reach more than $700 million in 2025
- As the demand for chronic condition therapies grows, an increasing proportion of patients will self-manage and self-administer in the home, otherwise acute services will be overwhelmed
- Connected devices are a critical tool to deliver the data flows which allows clinicians to remotely monitor and manage patient conditions
- As staff shortages grow and healthcare demand increases, home administration will accelerate in importance, amplifying the need for digital remote connectivity
- Connected drug delivery designers are under pressure to create products that enable connectivity but also minimise wastage, especially of embedded electronics that use rare-earth elements
- Governments, payers, healthcare providers and pharmaceutical companies are also having to work closely together to establish interoperability data standards, as well as collaboratively mitigating the risk of data protection breaches in a world of connected healthcare devices

Remote patient management

In times of world health crises, particularly those involving infectious diseases, remote consultation with clinicians and the ability for patients to self-administer in the home both come under a particular spotlight. In fact, the reality is that hard-pressed health services around the world will not be sustainable in the longer-term – crisis or no crisis – if patient self-management and teleconsultations are not systematically developed and expanded. Demand for healthcare is rising with the growth of non-communicable diseases and geriatric populations to the extent that the world health workforce will need to double by 2030, according to the World Economic Forum[i]. And this is at a time when all health services globally face staff shortages[ii].

Effective remote patient management relies on digital transformation in healthcare. A recent research paper from Siemens[iii] found that remote services was seen by healthcare systems all round the world as one of the three top benefits of digitalisation. Digitally enabled remote healthcare has to deliver several key capabilities to fulfil the social covenant with patients: enable access to clinicians; ensure prescribed therapies are administered in the right dosage and frequency; and monitor patient conditions and reactions.

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Growth in digital drug delivery devices

Patient monitoring is a relatively well developed area of healthcare digitalisation, especially for chronic respiratory conditions and for diabetes, where patient responsibility for self-management and administration has been in place for decades[iv]. Strides are now, however, being made in the area of digitally connected drug delivery devices. Analysis by Owen Mumford[v] estimates the global market for connected drug delivery devices (injection and inhalation) to be $706 million by 2025, rising from $225 million in 2020 – a CAGR of over 25%. Interestingly, research papers have also pointed to even stronger rates of growth of the use of connected devices in clinical trials[vi].

Clearly then, market analysts expect strong growth in connected drug delivery devices, although at a different pace country by country. mHealth (mobile health) technology adoption provides a useful picture of different national attitudes, which may well be replicated in the adoption of connected drug delivery devices. In Europe, for instance, general adoption of mHealth technologies has been slowest in Germany and Austria, moderate in the UK, and faster in France and Italy[vii]. In the USA, adoption is ahead of Europe[viii].

Stakeholder motivations and connected devices

There are a number of key stakeholders – payers, clinicians, pharmaceutical companies, patients - who have influence over the adoption of connected drug delivery devices. Each has a different perspective, and it is instructive to lay out their motivations, drivers and current attitudes.

1 Payers

Whether health insurance providers or state healthcare systems, payers are increasingly focused on delivering value for money from healthcare budgets. "Outcomes-based healthcare" has moved beyond concept and has now become healthcare policy in most of the world's developed nations. The change of perspective is designed to focus on creating more healthy societies who – by definition – consume less healthcare service, thereby reducing overall healthcare costs. This is also linked to the drive to enable patient treatment at home, outside of the (expensive) acute environment. And digital technology is critical to making this happen, creating one of the data channels for patient monitoring/prescribing data and consultative advice to flow remotely between clinician/care professional and patient.

Another factor for payers is the rise of biological therapies which can treat chronic and acute conditions where there were previously no effective treatments. The last wave has seen the introduction of biologics for inflammatory/auto-immune conditions such as Crohns disease and rheumatoid arthritis. The current wave of new biologics is focused on oncology therapies. While these therapies are likely to save on expensive treatments and co-morbidity escalation in the future, their initial cost is high, even when competitive biosimilar markets open up. Therefore, payers see connected drug delivery devices as a critical tool to ensure that patients adhere to their therapy regimes. Connected devices, with embedded electronics and sensors that report data on time and size of dosage self-administered, do not ensure patient adherence in their own right. However, they do provide the data flows that allow clinicians and care professionals to remotely monitor adherence where they would not otherwise be able to do so.

2 Clinicians

Clinicians are concerned to deliver the greatest health outcomes to the greatest number of patients. They want to ensure adherence from a patient benefit perspective, and are interested in connected devices as a means to this end. Some technology prototypes demonstrated in recent years even allow remote setting of dosage based on remotely monitored patient indicators[ix], but this kind of digital interactivity is still someway off mainstream commercialisation. Sophisticated monitoring capabilities where – beyond dose reporting/reminders – the device enables monitoring for side effects, or evaluation of the effect of regimen changes, are more likely to appear in the medium-term development pipeline[x]. Early examples include closed-loop systems where a diabetic's blood glucose is monitored and the insulin delivery regulated accordingly, at the same time providing a record of adjustments directly into a clinical database. Remote monitoring of patient adherence is also very important where more complex therapies – often the case with cancer treatments – need to be managed.

3 Patients

Research is regularly commissioned by Owen Mumford in its programme of Human Factors analysis around device development and design – now a mandatory element of the regulatory approval process. Human Factors ensures that the patient's comfort and ease-of-use are prioritised and understood right at the start of the device design process and any risks are mitigated. This ensures the highest likelihood of device acceptance by patients when introduced to the market, and removes unnecessary obstacles for hard-pressed clinicians as they seek to improve patients' lives.

Connectivity is likely to become of increasingly overt benefit to the patient as medicine becomes more and more personalised, in a bid to improve immediate patient outcomes and more long-term health. This is, again, embedded in overall health policy the world over, In Europe, for instance, the Horizon 2020 initiative, which has been running since 2015, focuses on personalising healthcare, supporting citizens' empowerment through self-management of health and disease, health promotion and disease prevention[xi]. Clearly, data flows from connected devices play an important enabling role in such initiatives. Who would not wish to be reassured that they are on track with their therapy and that it is being tailored to their precise needs? Nevertheless, precisely how that information is delivered to the patient has to be carefully managed; some don't want to know too much, while others become distressed, or even obsessed, with regular data feeds.

On the other hand, Owen Mumford Human Factors qualitative research conducted among a 120+ strong focus group revealed that currently digital capabilities are not uppermost in the patient's mind. Comfort and ease-of-use factors score highest for auto-injectors. At the same time, given the clear benefits to patients of adherence and personalisation, the authors of this report suggest of that a programme of patient (and nurse) awareness of the benefits of drug delivery device digitalisation may be required in most healthcare systems around the world to encourage enthusiastic adoption and use.

4 Pharmaceutical Companies

Regulatory authorities are not embracing digital technologies without at the same time exercising keen scrutiny and oversight of healthcare outcomes. For instance, the FDA[xii] in the United States and NICE[xiii] in the UK have established evidence-based standards for digital health technologies – requiring hard proof that they produce a measurable and proportionate return on investment. A tension exists in most healthcare systems: digital devices enable a more economic means of managing patients remotely; yet until there is widespread deployment of connected drug delivery devices, the overall proven benefit of those data flows cannot really be tested in the field.

At all events, there are many reasons why the pharmaceutical sector is welcoming digital connectivity in drug delivery devices. First, as we have already noted, there is a policy push towards remote patient management and self-administration. So pharma companies who do not offer digital capabilities are likely to lose market share over time, especially in competitive markets. Secondly, with the trend towards outcomes-based healthcare means that no pharma company wants patients using their therapy inefficiently, as this will affect the drug's performance success measurement. Connected devices help measure and manage adherence. The existing and forthcoming waves of biological therapies are expensive – so any method of reducing waste and/or misdosage is to be welcomed.

Finally, pharma companies (and medical device companies) are beginning to offer a managed service rather than just products. In other words, a healthcare organisation does not just buy stocks of a drug, but instead pays for a whole patient service package based around that drug – training, adoption, adherence monitoring, helplines, and so on. This is partly driven by healthcare staff shortages, partly by the recognition that training specialist staff in every hospital group may not be the most efficient or effective way of delivering healthcare. For the provider of a managed service, digital connectivity – especially through the drug delivery mechanisms – is critical to offering that service economically.

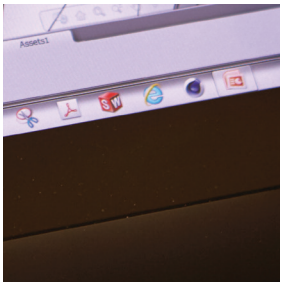
As one global consultancy[xiv] notes, "Many companies are also looking to demonstrate value for money through a combination of new pricing models, improved benefit tracking, and the introduction of 'wraparound' services that go 'beyond the pill'." Another[xv] confirms that, "Patient support programs are another way in which pharmaceutical companies can support patients with disease understanding and management, and treatment adherence." Governments and health insurers now want clear evidence that the medicines they buy are really effective. This has huge implications for pharma. The ability to provide demonstrable value for money is thus becoming a critical differentiating factor, and the supply-side will play a key part in providing that value by commissioning and supervising aspects of the services patients need to manage their health.

Connected devices – sustainable solutions

Early independent study evidence suggests that digitally connected devices are instrumental in encouraging therapeutic regimen adherence[xvi]. However, moving patient populations to connected devices has significant cost and environmental implications. Embedded electronics may be coming down in price with every day that passes, yet they use rare-earth metals which, as a responsible global society, we are concerned to waste[xvii]. At the economic level, moving from a traditional offline device to a connected device which is entirely disposable would introduce an uneconomic financial burden.

A sustainable hybrid approach is therefore being largely adopted in the development of connected drug delivery devices – driven by both cost and environmental concerns. Most designs embed the electronics in a connected 'shell' device which is re-usable. Traditional auto-injectors sit within this shell and act as the disposable consumable, allowing cost-efficiencies to be leveraged, while nevertheless introducing the advantages of digital connectivity.

In more recent product developments, a more sophisticated approach still to hybrid design is being taken. In a bid to take re-usability and sustainability to the next level, product designers are trying to make the electronics component into a discrete unit within the device. Even re-usable devices will wear out and require replacement. However, if the electronics component can be preserved and 'plugged in' to a replacement device, sustainability and environmental friendliness can take a leap forward.



Conclusions

The evidence presented in this paper all indicates that healthcare systems, patients and pharmaceutical companies all stand to benefit – in different ways – from the introduction of connected drug delivery devices. Device designers are working to create connected options which leverage existing auto-injector devices to reduce cost and environmental impact.

There remain several other potential challenges as connected devices come into play. First is the standardisation of data transfer protocols, so that devices are interoperable with standard clinical systems. Work to establish these standards is the joint responsibility of government, health insurers, healthcare providers and pharmaceutical companies alike. Collaboration is key. Second is the issue of data protection.

The issue of data security in a cloud-based world is not confined to healthcare, but to all walks of life where connected devices could provide the gateway for a breach. Again, collaboration between regulators and market players will be essential, and is likely to favour commercial suppliers who take an 'open' approach to data and data protection standards.

The growth of connected drug delivery devices seems inevitable, given the potential benefits for healthcare system efficacy and efficiency. This should motivate all stakeholders to work together and ensure any potential obstacles are collaboratively removed.

Footnotes

i. World Economic Forum, 5 ways to bridge the global healthworker shortage, 15 Jul 2019

ii. WHO, Addressing the 18 million health worker shortfall, 28 May 2019

iii. Siemens Financial Services, Priority Investment, Nov 2019

iv. See, for instance: European Journal of Public Health, How to govern the digital transformation of health services, 18 Nov 2019

v. Referencing proprietary data, along with third party reports such as: GrandView Research, Connected Drug Delivery Devices Market Analysis, Dec 2018; Acumen Research, Connected Drug Delivery Devices Market, Nov 2019; Future Market Insights, Connected Drug Delivery Devices Market, Dec 2019.

vi. C.Marra, J.L.Chen, A.Coravos, A.D.Stern, Quantifying the use of connected digital devices in clinical research, npj Digital Medicine 3:50, 3 Apr 2020

vii. BMC Health Services Research, Why does the NHS struggle to adopt eHealth innovations, 21 Dec 2019

viii. Gallup, One in Five U.S. Adults Use Health Apps, Wearable Trackers

ix. Electronics, A Survey on Internet of Things and Cloud Computing for Healthcare, 2019.8.708

x. Jenkins D, Smith T, "Why we need to think differently about drug delivery device connectivity". Medtech Media Europe, March 14, 2017

xi. https://ec.europa.eu/progtrammes/horizon2020

xii. See https://www.fda.gov/medical-devices/digital-health/guidances-digital-health-content for list of guidance documents relating to digital health content

xiii. 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

xiv. Deloitte, Pharma and the connected patient, 2017; also, from almost a decade ago, PWC, Pharma 2020: Supplying the future, 2011

xv. EFPIA, Value-based healthcare: an industry perspective, 24 Jun 2019

xvi. Medical Devices (Auckland, N.Z.), Connected drug delivery devices to complement drug treatments: potential to facilitate disease management in home setting, Med Devices (Auckl). 2019; 12: 101–127.

xvii. Deutsche Welle, Smart devices score poor marks on recycling, 21 Nov 2019

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