



Editorial

Digital health is touching many aspects of the medical device world. Here Beatrix Doerr provides her perspective on the ways digital

health and artificial intelligence have touched the medical device world and have already changed the way healthcare is provided and experienced by both the patient and health care

professionals. In the era of digital health, I think we can all agree that these are exciting times for medical device development.

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Digital health and artificial intelligence in medical devices

When I was a veterinary medicine student around 25 years ago, I remember standing with my classmates in awe in front of a computer that showed us the four different heart chambers when clicking on the respective symbols. Such a simple programme would not even be interesting for a 3-year-old today. How I would have loved to have today's technology during my time as a student – it would have saved me from learning 2,000 pages of boring anatomy!

Technical advancements permeate every single aspect of our lives these days. Telemonitoring of pacemakers is routine, not to mention digital transfer of electrocardiograms (ECGs) or imaging data to experts. I remember well how I would spend hours trying to manually measure and interpret an ECG when I started to work as a veterinarian. Nowadays, you can simply send ECGs to an expert, which is much faster and certainly more accurate. And in the future, artificial intelligence will help us to interpret ECGs.¹

Another disease area where digital health and artificial intelligence is very helpful is diabetes mellitus. Not so long ago, patients with diabetes had to prick their finger twice a day to measure their blood sugar and needed to manually control their insulin dose, while today insulin pumps automatically measure blood sugar and administer insulin.² What an increase in quality of life! Not to mention the improvement in patients' health due to more accurate and reliable blood sugar control.

Other rapidly expanding areas are artificial intelligence for big data and novelties such as digital patient files owned by the patients. The search term “(artificial intelligence) AND (medical device)” deliver more than 7,000 hits on PubMed. And new initiatives are arising, such as a centre for artificial intelligence in medicine that has been founded as a cooperation of

universities with different stakeholders,³ or a new master's degree in “life science informatics.”^{4,5}

Naturally, digital health also entails risks. As with any digital system, data can be hacked or devices even unduly influenced.⁶ Some digital health apps do not require a CE-certification as a medical device as they are not actually medical devices, e.g., your fitness tracker app. Other apps do require a CE-certification, e.g., when they are used to treat diabetes. However, some of the start-up companies are not aware of these regulations and might bring a non-CE-certified product on the market.

The new European Medical Device Regulation, MDR 2017/745,⁷ makes the following distinction:

It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of inter-connection between the software and a device.

There are efforts to control the potential negative effects of digital health and artificial intelligence and to set some compliance standards.^{8,9} This year, the first Cardiovascular Digital Summit has been organised by the European Society of Cardiology,¹⁰ and the British Standards Institution has published a White Paper on artificial intelligence that is worthwhile to read.⁹

These are just a few examples of this rapidly developing field. It is recognised that digitalisation has huge potential. A yearly increase in turnover of 16% is expected in Germany, and in

2028, nearly one-third of the revenue is expected from digital products. It is further expected that in the future most medical devices and services will have digital components.¹¹ We as medical writers and communicators can be glad to be a part of these interesting developments.

The ability of artificial intelligence to support humans to find information, to organise it, and to deliver it in a digestible format¹¹ will enable us to cope with the enormous amount of data out there in order to drive better decision making more quickly. Let's be curious of what the future will bring and be part of it!

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