MedTech Europe
from diagnosis to cure

The journey of health data in medical technologies

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What is health data?

Health data is **personal information that relates to the health status of an individual**, such as doctor referrals and prescriptions, medical examination reports, laboratory tests, medical imaging, etc. As health data is considered **highly sensitive personal information**, it is subject to particularly strict rules.[1] Data is generated by interactions with healthcare facilities as well as devices, such as digital applications. It primarily provides medical professionals with insights to decide on the treatment needs of the patient. Today, **around 30% of the data volume globally is being generated by the healthcare industry**.[2] However, not all this data is used: for example, **97% of all data produced by hospitals remains unused**.[3]

Why are medical technologies at the heart of health data?

The role of medical technologies is pivotal in the creation of health data. The WHO estimates that there are **around 2 million different kinds of medical devices on the global market[4], and many of them produce data**. They collect information (continuously or on demand) from an individual and transform this information into readable output - for individuals and healthcare professionals. Such technologies cannot only be found inside hospitals or laboratory information systems, but also on smartphones or wearables and are increasingly contributing to more timely and accurate treatment of a variety of conditions.

What kind of medical technology solutions produce and use health data?

Examples of medical technology solutions that produce and/or use health data:

Implantable devices: Pacemaker

Pacemakers are a key technology for patients living with certain cardiovascular diseases, of which there are around 60 million in the EU.[5] Certain pacemaker models can track information relating to changes in the heart, which is sent immediately and safely to the treating physician of the patient.

Remote patient communication: Telehealth platform

A common telehealth solution constitutes a digital platform for professionals and patients to communicate and exchange information about conditions and health status.[6] Some applications can also support healthcare professionals in monitoring the vital signs of a patient. This technology is particularly impactful for people living in remote areas of Europe, or who experience reduced mobility.
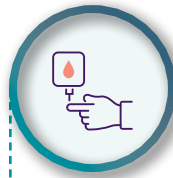
Patient self-management: Glucose monitors

Glucose monitors for patients living with diabetes contribute to patient self-management of the condition.[7] These devices measure blood sugar levels and can indicate to the patient whether they are within the normal ranges. Based on this information, in case of high blood sugar levels, a patient may decide to administer insulin. Some devices provide continuous readings and can act as an 'artificial pancreas' by administering insulin directly to the patient through an implant.

In-hospital monitoring: Smart hospital beds

Smart hospital beds support can monitoring a patient's vital signs and send real-time information to healthcare professionals who are looking after the patient.[8] Such beds can also automatically update the patient's medical record with the patient's vital signs or facilitate the patient's movement.

Patient monitoring: Cardiac testing monitor

Handheld cardiac testing monitors are used in ambulances. With a drop of the patient's blood, the ambulance worker can determine if and how long ago the patient has suffered cardiac arrest. This allows the hospital to already triage and prepare to receive incoming patients based on the severity of their heart condition.

# What are the benefits of the use of health data for all stakeholders?

For citizens there are multiple benefits of data sharing:

- Personalised healthcare provision,[9] even across country borders.
- Better access to care for citizens that live in rural areas[10] or who are not able to visit healthcare facilities as needed.
- Improved patient empowerment to manage their own conditions.[11]

- Predictive techniques foreseeing certain health events can ensure a timelier intervention and improved patient outcomes.[12]
- Enhanced insights in rare diseases, which can improve clinical benefits.[13]
- Access to state-of-the-art devices and the development of innovative technologies.[14]
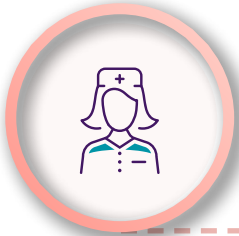
For healthcare professionals, the benefits include:

- Increased accuracy of healthcare provision, through increased evidence-based decision-making.[15]
- Reduction in the risk of adverse events.[16]

- Enhanced knowledge dissemination, helping healthcare professionals to stay current with latest clinical practices.[17]
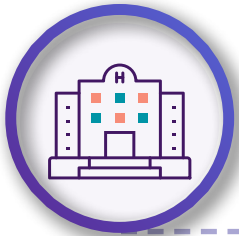
For the health system, benefits include:

- Increased efficiency of the healthcare provision, for instance by relieving burden on healthcare professionals.[18]
- Enhanced capabilities to identify risk factors for a disease at the population level.[19]

- Support in infectious disease surveillance and prevention possibilities.[20]

How is health data in the medical technology sector used and protected?

With the aim **to ensure that new products are safe and effective, medical technology companies use data from clinical studies for their evaluation**.[21]

To be allowed on the European market, medical technologies must comply with a broad set of requirements. Medical technologies **need to be manufactured and developed in accordance with the state of the art, while respecting information/cyber-security.**[22,23]

Once placed on the market, medical technologies transfer data for healthcare delivery, patient monitoring, maintenance of the hardware and software of the device itself, and for reimbursement purposes. Moreover, data is used to monitor the device's performance before and even after it has been placed on the market to ensure it continues to function safely and securely for market and post-market surveillance activities. Performance data further helps evaluate similar devices and contributes to understanding the state of the art. IIn this context, **health data is always collected with caution** due to its highly sensitive nature. **Any collection or use of health data can only happen if there is a legal basis in place** (i.e. based on the GDPR framework). **This also applies to the re-use of health data for research and development.**

In order to protect health data, **medical technology manufacturers continuously seek to update the security of their devices to guarantee their safety.**

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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