

## How Lack of Accepted Standards Prevents Connected Health from Taking Off

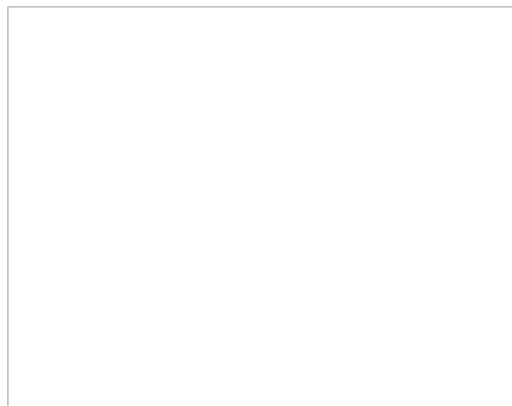


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Lack of globally accepted standards in health data management hampers the advancement of Connected Health, which we hope, can give the world faster, cheaper, and more accessible preventive healthcare. With thousands and thousands of personal medical sensors available on the market, dozens of electronic health record systems used at hospitals, and lack of clear procedures for patient health data ownership and donation, interoperability in healthcare is still hard, yet possible to achieve today.

Technology is fast. Healthcare is slow. New wearable devices and personal medical sensors seem to be popping up here and there at lightning speed, with no single regulatory body or government able to keep up. On the other hand, healthcare is conservative, highly regulated, and not eager to embrace the latest innovations on the spot. In fact, technology and healthcare do not go together “like a horse and carriage”. Even if headed in the same direction, the two are more like a cheetah and a turtle, moving at different speed, but expected to work together on bringing about the Connected Health revolution.

The unfortunate and terrible Covid pandemic, however, has become the catalyst for change, making it more likely that new technology in healthcare is viewed as a useful tool, rather than a potential threat. Connected Health means faster, cheaper, and more accessible healthcare for all. For the first time in human history, it is now technically possible to collect anonymized medical data from hundreds of millions, if not billions of people from all over the world, and analyze it. Artificial Intelligence and deep learning algorithms can be used to sift through data, helping doctors and researchers to recognize patterns and signs of disease before it sets in and does damage.

To make Connected Health a reality two things are needed:

1. Interoperability
2. Ownership and donation of health data by private citizens

## Interoperability in Healthcare

According to healthit.gov “interoperability is the ability of two or more systems to exchange health information and use the information once it is received.” Remote patient monitoring or RPM platforms are supposed to collect health data (such as vital signs) from patients in the home and channel it into electronic health records or EHR systems within medical facilities. In the US, the [21st Century Cures Act](#) ensures that patients can © For personal and private use only. Reproduction must be permitted by the copyright holder. Email to [copyright@mindbyte.eu](mailto:copyright@mindbyte.eu).

access all of their electronic health information (EHI), structured and/or unstructured, at no cost. This is easier said than done.

According to [HIMSS Analytics](#), an average hospital in the US relies on 16 different electronic medical record or EMR vendors for data handling. Thus, data consolidation is a huge and complex task. And this is just the tip of the iceberg. There are thousands and thousands of vendors making portable health and wellness sensors, such as blood pressure and glucose monitors, ECG recorders, thermometers, pulse oximeters, all kinds of smart weight scales, sleep and activity monitoring devices, etc. And innovation in sensors is not slowing down. The industry keeps churning out conceptually new devices: patches, implants, body scanners, headbands, and other unimaginable in the past gadgets. These are really hard to regulate. Moreover, device vendors, driven by fierce competition, try to coral users in and tie them down by their data, stored in proprietary formats on proprietary clouds. All this health data diversity makes the idea of interoperability almost a faint memory. And who owns and control all this raw and processed sensor data anyway?

## Ownership of Health Data and Right to Donate to Research

Affordable access to consumer health technologies allows users to generate tons of personal health information. “An issue with all the personal IOT data is it is locked in silos. There is an ecosystem war at play – with Apple, Google (now the owner of Fitbit), Samsung and Withings all competing for our data.” - says Jason Engelbrecht in his [publication at london tech leaders.io](#). It is hard for a user to extract their data from a vendor and to migrate it to a competing ecosystem. Actually, data does not really belong to the user, and it is not fully accessible to their doctor, so formulating a holistic synopsis of a patient’s well being is not possible. Information held by different monopolistic-minded vendors is kept fragmented and cannot be used for research or to improve early diagnostics.

Currently, there is no easy legal online or offline procedure in place, making it possible for a citizen to donate their medical data to research. Ironically, it is easier to donate our bodies than our health data. And while the Data Donor Movement and other initiatives push to eliminate this legal blockage, the technical integration of measurements recorded in thousands of different formats is a challenge in of itself.

## When are National or Global Health Standards Coming?

Widely accepted international data exchange formats would solve the interoperability issue. But standards take years to implement and even national new regulations often cause financial setbacks for the industry. Certification of medical device software is extremely complex. And while many of the world’s governments, faced with the pandemic, are looking to make advances in the connected healthcare realm, the US, with its FDA regulations and CPT Billing Codes is clearly ahead of the game. In the EU, the new MDR medical device regulation just came into force on May 26, 2021. Many experts perceive the new classification of software – especially of mobile apps - as too strict and potentially able to [undermine Europe’s innovation capacity](#). The implications are so serious, that the European Commission is considering revisiting some rules in the future.

MedM is a software company, uniquely positioned at the center of the Connected Health ecosystem. The company’s [RPM platform](#) is the only software solution in the world, able to collect 16 types of measurements directly from about 600 smart medical sensors via Bluetooth and to deliver the data into existing caregiver workflows. MedM also has a suite of five consumer health diary apps. Thus, working directly with end-users, device vendors, and healthcare providers on 4 continents for over a decade, MedM has a deep understanding of the market.

## Conclusion

With so much commotion in the ecosystem, MedM experts do not expect a closure with international standards to be reached in the next 5 or maybe even 10 years. Lack of industry standards for health data makes RPM deployments a risky endeavor. Fortunately, MedM technology is backing the early adopters in successfully rolling out their RPM services. And while health data and API standards may take years to come, MedM’s carefully crafted alliances with OEMs and the underlying flexibility of its software platform, equip the company to be an enabler of connected health already today, while also giving end-users the freedom to control their own health data.

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