

The rapid advancement of technology has paved the way for innovative solutions in the healthcare sector, with wearable devices emerging as a prominent tool for monitoring and improving health. Wearables have the potential to revolutionize healthcare by providing real-time data, personalized insights, remote patient monitoring, and more. However, to fully harness their benefits and ensure interoperability, it is crucial that best practices and standards are developed to match the growing patient and consumer demand.

Standards that establish a common framework to allow different devices, platforms, and systems to communicate effectively play a pivotal role in the successful integration and widespread adoption of wearables in healthcare. Standardization also fosters transparency, trust, and accountability in the healthcare ecosystem by addressing data security, privacy, and ethical concerns.

I have been lucky to be in a position to see how standards can encourage growth in technology and assist in accessing more efficient and effective healthcare.

As a Director of Standards at the Association for the Advancement of Medical Instrumentation (AAMI), I led efforts related to Artificial Intelligence (AI)/Machine Learning (ML) for medical devices. In this role I had the opportunity to collaborate with colleagues and AI experts both in the U.S. and abroad including participating in the IEC SEG 10, Ethics in Autonomous and Artificial Intelligence Applications and co-authoring a paper *Machine Learning AI in Medical Devices: Adapting Regulatory Frameworks and Standards to Ensure Safety and Performance*¹. While participating in these efforts, I saw how standards could encourage innovative healthcare solutions while also caring for risks and biases by developing best practices for data sets and more.

In my role as Senior Manager, Technology & Standards at the Consumer Technology Association (CTA)[®] I have seen standards becoming even more essential to health and wellness technologies. CTA's work on Over-the-Counter Hearing Aid standards² helps provide access and improve healthcare outcomes for the many Americans experience mild hearing loss. Additionally, standards for telehealth have the potential to provide benchmarks for remote exams, integration of biometrics/vital sign measurements, testing, and prescription management, as well as long-term care, management, and monitoring. These technologies can provide better access to healthcare for many people, and developing best practices and standards can increase their use.

The current landscape of standards development for wearables and healthcare is not without challenges. One of the major obstacles is the sheer diversity and rapid evolution of wearable technologies. The market is flooded with an array of devices, each with its unique features, sensors, and data formats. Furthermore, the regulatory landscape for medical devices and healthcare data privacy is complex and varies across jurisdictions, making it challenging to create global standards that cater to diverse legal requirements.

¹ AAMI, BSI, Turpin, R., Hofer, E., Lewelling, J., & Baird, P. (2020). *Machine Learning AI in Medical Devices: Adapting Regulatory Frameworks and Standards to Ensure Safety and Performance*. AAMI/BSI Initiative on Artificial Intelligence.

<https://www.bsigroup.com/en-US/medical-devices/resources/Whitepapers-and-articles/machine-learning-ai-in-medical-devices/>

² ANSI/CTA-2051-A, *Wearable Sound Amplifier Performance Criteria*, (June 2022), Consumer Technology Association (CTA). <https://www.cta.tech/standards>

The potential impact of international standards efforts in this space cannot be overstated. By participating in international standards efforts such as ISO/TC 198, Sterilization of health care products and attending ITU meetings as part of my role as a secretariat for oneM2M I have seen the importance of international standards firsthand. In particular, as a former US TAG Secretary and now a participating expert for IEC TC 124, Wearable electronic devices and technologies, I have seen how critical international standards can be to create a common understanding of terminology and definitions.

International standards bodies such as IEC not only help create common understandings of technology, but also provide an opportunity to create common understandings between countries and cultures. During my participation in international standards efforts, I have developed my own global network of trusted experts, colleagues, and friends. By participating in the IEC Young Professionals program, I hope to develop global connections with likeminded standards professionals to continue to create standards and best practices that encourage and increase the adoption of the many technologies emerging today.