The Standards We Never See:
How Medica Device Standards Protect Patients Around the World

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Abstract

I grew up in a home where a medical device was simply part of the furniture. My grandfather depended on it every day, and no one in our family ever questioned whether it would work. It was just there, steady and reliable, the way certain things in a household become so familiar that you stop seeing them entirely.

It was only after leaving Bangladesh, working in India, and eventually pursuing graduate training in public health in the United States that I began to understand what actually made that device trustworthy. The answer was not the device itself. It was an invisible system of internationally agreed upon standards that governed how the device was designed, tested, manufactured, and monitored for risk across its entire lifespan.

This paper explores that system. Drawing on my experiences across three countries and my training in epidemiology, I examine how medical device standards function as one of the most underappreciated forms of public health protection in the world today. Standards such as ISO 13485 for quality management, ISO 14971 for risk management, and FDA guidance on usability and interoperability create the shared foundation that allows healthcare providers to trust their instruments and patients to trust their care. Without these standards, healthcare would become less consistent, less equitable, and far more dangerous. Like clean water systems and vaccination programs, medical device standards succeed most completely when no one notices them at all.

A Device That Was Just There

My grandfather had a medical device that became part of the rhythm of our home in Bangladesh. It was not dramatic. There was no crisis that introduced it, no moment of high stakes that made the family gather around it with worry. It simply arrived at some point, took its place in the corner of a room, and became ordinary. He used it every day. We trusted it without thinking about why.

That kind of trust is easy to take for granted. I did, for most of my early life. It was only later, after moving to India for work and eventually to the United States for graduate training in public health, that I started asking a question that had never occurred to me as a child: what actually made that device reliable? Not reliable in the vague sense of "it seemed to work," but reliable in the rigorous sense of accurate, safe, and consistent across years of daily use in a home in South Asia, far from any manufacturer's service center, operating through heat and humidity and the general unpredictability of life.

The answer, I eventually learned, was standards. Not the device. The system behind the device.

What Standards Are and Why They Matter

A standard is an agreed upon way of doing something (American National Standards Institute [ANSI], n.d.). In the context of medical devices, standards are technical frameworks developed through international consensus that establish how devices must be designed, manufactured, tested, and monitored. They are not suggestions. They are requirements that manufacturers must meet before their products can be sold or used in healthcare settings.

Several of these frameworks are especially important. ISO 13485 establishes requirements for quality management systems used throughout the design and manufacture of medical devices (International Organization for Standardization [ISO], 2016). ISO 14971 provides a structured process for identifying hazards, estimating the likelihood and severity of harm, and implementing controls to reduce risk before patients are ever exposed to it (ISO, 2019). The U.S. Food and Drug Administration has developed guidance on human factors engineering, which focuses on designing devices in ways that account for how real people, often tired, often managing multiple tasks at once, actually interact with technology (FDA, 2016). Additional frameworks address software reliability, electrical safety, cybersecurity, and interoperability, meaning the ability of devices to exchange information safely with other technologies in a healthcare system (FDA, 2017).

Together these frameworks create something that is easy to overlook but impossible to replace: a shared foundation of trust. A physician in Delhi can use a monitoring device manufactured in Germany with reasonable confidence that it has been built to known standards. A nurse in Dhaka

can read a device display and trust that the number it shows reflects reality. My grandfather could use his device every day without understanding any of the technical specifications behind it, because those specifications had already been worked out, verified, and enforced long before the device reached our home.

That is what standards do. They move the burden of verification away from the patient and the clinician and place it where it belongs, upstream in the design and manufacturing process, before harm has any opportunity to occur.

The Problems That Standards Were Built to Solve

My epidemiology training has shaped the way I think about health. We tend to focus on outcomes, on disease, injury, and death, but behind every outcome is a set of upstream conditions that made it more or less likely. Standards are one of those upstream conditions. Their purpose is prevention, not response.

The most fundamental problem that medical device standards address is accuracy. Every clinical decision involving a medical device depends on the assumption that the device is telling the truth. A pulse oximeter that reads two percentage points low does not just produce a wrong number. It produces a wrong clinical impression, which can lead to a wrong decision, which can cause real harm. Standards establish performance benchmarks and testing requirements that manufacturers must meet before their devices are used on patients. They do not guarantee perfection, but they establish a floor below which no device should fall.

Standards also address safety through systematic risk management. ISO 14971 requires manufacturers to anticipate hazards before they cause harm and to implement controls that reduce risk to acceptable levels (ISO, 2019). In public health, we call this primary prevention. We do not wait for a disease outbreak to build a water treatment system. We build the water treatment system first, and the outbreak never happens. Medical device risk management works on the same logic. The goal is to find the problem in the design phase, not in the emergency department.

Usability is another domain where standards do critical work. A device can be technically accurate and still cause serious harm if it is designed in a way that makes errors easy and corrections difficult. Healthcare environments are not calm or controlled. Clinicians work under fatigue and time pressure. Alarms compete for attention. A confusing interface or an ambiguous display can turn a reliable device into a source of clinical error. The FDA’s human factors guidance exists because the research is clear: how a device is designed for human use is inseparable from how safely it will be used (FDA, 2016).

Finally, standards support interoperability. Healthcare no longer happens in a single room with a single device. Information flows between monitors, records systems, pharmacies, laboratories, and specialists across institutions and sometimes across countries. Standards create the common language that allows these systems to communicate without introducing new errors in translation.

Imagining a World Without These Standards

Public health teaches its students to learn from system failures. Outbreaks reveal gaps in surveillance. Policy collapses expose inequities in access. I have tried to apply the same habit of mind to medical device standards, and the picture that emerges is not reassuring.

The absence of standards would not produce a single catastrophic event. It would produce something slower and harder to see: a gradual erosion of the consistency and trust that healthcare systems depend on. Manufacturers with no shared requirements would make different design choices. Devices that looked similar would behave differently. Information that moved between systems would arrive with less certainty that it meant the same thing on both ends.

Think about the patient arriving at an emergency department with chest pain. Within minutes, clinicians are reading monitors, measuring vital signs, preparing medications. Every decision they make in that hour depends on equipment they may be using for the first time, from a manufacturer they may never have worked with before. They trust that equipment because standards have already done the verification. Without that assurance, the cognitive burden on every clinician in that room increases, and the margin for error grows wider.

The impact would not fall equally across healthcare settings. Large hospital systems with substantial resources could potentially develop their own internal evaluation processes. Smaller hospitals, rural facilities, and clinics operating with limited budgets could not. I have worked in healthcare contexts in Bangladesh and India where resource constraints already shape the quality of care in visible ways. A world without medical device standards would almost certainly make those disparities larger, not smaller.

Innovation would also suffer, though perhaps not in the way people expect. Standards are sometimes described as obstacles to creativity. In practice, they tend to do the opposite. When manufacturers know exactly what safety and performance requirements they must meet, they can focus their resources on genuinely improving patient care rather than resolving basic compatibility and liability questions. Standards do not constrain innovation. They give it a stable surface to stand on.

The Global Stakes

Having lived and worked across Bangladesh, India, and the United States, I have had the opportunity to see healthcare through more than one lens. The contexts are very different. The resources are very different. The infrastructure is very different. But the underlying need is identical in all three places: patients need devices they can trust, and clinicians need information they can act on.

This is why the World Health Organization has emphasized the importance of internationally harmonized medical device standards and regulatory frameworks, arguing that consistent standards protect patients regardless of which country they happen to receive care in (WHO, 2017). A blood pressure reading should mean the same thing in Dhaka as it does in Dallas. That consistency is not automatic. It is the product of shared standards that different countries and manufacturers have agreed to follow.

The importance of this global consistency is growing, not shrinking. Healthcare is increasingly decentralized. Patients monitor chronic conditions from home. Telehealth visits depend on consumer devices generating clinical data. Wearable technologies track health indicators continuously, outside any clinical setting. The more care moves into homes and communities, the more the standards governing those devices matter to ordinary people who have never heard of ISO 13485 and do not need to.

Conclusion

My grandfather's device worked. For years, through heat and humidity and the slow passage of time, it simply worked. Our family never questioned it. We never needed to.

I understand now that this reliability was not an accident. It was the product of a system that operates entirely out of view, built from technical frameworks and international agreements that most patients will never encounter. Standards made that device trustworthy before it ever reached our home, and they continue making devices trustworthy for millions of patients every day in ways that are almost entirely invisible.

In public health, the most effective interventions are often the ones that leave no visible trace precisely because they worked. Clean water arrives at the tap without drama. Vaccines prevent diseases that never happen. Medical device standards ensure that the equipment used in healthcare does what it is supposed to do, quietly, consistently, and without anyone having to think about it.

That invisibility is not a flaw. It is the measure of how well these standards are doing their job.

References

American National Standards Institute. (n.d.). *Introduction to standards and conformity assessment.* https://www.ansi.org/education/activities/standards-student-programs

International Organization for Standardization. (2016). *ISO 13485:2016 medical devices: Quality management systems: Requirements for regulatory purposes.* https://www.iso.org/standard/59752.html

International Organization for Standardization. (2019). *ISO 14971:2019 medical devices: Application of risk management to medical devices.* https://www.iso.org/standard/72704.html

U.S. Food and Drug Administration. (2016). *Applying human factors and usability engineering to medical devices.* https://www.fda.gov/media/80481/download

U.S. Food and Drug Administration. (2017). *Design considerations and premarket submission recommendations for interoperable medical devices.* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-and-pre-market-submission-recommendations-interoperable-medical-devices

World Health Organization. (2017). *WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices.* https://www.who.int/publications/i/item/9789241512350