

DECLARATION



The Seoul Declaration: A Manifesto for Ethical Medical Technology*

Preamble

Intersection of medicine, humanity and technology

It is often held that technology itself is incapable of possessing moral or ethical qualities, since “technology” is merely tool making.¹ But many clinicians and researchers believe that each piece of healthcare technology is endowed with affordances that can impact and challenge ethical values and commitments all the time. The technology’s “values” and artificial intelligence are embedded in the devices and implements by those that design them, and those that decide how it must be made, marketed and used. This is at the heart of the moral challenges surrounding the use of medical devices, AI and information technology.

We recognize that unsafe medical technology and avoidable patient harm represent a serious challenge to health care service delivery globally. The significant level of preventable human suffering, the considerable strain on health system finances, and the loss of trust by patients and society in health systems and in their governments is of great concern. The recent related reports around unsanctioned gene editing of embryos, biased AI data algorithms, and the Food and Drug Administration (FDA) and CE flawed certifications of devices often based on false or incomplete information provided by the vendors, raises many legitimate and ethical questions about medical device oversight systems. These reports extend from vaginal meshes to hip replacements to surgical endoscopes and more, make it seem that the oversight mechanisms are bent too far toward making it easier for industry rather than making protection of public health the primary goal.^{2,3} The International Consortium of Investigative Journalists reported that “Health authorities across the globe have failed to protect millions of patients from poorly tested implants that can damage organs, deliver errant shocks to the heart, rot bones and poison blood, spew overdoses of opioids and cause other needless harm.”⁴

Sadly, technology companies do not police themselves nor learn in a systematic and transparent manner and often only do the minimum of what the legislation demands. Recent reports suggest that the FDA granted medical device makers special “exemptions” creating a vast and hidden repository of reports on device-related

injuries and malfunctions hidden from doctors and from public view.⁵ Since 2016, at least 1.1 million incidents have flowed into this internal “alternative summary reporting” repository including deaths, serious injury and malfunction reports for about 100 medical devices, many implanted in patients or used in countless surgeries including minimally invasive and robotic-assisted. For example, the FDA has just alerted clinicians about an increasing number of medical device reports (MDRs) associated with the use of surgical staplers for internal use and implantable surgical staples reporting from 41,000 individual MDRs including 366 deaths, more than 9000 serious injuries, and more than 32,000 malfunctions. These reports speak to a profound crisis of public confidence in how medical devices and AI technologies are regulated.

New AI technologies and automation now entering health care as outlined in the MITAT AI special issue 2019 how to best raise questions about the downsides of all the automation, voice our concerns constructively, design more thoughtful technology assessments and experiments done under real world conditions, and demand more transparency about financial conflicts of interest and device failures during the development, marketing and post marketing surveillance periods. Patient safety isn’t just a matter of the technical risk, it is also about the public perception of risk. The recent Boeing Max 737 suggest that as with aviation, in AI and widespread automation acceptance depend on the public trusting the industry and in some cases that requires us to be extra cautious. Ultimately, regulators and policy makers will force upon medicine a more rigid and onerous risk avoidance accountability if we do not appreciate and actively address the highly coupled intersection of medicine, humanity and technology.

The goal of the *Seoul Declaration: A Manifesto for Ethical Medical Technology* is to be a clarion call for the ethical, research and policy issues that surround the development and implementation of new medical and AI technologies. We mean to not scare anyone from promoting and implementing new technologies based on sound human factors design that promotes patient safety and can improve service delivery systems, at all levels of health care and in all health care settings. We believe there is a global and urgent need for a robust public debate to address the trade-offs of automation vs safety

and to drive home just how much clinicians, policy makers and patients need to be made more aware and have the right to know what is coming down the technological pipeline or already is in our hospitals and can potentially cause patient and staff harm.

Our most challenging task will be to try to de-politicize as many of these discussions as possible so that we can truly address the scientific, safety, quality and reliability questions in a transparent and truthful manner. Of course, when it comes to implementing public policy or even suggesting that policy is the right way to approach an issue, politics creep right back in.

We welcome and invite the insights and feedback from clinicians, professional societies and medical industry leaders about the *Seoul Declaration* (below), in building a stronger political sponsorship and discourse, and a momentum at the highest levels of government and the house of medicine to actively address the development and deployment of ethical and human-friendly medical technologies globally. We need more public debate and scientific data about how to best address these tensions while increasing our public commitment to weeding out the reported rampant conflicts of interest in both drug and medical device approval, procurement and in physician remuneration. The medical device area can be particularly susceptible for paying physicians kickbacks for patient referrals and prescriptions for unnecessary equipment.⁶

The reports of over 176 million healthcare data breeches, has exposed the public to see how medical devices fueled by AI and information technology can impact society's moral values.⁷ As this data gathering becomes more automated and ever-present, we must ask can we trust the manufacturers to provide safety oversight of their own device innovations? Who is in control of collecting this data and what is done with it once it has been collected and stored by hospitals and medical device companies? Questions are being raised about the patient's right to know about the production, access, and control of patient and process information, and do we as a society have the ability and the correct balance of legal rights and tools to more meaningfully construct, exert control and positive influence, while not hampering innovation in this multi billion-dollar industry. We are pressed to address these questions while adhering to the precept that "Ethics is knowing the difference between what you have a right to do and what is right to do."

The Seoul declaration: a manifesto for ethical medical technology

The Seoul Declaration on ethical medical technology is founded on the policies articulated in the World Health Assembly resolution WHA55.18 (2002), which urged Member States to "pay the closest possible attention to

the problem of patient safety and establish and strengthen science-based systems, necessary for improving patient safety and the quality of health care".

Seoul is capital of Korea where the national ideology has been to "benefit all mankind" and has followed cultural values and norms of harmony, balance, and moderation which have been fundamental to Korean culture and prosperity for 10,000 years.

We welcome the vision and leadership of countries in building political sponsorship and momentum at the highest levels of government to address the development and deployment of ethical medical technologies globally as well as locally, adhering to the precept that "Ethics is knowing the difference between what you have a right to do and what is right to do."

We reaffirm our commitment to improving medical technology and patient safety in order to reduce all avoidable harm and the risk of harm to all patients and people during their interaction with providers and health care systems, whoever they are, wherever they live, and endorse the following Seoul Declaration, while:

- Recognizing that unsafe health care and avoidable patient harm represents a serious challenge to health care service delivery globally, including the significant level of preventable human suffering, the considerable strain on health system finances and the loss of trust in health systems and in governments;
- Recognizing that the need to promote and implement new technologies based on human factors design ensuring highest level of patient safety and strictly adhering to ethical rules are fundamental requirements of all service delivery systems, at all levels of health care and in all health care settings;
- Recognizing that the latest advances in medical technology, however, are raising many questions relative to ethics. The revolutionary inventions and advancements in the field of medicine have sometimes meant that traditional medical ethics could not be followed.
- Recognizing that smart implants, automated robotics, artificial intelligence, autonomous devices represent an ongoing opportunity to expand and support ethical technical innovation;
- Recognizing that ethical technologies that promote patient safety are important components of health care delivery and newer technologies are essential to achieve Universal Health Coverage (UHC), and moving towards UN Sustainable Development Goals (SDGs); and that patient safety systems and practices need to be established in all countries as one of the critical health care standards for achieving UHC on a sustainable basis;
- Recognizing the roles that information and communication technology play, from data collection and surveillance to monitoring and notification, anticipating risks,



Figure 1. Declaration signed by the attendees of iSMIT 30th international conference, Seoul, South Korea. 9th November 2018.

improved service delivery and improved safety and quality;

Recognizing the role of engaging and empowering patients and families in the design and implementation of medical technologies that help deliver safe and quality care and in all aspects in health care - policy development, organizational level, decision making, health literacy and self-care.

We declare that we will:

Pledge to support ethical medical technologies with the goal of “*Primum non nocere*”

Enable health care institutions, both public and private, from the level of primary care through to referral level care, to implement changes in an ethical and transparent manner, in terms of conflict of interest in systems and practices to improve patient safety and human values using new medical technologies, while contributing to achieving UHC and SDGs;

Support collaborative, ethical and transparent biomedical design methodologies working with industry for global health concerns. Collaboration is essential for successful engineering of complex projects and the biomedical engineering field stands out for the need of multidisciplinary teams capable of systematically addressing the development of medical devices considering medical, social, economical, technical, safety and regulatory issues.

Call on our governments to fund and support development of new technical standards and open-access e-infrastructures for global action. The development and employment of adequate data management strategies

and of methodologies for improved information sharing is intimately connected to the construction of healthy, sustainable, creative, effective and efficient collaborative design environments. Developing user-friendly, versatile, stable and safe open-access e-infrastructures, for supporting these online interactions in the collaborative development of biomedical devices, and following FAIR (findable, accessible, interoperable and reusable) data principles as the right direction for achieving global action towards the democratization of medical technology.

Strive for harmonization of medical devices directives and accessible standards. Construct a framework for enabling medical technologies to reach everyone and everywhere relies on the use of common design practices and on the fulfillment of broadly accepted regulations that must warrant patients' safety and improving human values that should allow for a compliant device to be commercialized and applied worldwide. Establish clinical follow up, post market surveillance and registries of the use of medical devices, if needed in addition to loco regional regulatory demands.

Sign and assume the present manifesto, as a symbol of commitment and deep respect for future collaboration. We will pursue the aims highlighted in this document, supporting our partners, promoting collaboration with significant stakeholders (from patients, patients' associations, medical professionals and biomedical engineers, to educators, policy makers, manufacturers and companies), working towards universally accessible, intrinsically safe and high-quality medical technologies and solving unforeseen issues with a balance between pragmatism and idealism (*pedes in terra ad sidera visus*).

Notes

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3. Faulty and unproven medical devices implanted in Canadian patients despite known risks. *The Star*, Nov 25, 2018. <https://www.thestar.com/news/investigations/2018/11/25/faulty-and-unproven-medical-devices-from-vaginal-mesh-to-hip-replacements-implanted-in-canadian-patients-despite-known-risks.html> - <https://www.thestar.com/news/investigations/2018/11/25/faulty-icij-implant-files.php>, Jon Allsop, Consortium of Journalists Reporters, November 26, 2018. Accessed March 12, 2019.
5. Hidden FDA Reports Detail Harm Caused By Scores Of Medical Devices, *Kaiser Health News*, March 07, 2019.
6. <https://www.prnewswire.com/news-releases/olympus-has-fallen-false-claims-act-whistleblower-lawsuit-prompts-medical-device-titan-to-strike-a-record-623m-settlement-kenney-mccafferty-announces-300228799.html>
7. Thomas H. McCoy Jr., and Roy H. Perlis. 2018, Temporal Trends and Characteristics of Reportable Health Data Breaches, 2010–2017. *JAMA*. 2018;320(12): 1282–1284. doi:jama.2018.9222/jama.2018.9222

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