Published in final edited form as:

Sci Transl Med. 2017 April 12; 9(385): . doi:10.1126/scitranslmed.aal4359.

The Engagement of the Medical Technology Sector with Society at Large

David Williams, D.Sc., FEng^a, Elazer R Edelman, M.D., Ph.D.^b, Milica Radisic, Ph.D.^c, Cato Laurencin, M.D., Ph.D.^d, and Darrel Untereker, Ph.D.^e On behalf of the Voice Initiative of the American Institute of Medical and Biological Engineering

^aProfessor of Biomaterials and Director of International Affairs, Wake Forest Institute of Regenerative Medicine, Winston-Salem, NC, (dfwillia@wakehealth.edu).

^bMIT Cabot Professor of Health Sciences and Technology and Harvard Medical School Professor of Medicine, Brigham & Women's Hospital, Boston, MA, (ere@mit.edu).

^cProfessor, Institute of Biomaterials and Biomedical Engineering, Department of Chemical Engineering and Applied Chemistry, University of Toronto, Canada, (m.radisic@utoronto.ca).

^dUniversity Professor, University of Connecticut and CEO, Connecticut Institute for Clinical and Translational Science, Farmington, CT, (laurencin@uchc.edu).

^eVP of Research and Technology, Medtronic, Inc., Minneapolis, MN (darrel.untreker@medtronic.com).

Abstract

As part of its mission to inform the public of the value of medical technology the American Institute for Medical and Biological Engineering (AIMBE) charged us to consider *"How can the medical technology sector engage with society at large to educate people, in an unbiased, non-sensational and rational way, about the successes and benefits of medical and biological engineering?"* This perspective addresses this charge, seeks to understand the discrepancy in resource allocation to healthcare in the US and the perception of good, and submits that targeted effective communication can correct misconceptions and narrow the perceived gap between investment and return in biotechnology innovation.

One Sentence Summary

This perspective addresses how the medical technology sector can engage with society at large to educate people, in an unbiased, rational, way about the successes and benefits of medical and biological engineering, and seeks to understand the perceived discrepancy between investment and return in biotechnology innovation.

Introduction

There is a tension in the United States - as clinicians and scientists we clamor for more support for research and health care, and yet the public does not feel that it is getting its return on investment in medical technology innovation. We have not made our case and we must close the communication gap.

The data support the public perception. Health expenditure in the US is 17.1% of GDP, far higher than other developed countries, which are in the 6–11% range. And while over 65% of top medical device companies are based in the US and 70% of medical device patents granted in the US are filed by US organizations the life expectancy of 79 years placed the US 29th in the world and 2–5 years lower than other countries. Infant mortality was 4 per 1,000 live births in the US; most other developed countries had fewer than 3 per 1,000.

Public distrust rises further as we ask for and promise more. It is in the American character to embrace technology - physicians actively embrace and aggressively acquire emerging technologies, and patients believe it their right to be treated with the latest technology, with minimal tolerance for risk or loss of physician contact. This emerging crisis requires that we explain ourselves and our technology and, as we seek innovative therapies, make use of the vastly changed environment associated with information technology to provide the relevant data and background that people need.

Medical Technology Communications

The terms *communication* and *community* share a mutual etymology; the former makes the latter whole, there cannot be community without communication. The community that nucleates about medical technology expands in concentric circles. At the core are those who are affected by technology and, moving ever outwards, those who use technology, advocate its use, develop technology, ensure safety and approve reimbursement. We have a community of patients, technicians, clinicians, engineers, industrialists, regulators and legislators. Yet, we currently focus on the developer and user rather than the patients who are the most vulnerable and sensitive to misinformation, least well-informed and rarely considered in analysis of technology impact. Each of the other members of society possess a regulated vehicle for communication; the core does not. Once communication involved print news and books; today it is an electronic, instantaneous media that is often sensational, where time and immensity preclude precision oversight. Society is subject to a barrage of exaggerated claims of the benefits of devices or drugs. A recent communication in *JAMA Internal Medicine*, entitled “A guide to reading health care news stories”, reflected experiences of an organization that monitored medical journalists (1). Failures to independently verify claims from parties with vested interests, misrepresentation of risks and misleading uses of surrogate markers of health benefits revealed disturbing patterns.

Media is by its nature entertainment and dramatic. That we revel in the hyperbole of our good should make amplification of our bad no surprise. Medical devices, especially implantable devices, do not always provide satisfaction and, often the press aided by plaintiff's attorneys, celebrate the rare failure, for we have taught them to celebrate each

minor success as a major windfall. The reputation and indeed retention of therapies is rarely defined by the universality of good outcomes - more often by singular failures. We cannot indict the media alone for they disseminate what we provide. Universities, hospitals and companies issue press releases that are meant to inform the public but are often sensational. Scientists, clinicians and engineers all publish their findings, primarily promoting positive findings, minimizing the negative and ambivalent. The public is left with the impression that the explosive march of technology is accompanied by a concomitant diminution, or even elimination, of risk. It is our responsibility to make communication relevant and accurate.

Public Confusion About Benefits of High Cost Medical Instruments

The public is confused about many aspects of health care, and they have a right to be, given the plethora of advice, often contradictory, that is provided, for example over cancer risks with foods. When highly respected organizations suddenly change guidelines, such as the decision of the American Cancer Society to raise the age at which breast cancer screening should commence and frequency of screening (2), many are unsure about guideline objectivity. This comment is not meant to argue with the ACS decision, but to emphasize the difficulties of handling medical information within a skeptical society where the scientific community is often challenged by competing interests.

In January 2015, President Obama announced the “Precision Medicine Initiative”. Driven by the NIH the initiative was quickly supported by medical, academic and industrial stakeholders (3) but we need to be careful. Social media early reflected concern that precision medicine is no more than repackaged personalized medicine with unacknowledged scientific, economic and ethical challenges. We have a responsibility to tackle an issue of such fundamental importance with honesty, treading the fine line between hope and hype using evidence-based arguments. The scientific literature is showing signs of objectivity; Arnedos *et al* (4) challenged the appealing concept that genomics could improve metastatic breast cancer outcomes but also discussed how operational challenges might be overcome. Cancer medicine clinical trials will have to change and physicians will require informatics support.

Robots and Protons

Often individual choices must be made with unclear evidence, as in robotic surgery, where enthusiasm for techniques predict markedly expanded use but with questionable justification. Hospitals and manufacturers extol its virtues through social media, but the scientific literature is concerned that with all the sophistication and cost there no firm evidence of improved outcomes. In 2013, the President of the American Congress of Obstetrics and Gynecologists cautioned that “the number of robot-assisted hysterectomies had increased from 0.5% to 10% in three years without demonstrable benefit” (5). Public perception adds confusion, since many believe that robotic surgery is safer and less painful, but the majority (including physicians themselves) would personally prefer conventional surgery. Proton beam therapy (PBT) has a similar profile: in the face of high cost, large and specialized facilities and equivocal outcomes, the American Society of Radiation Oncology

has concluded that there was insufficient evidence to recommend PBT in lung cancer, head and neck cancer, GI malignancies and pediatric non-CNS malignancies (6).

Optimizing the Benefits of Medical Technology

Some technologies do balance the demands of innovation, cost containment, quality control and patient care, unequivocally enhancing quality of life, longevity, and cost-effectiveness across the life cycle. Cochlear implants have treated hearing loss in the young, in mid-age advances in trauma care, craniomaxillofacial reconstruction, and rehabilitation medicine are made possible by virtual surgical planning and computer modeling, and as we age, the treatment of cataracts has been revolutionized by intraocular lenses, Parkinson's disease by deep brain stimulation, and heart disease by endovascular stents and transcatheter heart valves.

The question is how we can engage with society to educate the public about success with balance and context. Several authors have considered cost control but there are few serious suggestions of how this could be done. The words of Callahan at the Hastings Center are worth repeating (7); *“health care economists estimate that 40–50% of annual cost increases can be traced to new technologies ...medical technology is highly valued as a beloved feature of American medicine; patients expect it, doctors are primarily trained to use it, the medical industry makes billions of dollars selling it and the media loves to write about it; the economic and social incentives to develop and diffuse it are powerful and the disincentives weak and almost helpless”*.

Solutions lie not with cost containment but with the translation of costs into better outcomes. We need to target new technologies to the right patients, and provide better, unbiased information to the media to improve objectivity in reporting. The full spectrum of challenges requires frank communication among stakeholders, including professional societies, which are well positioned to orchestrate this dialogue.

Critical Areas of Concern

Messaging and managing roles

A major part of the problem is the pressure to motivate expenditure with impact. Indeed, the review process of the National Institutes of Health now makes this matter central to grant funding and few major clinical acquisitions can be made without identifying influence on the service pay line. As clinicians and scientists we are increasingly conditioned to emphasize the promise and minimize the risk – deluding those around us to believe that one can get “something-for-nothing”. The FDA and Industry test devices in order to pass often arbitrary thresholds of safety, and do not drive devices to failure - depriving us of knowledge as to the limits of therapies and providing the false sense of security that interventions can never fail. There needs to be a cultural shift to acknowledge and embrace risk, for it is risk that supplies insight into a therapy and the real motivation for continued innovation. Such a shift requires definition and alignment of roles and their explanation to community

We need to emphasize that ideally, patients should want rapid development and access to products that offer benefits at an acceptable risk. Clinicians should want information on real effectiveness and the freedom to guide patients contextually, and industry to market safe, profitable products while government ensures that populations are protected from harm. We have not made this clear – there remains for every group a disconnect, for the patient the lack of understanding that scrutiny takes time and that no one can foresee all risk, for physicians that it is alright to admit when one is uncertain, for government that regulatory agencies need not cover every exigency and for industry to admit that every drug can have toxic effects and every device or material can fail in some way, and that the community should know when.

Managing expectations

Success involves managing expectations through recognition of the appropriate metrics to define innovation and tools to derive highest quality data. We need to explain why we need clinical trials but that drugs and devices cannot be tested in similar fashions, why the mechanisms of action and lifecycles of each innovation are different (for this will help people understand why we need to consider disparate technologies differently), what blinding, randomization and crossover mean, how we power trials and when adaptive design is in order, and when controls are needed and when impossible. We need to create expansive trials that involve the breadth and diversity of our community but not at the risk of losing trial rigor and here is where we need to communicate how operator performance and patient selection can bias results. We must explain that each successive innovation adds to our armamentarium of therapies but almost never eradicates disease. The risk factors that lead to diseases that are imposed by nature and genetics, and those by choice and abuse cannot be undone but can undo anticipated benefit. Patient education, intensive rehabilitation and treatment algorithms are very important, but those that do not emphasize lifestyle modification, adherence to clinical follow up and medication compliance doom the most effective of innovations. We need to ensure that people understand that first generation drugs and devices can never be as safe or effective as those that follow, that new applications and techniques will unveil new risk, and acknowledge that there are ethical issues at play.

In short, we need to involve the entire community in the translation process openly and honestly in authoritative, publicly available forums. Only then will the public understand that precision trial design reduces uncertainty in more rapidly driving products to clinic, but that reduction of uncertainty is not elimination. Perhaps then we can allow FDA to find the common ground between unobtainable poles of absolute safety and immediate access for all.

Mode and Disparities in Communication—Specific mechanisms of communications in public engagement are difficult to define because of the changing nature of social intercourse and objectives of different sponsors. Passive transfer without direct engagement is less-and-less effective. Public input should be sought (9). Once abhorred, social media is now extensively used within health care (10) and embraced formally by professional societies, major publications, constituency agencies, and hospitals – creating opportunity for rapid updating and disseminating communication but also opening Pandora’s box. Care must

be taken to ensure quality of information, maintenance of professional image and clarity. Here we must avoid becoming simplistic or overbearing, condescending or overreaching.

Wealthier and better-educated people have more time to attend to their health and greater access to expanding health resources. Technologic advancement can exacerbate the have:have not gap but effective communication can narrow the divide if it is targeted and not stigmatizing. Patient access to electronic medical records is a wonderful example of empowerment but it must be made available to all not just those with the latest model computers and handheld devices. Technology innovations should simplify the lives of educationally or financially disadvantaged not make it more difficult and if communication is directed only towards the socially privileged health indicators will not improve.

Conclusions

While the public is proud of innovation in medicine, they are increasingly less sure that benefit has been universal with each advance. Only education, communication, active outreach to and empowering of the community can remove the source of tension and correct misconceptions. This is the charge to technology innovator and associations like AIMBE, to harness information flow and improve the information in the public domain for only this will improve life quality for all.

References

1. Schwitzer GA, A guide to reading health care news stories, *JAMA Intern. Med* 174, 1183–1186 (2014). [PubMed: 24796314]
2. American Cancer Society, Breast cancer screening for women at average risk; 2015 guideline update. *JAMA* 314, 1599–1614 (2015). [PubMed: 26501536]
3. Aronson SJ, Rehm HL. Building the foundation for genomics in precision medicine, *Nature* 526, 336–342 (2015). [PubMed: 26469044]
4. Arnedos M, Vicier C, S. Loi S, Lefebvre C, Michiels S, Bonnefoi H, Andre F. Precision medicine for metastatic breast cancer - limitations and solutions, *Nat. Rev. Clin. Oncol* 12, 693–704 (2015). [PubMed: 26196250]
5. American Congress of Obstetrics and Gynecologists: Statement on Robotic Surgery by the President, James T Breeden, MD, Issued March 14th 2013. (www.acog.org)
6. Allen AM, Pawlicki T, Dong L, Fourkal E, Buyyounouski M, Cengel K, Plastaras J, Bucci MK, Yock TI, Bonilla L, Price R, Harris EE, Konski AA, An evidence based review of proton beam therapy: the report of ASTRO's emerging technology committee, *Radiother. Oncol* 103, 8–11 (2012). [PubMed: 22405807]
7. Callahan D, Health care costs and medical technology, In 'From Birth to Death and Bench to Clinic', Crowley M (Ed.), The Hastings Center, Garrison NY, 79–82 (2008).
8. Rowe G, Frewer LJ, A typology of public engagement mechanisms, *Sci. Technol. Human Values* 30, 251–290 (2005).
9. Wortley S, Tong A, Lanscar E, Salkeld G, Howard K, Public preferences for engagement in Health Technology Assessment decision-making; protocol of a mixed methods study, *BMC Med. Inform. Decis. Mak* 15, 52 (2015). [PubMed: 26166149]
10. Ventola CL, Social media and health care professionals; benefits, risks and best practices, *PT* 39, 491–520 (2014).