

POLICY

Engagement of the medical-technology sector with society

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The medical-technology sector must educate society in an unbiased rational way about the successes and benefits of biotechnology innovation.

There is a tension in the United States between medical-technology innovators and the public. The former clamors for more funding to support research and health care, whereas the latter does not feel that it receives an adequate return on investment in medical-technology innovation. We clinicians and scientists have not made our case to the people, and we are responsible for closing this communication gap.

Data support the public's perception. U.S. health expenditure is 17.1% of the gross domestic product—far higher than the 6 to 11% range in other developed countries. And although more than 65% of top medical-device companies are based in the United States and 70% of medical-device patents granted in the United States are filed by U.S. organizations, a life expectancy of 79 years places the United States 29th in the world and 2 to 5 years lower than that in other developed countries. Further, U.S. infant mortality is 4 per 1000 live births, whereas most other developed countries have fewer than 3 per 1000.

Public distrust rises further as innovators ask for and promise more. It is in the American character to embrace innovation. Physicians actively and aggressively acquire emerging technologies, and patients believe that it is their right to be treated with the latest therapeutic products, with minimal tolerance for risk or reduction in physician contact. The emerging crisis in public confidence 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.

As part of its mission to inform the public about the value of medical technology, the

American Institute for Medical and Biological Engineering (AIMBE) charged us to consider the following: “How can the medical technology sector engage with society at large to educate people, in an unbiased, nonsensational and rational way, about the successes and benefits of medical and biological engineering?” Here, we explore how targeted, effective communication can correct misconceptions and narrow the perceived gap between investment and return in biotechnology innovation.

HIGH-COST CONFUSION

The terms communication and community share a mutual etymology, the Latin word *communicare*—to share. Communities unite through communication and common interests. The community that nucleates around medical technology expands in concentric circles, beginning with the core group—those who are affected by technology—and moving ever outward, to those who use technology, advocate its use, develop technology, ensure safety, and approve reimbursement. The community consists of patients, technicians, clinicians, engineers, industrialists, regulators, and legislators. Yet, the technology ecosystem currently focuses communication efforts on the needs of the developers and clinician users, rather than that of the patients, who are the most vulnerable and sensitive to misinformation, the least well informed, and rarely considered in the analysis of technology impact. Each of the other members of society possesses a regulated vehicle for communication; the core does not. Once, communication involved print—news and books—but today, it is mostly via electronic, instantaneous media, which are

often sensational and preclude precision oversight. Thus, society is subject to a barrage of exaggerated claims on the benefits of new drugs or medical devices. A recent communication entitled “A guide to reading health care news stories” reflected experiences of an organization that monitored medical journalists (1). Failure to independently verify claims from parties with vested interests, the misrepresentation of risks, and misleading uses of surrogate markers of health benefits reveal disturbing patterns.

We innovators revel in the hyperbole of our societal good and encourage the public to celebrate each minor successful advance as a major windfall. Therefore, the amplification of our negative impact should come as no surprise. Electronic media are, by their nature, entertainment and thus tends toward the dramatic. For example, medical devices, especially implantable ones, do not always provide patient satisfaction, and often the press, aided by plaintiff's attorneys, celebrate the rare failure. Thus, the reputation and retention of therapies are rarely defined by the universality of positive health outcomes but, rather, more often by singular failures. We cannot indict the media alone, because they disseminate the information 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 the positive ones and minimizing the negative or ambivalent ones. 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 the responsibility of technology professionals to make communications about biomedical innovations relevant and accurate.

The public is puzzled about many aspects of health care, and they have a right to be, given the plethora of often contradictory advice that is provided (for example, cancer risks associated with various foods). When respected organizations suddenly change guidelines—such as the decision of the American Cancer Society (ACS) to raise the age at which breast cancer

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screening should commence and to modify the frequency of screening (2)—the public becomes unsure about guideline objectivity. This comment is not meant to argue with ACS's decision but to emphasize the difficulty of a skeptical society's handling of medical information when the scientific community often is challenged by competing interests.

In January 2015, U.S. President Barack Obama announced the Precision Medicine Initiative, which was quickly supported by medical, academic, and industrial stakeholders (3). But we all need to be careful. Early on, social media 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 and 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. Clinical trials for precision cancer medicines will require changes from current protocols, and physicians will need informatics support.

Often individual choices must be made with unclear evidence. One such example is robotic surgery, in which enthusiasm for techniques predicts markedly expanded use but with questionable justification. Hospitals and manufacturers extol robotic surgery's virtues through social media, but the scientific literature reveals a concern that, with all the sophistication and cost, there is 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, because many believe that robotic surgery is safer and less painful than conventional surgery, but the majority (including physicians themselves) personally prefers the latter. 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 is insufficient evidence to recommend PBT in lung cancer, head and neck cancers, gastrointestinal malignancies, and pediatric non-central nervous system malignancies (6).

OPTIMIZING THE BENEFITS

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, and in middle-aged patients, advances in trauma care, craniomaxillofacial reconstruction, and rehabilitation medicine are made possible by virtual surgical planning and computer modeling. In older patients, 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. But the question remains: How can we engage with society to educate the public about successes 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: "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" (7). Solutions depend on the translation of costs into better clinical outcomes. We need to target new technologies to the right patients and provide accurate, 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 dialog.

Messaging and role management

A major part of our current communication problem is the pressure to motivate expenditure with impact. Indeed, the review process for National Institutes of Health grants 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 risks of our creations, thus deluding those around us to believe that one can get "something for nothing"—that is, benefit without risk. The U.S. Food and Drug Administration (FDA) and industry test

devices to pass often arbitrary thresholds of safety, rather than pushing devices to failure during preclinical testing. This approach deprives inventors and the public of knowledge on the limits of therapies and provides a false sense of security that interventions never fail.

The biomedical environment needs to shift to a culture that acknowledges and embraces risk, because it is risk that supplies data-driven motivation for continued therapeutic innovation. Such a shift requires the definition and alignment of the roles of all members. Ideally, patients should demand rapid development of and access to products that offer benefits at an acceptable risk. Clinicians should seek robust information on the effectiveness of therapies as well as the freedom to guide patients in the context of their personal medical conditions and to guide industry in their mission to market safe, profitable products—all while government regulatory agencies ensure that patients are protected from unnecessary preventable harm. In the current culture, there remains, for every group, a disconnect: Patients lack an understanding of the time it takes to properly scrutinize a new therapeutic innovation and of the fact that no one can foresee all risk. Physicians have not accepted that it is all right to admit when they are uncertain. Government officials fail to acknowledge that regulatory agencies cannot and need not cover every exigency, because not all adverse events can be prevented. Industry has yet to admit that every drug has toxic effects and that even a successful device or material can fail in some patients.

Managing expectations

Success involves the managing of expectations with the use of appropriate metrics to define innovation and tools to derive high-quality data. Clinicians and scientists must explain, to patients and government officials, why we need clinical trials; why the mechanism of action and life cycle of each innovation differs and why each must be tested differently (for example, drugs versus devices); what is meant by blinding, randomization, and crossover; how we power trials; when an adaptive trial design is in order; and when controls are needed or impossible. Clinical trial designs must span the breadth and diversity of our community but not at the risk of loss of trial rigor—and here is where we need to communicate how operator performance and patient selection can bias results.

We also must explain to patients 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 that there are ethical issues at play. And it must be clear that each successive innovation adds to our armamentarium of therapies but almost never eradicates disease; risk factors imposed by genetics, environment, or behavior cannot be undone but can undo the anticipated benefit of therapies. Last, patient education, intensive rehabilitation, and treatment algorithms are important, but those that do not emphasize lifestyle modification, adherence to clinical follow-up, and medication compliance doom the most effective of innovations.

In short, we must involve the entire community in the biomedical translation process, openly and honestly, with the use of 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 does not mean its elimination. Perhaps then, the community will be equipped to 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 communication in public engagement are difficult to define because of the changing nature of social intercourse and sponsor objectives (8). Passive transfer without direct engagement has become less and less effective. Public input is now sought by clinicians and scientists (9), and social media, once abhorred, are now used extensively in health care (10) and embraced formally by professional societies and publica-

tions, constituency agencies, and hospitals. These movements create an opportunity for rapid dissemination of information but also have opened a kind of Pandora's box. Thus, we must take care to maintain the quality of biomedical information and professional standards and to avoid overly simplistic, overbearing, condescending, or overreaching communication styles.

Wealthier and better-educated people have greater access to expanding health resources. Technological advancement can exacerbate the have-have not gap, but effective communication can narrow the divide if it is targeted properly and is not stigmatizing. Patient access to electronic medical records is a wonderful example of empowerment, but it must be made available to all and not only to those with the latest-model computers and handheld devices. Technology innovations should simplify the lives and address the health issues of the educationally or financially disadvantaged. If communication is directed only toward the socially privileged, overall health indicators and patient wellness will not improve. We suggest that all professionals involved in medical technology innovation have a responsibility in this regard.

Although U.S. citizens are proud of American medical innovations, they are increasingly less sure that the benefits of these advances have been universal. Only education, communication, and active outreach to and empowering of the community can address sources of tension and correct misunderstandings. This is the charge to technology innovators, users, and professional associations: to improve the quality of life for all citizens by harnessing the flow and improving the quality of information in the public domain.

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