

Virtual Mentor

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Patients, Doctors and Medical Device Technologies

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From the editor

Ethics in the age of medical device technologies

The infiltration of technology into all aspects of daily living was both rapid and pervasive during the latter part of the 20th century, and it changed the world in which we live. Medicine was not immune to this extraordinary revolution [1]. CT, PET and MRI scanners are now found in many hospitals around the country and have become important imaging modalities for most specialties.

Once-incredible advances in robotics are making their way into surgical practice [2]. Insights into the human genome and concurrent developments of gene-chip and nanoscale devices herald an era of personalized and personality-changing medicine [3]. At a more prosaic level, electronic thermometers and automatic blood pressure cuffs are now found in many doctors' offices.

Compared to the other branches of technology that promise to revolutionize medicine in the foreseeable future, namely, biochemical and information technology, medical device technology has deep ties with the medical fraternity. Physicians have driven the development of numerous devices to aid their practice in the past [4, 5]. Indeed, one of the defining aspects of the bond between the patient and physician, the stethoscope, was invented by a doctor.

The increased use of medical devices in all aspects of medicine has presented ethical challenges. Like the interaction between doctors and pharmaceutical companies, relations between physicians, hospitals and medical device corporations are necessary but fraught with ethical dilemmas. These dilemmas arise in educational settings, where doctors learn from company representatives how to use new devices, and in research ventures where physicians collaborate with companies. Because many medical devices are designed to prolong life in cases where pharmaceutical treatments have failed, they are frequently offered to extremely sick people. Hence their development must proceed in a highly supervised and transparent way.

At the other end of the spectrum, advances in diagnostic technologies allow doctors to find disease earlier and with greater acuity, sometimes preventing manifestations of complex disease. These technologies promise a new era of preventive medicine [6]. It is important to temper the public's and physicians' excitement about the potential of such technologies with accurate information for patients and proper use by physicians [7].

Recent innovations in medical science and engineering have led to great speculation about the advances that lie ahead [8]. With increased research into devices that blur the line between man and machine, medicine has the potential to redefine the concept of the self. Neuroprosthetics and other implants can alleviate the plight of many people with disabilities and may ultimately affect a wider public. The ethical ramifications of these technologies are likely to be hashed out not only in the medical arena but in society at large.

While it is probably true that all doctors, scientists and engineers design and implement medical devices with only good intentions, the rapid pace of their development and integration into medical practice and other areas of health care makes it impossible to anticipate all the possible consequences that may result from their use [9]. The stethoscope, for example, has come to symbolize the connection between the patient and doctor, while the use of newer devices are viewed as detracting from the intimate bond between the two parties. Use of heroic devices able to prolong the lives of patients who would otherwise die have transformed end-of-life decision making.

This edition of *Virtual Mentor* highlights some of the ethical issues that have arisen from the recent proliferation of medical devices and offers a glimpse at the ethical hurdles that can be expected from the expansion of medical technologies. The integration of biochemically inspired, information-related and device technology will drive the future of medicine. While it is not possible to cover all the questions raised by all devices currently in the market, we hope that the analyses presented here stimulate awareness of the ramifications of this whirlwind change and provide guidance in the face of the revolution that will impact not only our profession but all aspects of our lives for years to come.

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Clinical case

Ethics of cutting-edge device research

Commentary by Harvey L. Gordon, MD

Mr. Roberts was admitted to the University Medical Center with heart failure. He was well known to the staff, having had quadruple bypass surgery 10 years prior when he was 55. He had been a frequent visitor to the cardiology and surgery service with various heart complications since then. After a long night of tests and consultations, the cardiology team diagnosed Mr. Roberts with end-stage heart failure. Due to his past medical history, he was deemed to be ineligible for a heart transplant. Visibly distressed by the news, Mr. Roberts, his hands tightly clasping his wife's, asked the attending physician about his prognosis. In his current condition, he was told, he probably had a month to live. "Come on doc, there must be something you can do." The attending physician told Mr. Roberts he would consult with his colleague, Dr. Jones, to see whether there were any treatment alternatives.

Dr. Jones, an eminent cardiac surgeon at the medical center, had been preoccupied with transplants and machines since his medical school days. Although he had performed numerous heart surgeries in his 25 years of practice, the goal of creating a cardiac device that would eliminate the problems of rejection or failure had long been in his dreams. For the past 20 years, he had been developing an artificial heart in collaboration with its manufacturer, Hipprotech. In the past year the FDA approved the device for a clinical trial with humans, and 10 months ago they implanted one in a patient to much fanfare.

Although the implant occurred without incident, the patient sustained several embolic strokes and died after two months. The autopsy had shown a thrombus within the artificial heart, a problem thought to have been resolved in developing the device. After deliberating, Dr. Jones's group had decided to press ahead with the trial and to collect more data from the next eligible patient to determine whether the clotting problem was device-based or due to the patient, as well as to gather more data about the implant.

They could not decide, however, whether to disclose the clotting problem to the next patient. It was not part of the informed consent protocol, but some of Dr. Jones's colleagues argued that the problem might be in the device. They adjourned the meeting without a consensus. At that point, the cardiology service paged Dr. Jones with the news of a new candidate for the trial. Driving in to the hospital, he was excited about continuing his research. On arrival, he found that the patient's file was already on his desk. Eager to familiarize himself with the profile before talking to the

patient and family about joining the trial, he immediately flipped open the folder. To his surprise, the patient was one that he had operated on several times in the past decade: Mr. Roberts.

Commentary

This case illustrates a number of ethical risks:

- Mr. Roberts knows that with optimal therapy he probably has a month or less to live.
- An artificial heart (AH), a cutting-edge technology in early clinical trial, may be an alternative.
- The principal investigator for an experimental device is a surgeon who is deeply and emotionally committed to the success of the device.
- The principal investigator has been Mr. Roberts' surgeon in the past.
- The research team has not decided whether to reveal information acquired thus far in the trial to Mr. Roberts.

Informed consent

A physician is ethically and legally bound to obtain informed consent to treat a patient. The patient needs enough information to balance the benefits of treatment against its risks. The more invasive or dangerous the intervention, the greater the risk and, consequently, the greater the duty to inform. In human research risks may be greater than anticipated, and the benefits, only speculative. Moreover, the history of human experimentation includes many abuses of human rights. For a number of reasons then, there is a heightened ethical duty to obtain valid informed consent from research subjects [1, 2].

What might Mr. Roberts not realize about the AH? While it may pump efficiently, it can't reverse the consequences of chronic congestive heart failure (CHF). Chronic CHF is a systemic disease that can irreversibly damage the liver, kidneys, lungs and other organs. His postoperative care may be compromised, increasing the risk of complications. For example, it's possible that stroke-threatening clots might again form in the AH. With chronic CHF, Mr. Roberts might not tolerate prophylactic anticoagulation treatment without cerebral, gastrointestinal or pulmonary bleeding.

The chance of Mr. Roberts' living longer comes at a price—the risk of suffering and dying in an intensive care unit. Patients like Mr. Roberts who know they are close to death are sometimes unable to make fully rational assessments of their options. This may limit their ability to provide fully informed consent [3]. (Note that Mr. Roberts would be a patient-subject. For simplicity I will use the terms “patient” and “research subject” interchangeably.) Mr. Roberts may understand, but fear of death can evoke denial. He may not *appreciate* that he could himself experience a negative outcome [4]. It is ethically imperative for Dr. Jones to try to evoke both Mr. Roberts' understanding *and* appreciation. A person who not only understood but could identify with the risks, benefits and alternatives might well reject the AH in favor of hospice.

Divergence of goals

If Mr. Roberts enrolls in the AH trial he will encounter Dr. Jones in the changed role of clinical investigator. While sharing the hope that Mr. Roberts will benefit from the device, Dr. Jones's primary goal is to learn whether the AH can be an option for future patients with terminal heart failure. Although Mr. Roberts may wish to help future patients, his primary goal is to avoid dying of heart failure. Because he is accustomed to thinking of Dr. Jones as his physician, he is at particular risk for *therapeutic misconception*, the erroneous assumption that the AH is actually innovative *therapy*. Dr. Jones must make a clear distinction between treatment and research, both in goals and promises [3, 5].

Conflicts of interest

That physicians and researchers bring conflicts of interest to their work is inevitable and must be accommodated [3, 6, 7]. The first step is to recognize that the conflict exists. If an investigator stands to profit financially from the outcome of a study, the conflict can be addressed ideally by ensuring complete financial detachment. The conflict is more subtle when an investigator is so passionately committed to the success of the trial that he loses objectivity. In our case the only person to have received the implant died in two months. Dr. Jones's optimism has yet to be justified, but were he inadvertently to transfer that optimism to Mr. Roberts, it could distort the latter's ability to judge the risks and benefits of participating in the research. A few trials have provided subjects with an independent patient advocate, a knowledgeable third party committed exclusively to the interests of the research subject [8]. Absent a patient advocate, the primary physician or some other knowledgeable designate must act as a consent intermediary, identifying and redressing any lack of objectivity on the part of the principal investigator.

Updating the consent form

The consent form, approved by the hospital's institutional review board (IRB), reflects information known at the time of board approval. In one important case the courts chose not to require continuous updating of consent forms with evolving experience [9]. Nonetheless, IRBs that follow FDA guidelines periodically review consent forms to ensure that they reflect new data such as serious adverse events that might be related to the study device and that might materially affect risk-benefit deliberations [2]. While the legal requirement to update the consent form may be ambiguous, the ethical obligation to do so is clear. In this case, the consent form should be changed to reflect that clots and strokes have occurred, information surely relevant to Mr. Roberts' deliberations.

Withdrawing from the study

Patients often decide to become research subjects because of the possibility that the modality under investigation will offer a better outcome than conventional therapy. They are told that they may withdraw from the study at any time, without causing bias on the part of physicians toward their future care [1]. What would that mean for Mr. Roberts? His native heart will have been excised. As his candidacy has already been rejected, the AH can't be a bridge to transplantation; it is destination therapy.

And since there is no possibility of reverting to conventional therapy, “withdrawing from the study”—turning off the AH—could only mean certain and immediate death. Mr. Roberts must understand that once he has the AH there is no turning back.

How does one die with an artificial heart? Were the clinical trial to succeed, a new techno-ethical question would arise. Mr. Roberts may well suffer complications to which a biological heart would succumb, but, barring technical failure, the AH will pump until it is turned off. Death by cardiopulmonary criteria won't occur; waiting for brain death can make dying seem interminable. Both legal and ethical consensus support the right to refuse unwanted care, including life-sustaining therapy [10]. Because he may become incapable of making that demand, it is essential for Mr. Roberts to appoint a health care proxy to act in his place. Mr. Roberts needs to explain to both Dr. Jones and the proxy the circumstances under which he would no longer want to live. Should that point be reached, the proxy would be obligated to ask Dr. Jones to deactivate the AH, and Dr. Jones would have to comply.

Conclusion

With increasing regularity we are called upon to evaluate sophisticated medical technology for treating the most desperately ill patients. Meeting that task will require heightened ethical vigilance in studying innovative devices like an artificial heart and in recruiting patients like Mr. Roberts who are terminally ill.

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Clinical case

Turning off an implanted life-saving device

Commentaries by Lofty L. Basta, MD, and Katrina A. Bramstedt, PhD

Mr. Stone had been experiencing cardiac problems, ranging from chronic hypertension to cardiomyopathy, for about 10 years when he was diagnosed with heart failure and was told that he would need a heart transplant. With a heart not forthcoming in the near future, Mr. Stone's long-time cardiologist, Dr. Holmes, suggested the possibility of inserting a left-ventricular assist device (LVAD) as a bridging strategy while they waited for a suitable donor to become available. Mr. Stone readily agreed to the idea. At 53 and a mechanic by trade, he told Dr. Holmes that he would do anything to relieve the burden he was currently placing on his wife by being unable to work and asked that the LVAD implantation be done as soon as possible. Dr. Holmes asked Mr. Stone if he had changed his advanced directives since his last surgery: "No doc, I still got the DNR order in there. I don't want to be a burden if it comes to that." Satisfied, Dr. Holmes called the hospital and scheduled the surgery.

On the appointed day, Mr. Stone arrived at the hospital for the surgery, his wife, Martha, at his side. As he was being wheeled to the operating theatre, Mr. Stone gave his wife a quick peck on the cheek: "Don't worry, dear. I'll be back in a jiffy. Dr. Holmes will look after me." The operation itself appeared to be another routine procedure for Dr. Holmes. After closing up the last skin wound, he checked Mr. Stone's cardiac function. On finding that it had improved as expected, he went off to scrub down, leaving his nurse aide, Mary, to take Mr. Stone to the recovery room. As he was washing his arms, Mary rushed in.

"Dr. Holmes, Mr. Stone just had a seizure."

"Call neurology, Mary. I'll be there right away."

Anti-convulsant treatment stabilized Mr. Stone's condition and he was kept in the intensive care unit. Although he regained consciousness a few days after the surgery, Mr. Stone developed complications with pneumonia and was placed on a mechanical ventilator, forcing him to stay in the ICU.

The pneumonia failed to resolve in the following weeks. On consultation with the respiratory service, Dr. Holmes discovered that Mr. Stone's lung parenchyma had been irreversibly damaged and it looked like his condition would not improve much.

This was bad news; as a member of the hospital transplant committee, he knew very well that this would make Mr. Stone ineligible for a heart transplant.

Entering Mr. Stone's room, Dr. Holmes moved up close to the bed so that Mr. Stone could hear him better. "Mr. Stone, I am afraid that there are some complications to your case." Mr. Stone listened, and, apart from a few labored breaths on the ventilator as Dr. Holmes mentioned his loss of eligibility, he remained unemotional.

After Dr. Holmes finished, Mr. Stone shifted, and, motioning Dr. Holmes up close so he could whisper to him, Mr. Stone breathed: "You and I both know I'll be stuck like this for the rest of my life. I don't want to. This will blow our savings and I want Martha to get on with her life. Can you turn off the machine in my chest and let me be?"

Commentary 1

by Lofty L. Basta, MD

Death is a natural event. Every life on earth will have a beginning and an end. Thanks to astounding advances in medicine during the past half-century, health has improved for many. For some, the moment of death can be postponed by technological interventions, but the interventions may not bring back independence or former quality of life. Unfortunately, death has been transformed into a blame-seeking pathology. When someone dies there must be a mistake by an offender.

This mind-set is propagated among the lay public as well as among physicians and is fueled both by our health care system, which rewards the use of more interventions [1], and by our legal system, which punishes physicians who dare to do less than the latest tests—although fear of such reprisals tends to be greatly exaggerated. The inevitable result is that many dying people undergo procedures that they would not have chosen had the procedures and their ramifications been explained clearly—and understood—allowing them to make rational decisions [2].

The foregoing case does not present a true ethical dilemma; the patient had advanced heart disease that could not be improved by medication. After careful discussion with Dr. Holmes, Mr. Stone agreed to have a LVAD inserted as a bridge to a cardiac transplant. He was placed on the ventilator because of a postoperative irreversible lung disease that rendered him ineligible for a heart transplant. The fact that the patient was only 53 years old made an imminent death more tragic but did not alter the medical facts. He asked for his LVAD to be stopped and he wanted to discontinue all efforts to keep him alive by technical means [3].

The implanting of devices in terminally ill cardiac patients has proliferated enormously over the past 10 years to the extent that the majority of dying cardiac patients receive one or more devices before saying their final goodbyes [4]. This habit derives from a couple of sources: physicians' applying recommendations from studies to patients who may or may not be similar to the patients in the study and,

secondly, from patients' own preferences. Less influential in the clinical decision making are complications and failure rates of these devices and whether they interfere with the natural process of dying. It is as though inserting such devices in the dying has become the rite of passage before the death of a cardiac patient [5].

Informed refusal of treatment

Usually, left ventricular assist devices are employed as a bridge to heart transplant [6]. It follows that they should be discontinued once one is no longer a candidate for transplant. Unfortunately the decision is not that easy; recent research suggests that a significant number of patients with advanced cardiomyopathy show a reduction in heart size and improvement in left ventricular function after receiving these devices [7]. This recent data must be shared with the patient and a recommendation made about whether to keep the device for a certain period of time before discontinuation. Of course the ultimate decision will depend upon the nature of the original consent and upon a sincere discussion with the patient about the recent clinical findings. It must be emphasized that the decision either to persist with a treatment or discontinue it and bear the consequences rests with the patient; this is the doctrine of informed refusal of treatment. It is particularly applicable if the initial consent was for transient use of the device [8].

Physicians often are tempted to accept treatment burdens on behalf of their vulnerable patients and to act paternalistically, as if "the doctor knows best." This is wrong; the impulse must be resisted at all times. It is the sacred duty of the treating physician to fulfill the patient's expressed wishes [9]. Doctors have to learn to see through their patients' eyes [10] and understand that they are fellow human beings whose wishes must be honored and obeyed so long as they are not making irrational decisions prompted by dementia, pharmacologically altered mental states, depression or feelings of being unwanted.

Furthermore, advance care planning should be instigated by the primary care physician [11] and should address conditions of irreversibility when death is near and unavoidable. These conditions can be associated with states of unawareness, such as deep coma, advanced dementia or permanent vegetative state [12], dependence on machines, or eligibility for hospice care. The decision makers must determine when and how to use or withhold cardiopulmonary resuscitation (CPR), life-sustaining machines, antibiotics and blood substitutes, and artificial feeding and hydration [13].

Documents that outline the use or nonuse of life-sustaining treatment are widely available. One such document has been developed by Project GRACE and is available at no cost [14]. The patient can indicate decisions about specific interventions on the document after learning more about each procedure and the risks and benefits associated with its use. To leave these weighty decisions in the hands of lawyers or other parties who speak in vague legal jargon about the heroic, terminal and irreversible ignores the patient's right to make his own choices. As an example, patients with advanced but not terminal dementia who had complicating, but

potentially reversible, pneumonia—patients who stated that they wanted to die peacefully—ended up receiving aggressive treatment despite having signed such a legal document [15].

To let a person die by allowing nature to take its course is legally, morally and ethically right and, in the case under discussion, desirable. By contrast, to prolong a patient's suffering despite his request is morally and ethically reprehensible and should not be condoned [16]. For Mr. Stone, the left ventricular assist device and the ventilator only postpone his moment of dying; the intervention was initiated in the hope that he would recover lung function. The ventilator failed to achieve its desired effect, so Mr. Stone can no longer be a candidate for a heart transplant, and the treatment should be discontinued. Understandably, it is easier on the treating physician and the family not to initiate a certain treatment than to withdraw it, especially in this case where the device is implanted inside the body. Ethically, however, there is no difference between the acts of withholding and discontinuing life-sustaining treatment when a competent patient has requested it [17, 18].

Medicine was meant to be a loving, caring and compassionate profession [19]. It upholds the primacy of the patient's own wishes. The basic principles of medical ethics remain those of beneficence, nonmaleficence and justice. Beneficence means that the physicians have an obligation to further their patients' interests and welfare. Nonmaleficence dictates that they do no harm and minimize risks to their patients. Justice implies that there is fairness in distributing access to care and services across all patients without discrimination.

Where is nonmaleficence when, through modern medicine, we enslave an unwilling patient while we intervene aggressively in a terminal, irreversible condition? We render an otherwise peaceful death harsh. We may even be denying a spouse a decent life or a grandchild the opportunity to go to college by persisting with a futile, expensive medical intervention [20]. To die on somebody else's terms when you have clearly stated your choices is an unfortunate consequence of modern medicine [21].

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Commentary 2

by Katrina A. Bramstedt, PhD

End-of-life situations are rarely easy due to the emotional bonds between patients and families. Medical technology that prolongs life without cure or relief of suffering further complicates these difficult situations. Today, there are many life-saving medical devices such as implantable cardioverter defibrillators, pacemakers, ventricular assist devices and even a totally artificial replacement heart. These technologies bring the potential for additional ethical dilemmas at the end of life because they have the ability to keep the body alive in futile clinical situations (e.g., multiple organ system failure with sepsis).

Knowing a patient's values and preferences for health care is critical to medical decision making. When patients are alert and manifest the functional capacity to make their own decisions, they can cogently express their thoughts and desires. At the end of life, however, few patients maintain their decision-making capacity; they are often heavily sedated, encephalopathic or even comatose. In such cases, it is impossible to converse with patients to understand their wishes, so the medical team must turn to family, friends or prior known expressions of the patient's values. In these situations, medical personnel and surrogate decision makers can be assisted by the presence of the patient's advance directive (also known as a living will) [1].

A living will is a document created by adults at a time when they have decision-making capacity. These documents do not have to be drafted by an attorney, and in most states they do not have to be notarized. Their content expresses the person's wishes with regard to life-saving therapies such as cardiopulmonary resuscitation, ventilatory support, artificial feeding and hydration, and dialysis. Some living will template forms allow patients to note with a checkmark which therapies they want at the end of life (e.g., when terminally ill or permanently unconscious), and other forms allow individuals to insert text that specifies their values and wishes.

An alternate form of having one's wishes followed when one has lost decision-making capacity is the durable power of attorney for health care (DPAHC). On this form, adults appoint another adult to make their medical decisions when they lose the ability to do so themselves. Often the surrogate decision maker is a spouse, sibling or child, but a friend or clergy member can also serve in this role. Alternate surrogates can and should be named on the form in case the primary surrogate cannot be located, has died, or is otherwise unwilling or unable to function as decision maker. When living will and DPAHC forms are completed, a copy of each should be given to the individual's primary care physician, and one should be placed in the medical chart if the patient is hospitalized. Adults should have formal discussions with their surrogates about the contents of their living wills and be sure that the surrogates have copies of the documents.

Timely discussions with patient and family

In the case described, a ventricular assist device was implanted without a *detailed* prior discussion of the patient's health care values. While Mr. Stone informed Dr. Holmes that his advance directive specified no cardiopulmonary resuscitation be performed, there was no discussion between the two about the significance of the ventricular assist device in making the patient pump-dependent. In this way, the assist device would essentially provide constant cardiac life support, even in situations of clinical futility, unless it was turned off (deactivated) [2]. Such a concept can be psychologically stressful, thus the time for these discussions is before implantation, rather than afterward during critical clinical situations when families are stressed, emotions are strained and patients are often without the ability to make their own medical decisions.

At the Cleveland Clinic, it is standard practice for all patients who are being considered for destination ventricular assist device therapy (permanent implantation) to be evaluated by a social worker and an ethicist who ascertain the patient's current level of decision-making capacity and his or her understanding of the device and its function, the risks and benefits of the implant procedure, and the concept of pump dependence. All patients are also strongly advised to complete living wills and to appoint surrogate decision makers. For those who decide not to complete a living will, expressions of their values are documented in the medical chart for future reference.

At the end of life, when it is clinically and ethically appropriate to turn off medical devices such as ventilators and feeding pumps, the medical team must not forget other concurrent technologies, even if they are implanted in the patient. As an example, powerful shocks from an implantable cardioverter defibrillator at the end of life are not only burdensome, they can prolong the dying process [3]. Ventricular assist devices can keep patients alive almost indefinitely, while their bodies try to shut down and die. Turning off these devices is not a form of euthanasia because doing so allows the patient's disease process to progress naturally until it causes death. Nonetheless, facing these deliberations at the end of life without any prior discussion and contemplation can be very difficult for all involved.

In the case described, Mr. Stone's request for deactivation of his LVAD can be troubling for the medical team and family [4]. A clinician or ethicist should assess Mr. Stone's level of decision-making capacity and verify whether or not he understands his clinical situation and the implications of turning off the device (as well as keeping it on). Mr. Stone should be asked about the content of his advance directive in light of his clinical status and prognosis. Ideally, this discussion should occur first without family present, then with family at the bedside. All patient requests for device deactivation should be thoroughly documented in the medical chart, as should consultations with the medical team. In all situations, the wishes of a patient who has decision-making capacity should be honored. When patients lack this capacity, prior expressions of their health care values and preferences can be used by surrogates for decision making. If a patient's values and preferences are

unknown, decision making should proceed on a best-interest basis that reflects on the patient's clinical status (including coexisting technology burdens and benefits) and prognosis [5].

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Related article

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Clinical case

Risks and benefits of the new medical imaging enterprise

Commentary by Judy Illes, PhD, and Scott W. Atlas, MD

“Dr. Peterson, it’s been a while.” Lifting his head up from a plate of stuffed mushrooms, Dr. Peterson eyed a familiar face—Dr. Kelly. Although the two had been friends since the very first day of medical school, the residency match had assigned them to lives on opposite coasts; Dr. Peterson in internal medicine in New York; Dr. Kelly in radiology in Los Angeles, and they had lost contact. Indeed, one motivation to attend this medical school reunion was to finally catch up with each other.

“It has been a long time, hasn’t it? I really should have gotten here earlier, but our practice just opened a new clinic and I had to stay late, what with everyone cashing in on that coupon we placed in the paper. Here’s our new business card.”

Eyeing the card, Dr. Peterson noticed the bold letters: “Kelly Health-E-Scan: Full Body Imaging.”

“Our radiology group is creating a straight-to-the-public, full-body scan clinic. We have CT and MRI facilities in the office. We can see potential tumors and calcifications before they become symptomatic. Surveying the community around our practice, we found a sizable interest in such a service, and voila!”

It appeared that Dr. Kelly’s famous showmanship had not waned. But Peterson, ever the debater, retorted immediately.

“It does look snazzy, but don’t you think that it’s rather costly to do scans just on a whim? What about all those false positives? You could put patients through so much unnecessary grief.”

“We don’t just scan any guy off the street,” Kelly replied. “We have it all thought out; we make sure that the patient is at risk before we scan them. Our radiologists go over the results thoroughly with them and send a report to their primary care physicians. There will always be benign findings in every setup; I think it’s better to do these scans early and potentially save people from the blocked artery or a brain tumor. If the technology is there and a market for it exists from the patients, I don’t see why we shouldn’t allow patients to take their health care into their own hands. It doesn’t do them any harm. Come on, it’s the ultimate public health initiative; giving

the patient the latest and greatest to stop them taking up a hospital bed 10 years down the line!”

Commentary

While the American health care system leads the world in many aspects of medical innovation and advanced medical technologies, it also suffers from serious problems that form the context for any discussion of this scenario. The problems include, most notably, high costs that are still increasing and a growing number of people who are uninsured. More than 45 million Americans do not have health insurance, due, at least in part, to a lack of affordability. For those who do have coverage, indecipherable layers of complexity and restrictions prevail over personal choice.

On the one hand, drawbacks of the current U.S. health insurance system can be traced historically to the interposition of employers between individuals and access to insurance, as well as to complex government mandates and other multifactorial influences outside the patient-physician construct. On the other hand, virtually every country, regardless of the fundamental structure of its health care system and the degree of government regulation, is struggling to control costs while grappling with limitations in access to modern medical advances. Needless to say, there is no simple solution.

The U.S. health system is often held up as an example of the failure of “private” medicine, yet this characterization is misleading. Indeed, the vast majority of payments to physicians or hospitals are directly or indirectly set by government and not by market forces. Moreover, the U.S. has one of the most government-regulated health systems in the world—and at a huge cost. Beyond payment, the close linkage between employment and health insurance just mentioned has severely limited choice and autonomy for the individual patient. For these reasons, many policy makers and consumers welcome movement away from governmental dictates toward individual consumer empowerment with information and control of the health care dollar.

Unfortunately, imaging-based screening centers, as an example of consumer-directed care, have so far fallen short of their laudable goals. One serious limitation is that they require out-of-pocket payment because the vast majority of health care insurance policies do not cover such screening. This type of service, then, may be accessible only to the socioeconomic group that has the means to pay out-of-pocket or to consumers who carry newer high-deductible insurance with health savings accounts. Access and a means to pay, though, are only parts of the problem.

Notwithstanding the obvious irregular quality and other controversies about implementation [1], the basic idea of screening for disease at imaging centers should not be immediately discarded. These centers may potentially benefit consumers of health care a great deal. It is widely acknowledged that providing medical care only for those who are already sick is neither efficient nor optimal from a public health perspective. Thus, screening and preventive care with pre-morbid detection of

disease is extremely significant if implemented correctly. Estimates are that even a mere 1-percent permanent reduction in cancer death rates would save \$500 billion [2].

The case of Dr. Kelly

The case described by the dialogue between Drs. Peterson and Kelly is hardly fiction. More than 108 imaging centers offering heart, lung, brain and other scans exist in the U.S today. In 2001, 88 centers were operational, distributed across the country and highly concentrated in coastal regions such as California, Florida and New York [1]. The distribution has changed over the past five years, but only slightly. Peaks in areas of concentration are less sharp than before and centers are now distributed across 31 states. In Canada and Europe, availability is also increasing steadily [3].

Benefits. The potential benefits of consumer-directed, self-referred imaging are significant. At the top of the list is the possibility of a life-saving finding or early intervention by virtue of detecting preclinical disease. While a life-saving discovery may be rare, and empirically established true positive rates are not as well-documented as widely cited anecdotal testimony of good outcomes, the early detection of subclinical disease has undeniable value. Second on the list of benefits is patient empowerment. For individuals to take control of their own health care is a good thing—for them and for society—assuming that appropriate access to information, full disclosure about risks and assistance for follow-up by physicians is available. Third is autonomy and privacy. In this electronic age when personal privacy may be all but an illusion, the opportunity to seek a medical answer to a nagging private question outside the traditional health care system is also desirable. This is true whether a consumer-patient is entirely asymptomatic and seeks reassurance of fine health or is one who worries in the wake of a medical scare.

Risks. A list of risks arises from indiscriminate use of imaging marketed to consumers without physicians in the loop. Our own work has shown that, given the current culture, design and framework for screening imaging, risks outweigh benefits in number and quality. The risks include:

- Psychological, health and financial costs of false positive findings and the potential for unnecessary, invasive follow-up tests.
- Risks incurred when an anonymous diagnostician relays highly significant information to a patient with whom he or she has no relationship or rapport.
- Diagnosis with no available therapy.
- Lack of standards for disclosure of benefits and risks.
- Caregiver conflict of interest.
- Unregulated quality control of radiologist and scanning methods and equipment.
- Risks of radiation from repeat CT scans; patients may visit many centers, and record-keeping across centers is not required.

- Inadvertent changes to patient lifestyle due to over-confidence in clearance from disease by screening imaging technology.

The impact of misleading marketing and advertising must also be taken seriously [4]. There is no question that competition among health care professionals is beneficial to all, but in medicine, where the asymmetry of information between clinicians and patient is high, competitive marketing can lead to problems. Most worrisome are aggressive advertising campaigns aimed at vulnerable prospective consumers: the patient who suffers from mental illness or the patient who is desperately seeking relief from untreatable disease or incompletely explained symptoms. The free availability of a wide range of information on the Internet is extremely positive, but the very nature of the Internet also allows medical information to be of variable quality, completeness and reliability, which exacerbates these risks [5].

Conclusion

Unlike the sales and marketing of pharmaceutical products, the market for consumer-directed imaging is currently unregulated and suffers from dramatic variations in quality on numerous levels. Individual physician caution, improved information and organized professional self-regulation would go a long way in ensuring the integrity of the practice and tipping the scale towards benefit over risk for the consumer. While current implementation of consumer-directed imaging centers for disease screening is problematic, the potential benefits of such technology should compel interested parties to figure out how to make it work for patients.

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Clinical case

Guiding patients toward prudent use of technologies

Commentary by Pamela Saha, MD, and Subrata Saha, PhD

Dr. Lee runs a health care clinic in a suburb of New Jersey. Because it is the only primary care clinic in her small neighborhood, Dr. Lee has given continuous care to many of her patients for a long time. She enjoys working in such an environment; not only does she have strong relationships with most of her patients, but her intimate knowledge of their health history allows her to diagnose and manage many of their problems effectively. To supplement this, she actively keeps up to date with the latest treatments and medical information, especially those that relate to the health problems of her patients in the clinic.

Mrs. Williams, a regular clinic patient, came by because of back pain that she had had for a week. After completing a thorough physical check-up and precautionary X-ray, Dr. Lee concluded that the back pain was due to a slight muscle strain, and she prescribed some analgesics to relieve Mrs. Williams' discomfort until the strain healed.

As she did during every patient visit, Dr. Lee asked Mrs. Williams, who was a librarian and 52 years old, if there were any other concerns she wanted to talk about. Mrs. Williams told her that she wanted an MRI of her back. "My friend Laura had some back pain a while back, just like what I have now, and it turned out to be a herniated disc." Dr. Lee was sympathetic to Mrs. Williams' concerns, but she explained that her physical exam did not indicate any need for a scan right now. "From my experience," Dr. Lee said, "a \$1,000 MRI is not necessary. I think that it would be better to wait a few weeks to see if the pain, which appears to be due to a muscle strain, subsides before we consider a scan."

Mrs. Williams remained insistent on obtaining a referral. "After all," she argued, "the technology is there to diagnose problems, so why don't we use it, Dr. Lee? Better safe than sorry, right?"

Commentary

The case of Mrs. Williams and Dr. Lee is common throughout the country. It raises many issues, which include public perceptions and expectations of technology, trust in the patient-doctor relationship, lawsuits, cost, marketing strategies by the biomedical and pharmaceutical industries, and concepts of patient empowerment and autonomy.

Expectations

Technology has helped create a more evidence-based model of medicine and has reduced much of the subjectivity in clinical decision making. Improvements in the accuracy of diagnosis and in the effectiveness of treatment continue to raise public expectation of solutions once thought unattainable. Technological “miracles” have created demand for the best and the perfect. But technology’s limitations remain under-appreciated or incompletely understood. Advanced diagnostic testing such as magnetic resonance imaging (MRI) is often perceived to be the sole means of establishing a diagnosis or planning treatment. This is not only a misperception of the public, it is also a stumbling block for physicians.

Even when a specific test or scan would provide no added clarity in a given clinical situation, it is still often viewed by patients as more reliable than an unaided physician’s assessment. This is a perplexing phenomenon, given the common patient complaint that physicians do not spend enough time listening to them the way an empathetic human would and an instrument most certainly cannot.

An MRI study is superior to X-ray studies in detecting joint erosion and soft tissue damage, but the correlation of MRI findings with clinical presentation is not reliable [1]. A patient may experience significant disability and pain with minimal signs on radiological studies (X-ray or MRI). Another may have significant signs on an MRI and be relatively asymptomatic. Over-reliance on the MRI or X-ray at the expense of the clinical picture can become a barrier rather than an aid to communication with the patient.

Educating patients about the limitations of the technology, the meaning of the results and the implications of various results for the treatment plan could bring about greater acceptance of the proper timing for the use of the technology.

Patient-physician relationship

Mrs. Williams’ concern should not be dismissed; anxiety can aggravate her back pain by causing increased muscle tension and strain. Likewise, Dr. Lee’s established relationship with Mrs. Williams is based on trust, which is threatened by the possibility that Dr. Lee may be withholding the best care available because she doesn’t deem it necessary at this time.

Should Dr. Lee consider an MRI to relieve Mrs. Williams’ anxiety and retain her confidence? Not necessarily. Dr. Lee can lessen Mrs. Williams’ anxiety by exploring the source of her concern and educating her on the signs and symptoms found during her physical exam and their implications for treatment. Most importantly she must assure Mrs. Williams that her complaints are not being dismissed and that whatever might appear on an MRI would not alter the initial treatment recommendations significantly. More aggressive treatment including surgery would still be preceded by approaches associated with less risk. A trial of analgesics is a good example of a conservative approach. Mrs. Williams’ pain and anxiety can be addressed by

acknowledging that, although the X-ray showed no changes at this time, her complaints are taken seriously and will be followed systematically.

Defensive medicine: the influence of litigation

Lawsuits have been found to be related more to patients' anger than to adverse outcomes [2]. Although such suits seldom result in decisions against the physician, they can still have a negative impact, resulting, for example, in demands for reporting credentials to hospitals in order to gain privileges and to health insurance plans in order to be included as providers. The very fact of the suit can complicate procedures for gaining future state licenses and may wind up in public online disclosure in some states [3, 4]. Attorneys are able to file suits on limited grounds that nevertheless may require a physician's attention for years before being removed from the court file. Aware of these tort abuses, some physicians may decide to give patients what they want rather than risk frivolous lawsuits.

Will an MRI protect Dr. Lee against litigation in Mrs. Williams' case? While a negative MRI result might diffuse her interest in suing, Dr. Lee's attempts to reduce her fear, anger and loss of trust will trump MRI results. It is far better to focus on the patient than on the demanded technology.

Cost

Insured patients' disregard of cost (because they are not paying out-of-pocket) promotes overutilization of expensive tests, as physicians struggle to assure their patients that the best care is not being withheld. While one may believe that "best care" for every sprained knee in the ER includes MRI and other studies to rule out osteosarcoma, acting on such a belief would soon bankrupt the U.S. health care system, and it would delay treatment for patients who must sit and wait while an extensive work-up of all complaints takes place. Physicians must speak out as a group and educate the public on judicious use of medical technology to ensure that proper interventions are available when they truly *are* needed.

Marketing

Information on the latest drugs and technologies is available on the Internet, in self-help books and even on television. TV ads recommend that patients ask their physician about specific products. Representatives from the pharmaceutical and biotechnology industries approach physicians with gifts intended to sway them to use and prescribe the company's products. Industry's entrepreneurial activities increase public interest in brand name products but also create the fear among prospective patients that they may not have access to the right treatment unless they ask for it themselves—that their physicians may not be knowledgeable about a product or simply may not think that the patient needs it at a given time.

Patient autonomy versus paternalism

This wide access to information has resulted in significant behavior change. Patients now shop for medical information as freely as they do for recipes, which gives them a greater sense of power over their care and an impatience and suspicion of

physicians who do not share their views of diagnosis and treatment. Respect for patient autonomy is increasingly coming to mean that the patient informs the physician of the diagnosis and treatment plan. Having a medical opinion informed by years of training, testing and governmental oversight that does not agree with the patient's self-assessment and Internet search has suddenly become "paternalism."

Entitlement versus allocations of resources

The notion of rationing scarce resources is well understood in other nations, but not in America, where needs are believed to be entitlements. Medical care is certainly a necessity. It can even be argued that access to a basic level of medical care should be available to all [5]. Taking this a step further, one can ask whether the most expensive medical care should be available to all. There are likely to be more affirmative answers to that question in America than in any other nation. This is partly due to the high expectations of excellence in America and partly due to the sense on the part of many that they are entitled to have anything they need.

Conclusion

We have looked at a few issues that are raised daily all across the country in cases similar to that of Mrs. Williams and Dr. Lee. The physician has the daunting task not only of communicating effectively with individual patients but of serving the public interest through just allocation of available resources. If health care is going to be optimized for all, an understanding of the proper use and application of technology will need to be guided by those most in the position to do so. Certainly that should include physicians.

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Medical education

Corporate sponsorship of continuing medical education

by Rosamond Rhodes, PhD, and James D. Capozzi, MD

Everybody knows that advertising works. Corporations that pay for it know that it is effective and that their investment in product promotion is well spent. Advertising even works effectively on physicians; recent studies have irrefutably demonstrated that advertising has a direct impact on physician prescribing patterns [1-4]. Nevertheless, most physicians, even those who are aware of the data, consider themselves to be immune to the phenomenon, and, because the effects are invisible to each affected individual, they continue to deny that they are or can be moved. Physicians may, therefore, be dismissive of concerns about conflict of interest that are raised by the gifts and the attention of drug and medical appliance manufacturers. The obvious problem with accepting manufacturers' largesse is that physicians' critical assessment of products may be dulled and their judgment skewed away from a profession-directed focus on the benefit of patients. That influence, coupled with the pervasive denial of the phenomenon, creates one arm of this dilemma.

The other arm relates to the need for medical education in the face of current financial arrangements that leave institutions of academic medicine unable to fund important training programs. Current U.S. tax policy allows corporations to accumulate the wherewithal to fund product promotion and enables them to write off product promotion costs as business expenses. The only restrictions on product promotion business activities are minimal fair-trade, truth-in-advertising standards. At the same time, current U.S. policies for funding medical education are woefully inadequate for meeting the need to keep physicians up to date with rapidly advancing pharmaceutical and technological developments. Physicians cannot do the best for their patients when they are not well-informed about relevant scientific advances, the latest developments in drugs, surgical techniques and medical devices or when they do not have the opportunity to develop and refine their skills in using them. Continuing medical education is an essential feature of physicians' professional responsibility. Patients can miss opportunities for better outcomes or can suffer harm because of the lack of physician education.

While a change in our tax structure could, in the future, go far toward resolving the dilemma of either forgoing crucial physician education or funding it through means that can generate conflicts of interest, in the here and now choices have to be made. The American Medical Association Council on Ethical and Judicial Affairs (CEJA) [5] and the American Academy of Orthopaedic Surgeons' (AAOS) Committee on Ethics [6] should be applauded for their efforts to outline a path between the Scylla

and Charybdis of compromising options. As philosopher, political theorist and historian of ideas Isaiah Berlin noted,

...the ends of men are many and not all of them in principle compatible with each other, the possibility of conflict—and of tragedy—can never be wholly eliminated from human life, either personal or social. The necessity of choosing between absolute claims is then an inescapable characteristic of the human condition [7].

A caveat that should be gleaned from Berlin's insight is that no plan or guideline for navigating such situations can avoid transgressing ethical borders. Every resolution reflects the competing hazards and advantages. No concession can claim ethical purity; that is not in the nature of compromise. Guidelines can only identify some of the key considerations and provide reasons that publicly explain their importance.

When comparing the competing goals of promoting medical education and avoiding conflict of interest, the likelihood and significance of the opportunities lost by forgoing what industry offers have to be assessed and compared to the likelihood and significance of undue influence on physicians' judgment. In sum, the question that must be considered is whether the package being offered is worth the costs. We consider the following criteria to be critical:

1. The accessibility of information without industry interaction is an important consideration in deciding whether to allow any extra opportunity for industry influence on physician judgment and decision making. When information is available through journal articles or other nonindustry-sponsored medical education, no form of gift is acceptable. Education through less-biased means, even though it may require greater effort, is more useful, less likely to be corrupted by industry agendas and less likely to corrupt physician judgment. Sometimes, however, particularly in the use of medical devices, essential training is available only through the manufacturer, and sometimes that limitation is well justified by the need for the equipment or facilities and the manufacturer's expertise in its employment.
2. The likelihood of influence has to be considered. Current policies tend to focus on restricting cash incentives to physicians and other services or items that have financial value, and they overlook forms of interaction which may be even more likely to affect physician judgment. Industry public relations experts know the power of personal contact—drug reps are typically young, attractive and personable. Ad experts are also aware of the social and psychological significance of breaking bread together. Some personal contacts can be more seductive than cash, and their effects can be more difficult to discern. Furthermore, a physician's eagerness to be the first one in the neighborhood to have some new piece of equipment or just to do something different is psychologically compelling and may also be part of a (self-interested) physician's marketing considerations. These facts must be taken into account when policies are set.

3. The importance of the education for patient well-being and the likelihood that physicians will avail themselves of it without industry support or incentives has to be assessed. Development of a new skill that requires training will also take time. Yet, if the skill is a necessary addition to the physician's armamentarium and if taking the time to learn it properly will minimize risks to patients, a financial incentive to encourage physician participation can be justified. Some education may be so career-enhancing that physicians will pay their own way to develop the expertise. Other training may require considerable personal sacrifice and confer significant patient advantage but little personal reward. Drawing a line in such circumstances turns on an assessment of what it takes to move those who need the education to get it.
4. The likelihood and degree of the possible harm of accepting the gift must also be taken into account. Little harm can be done when a physician receives some incentive to use one device instead of a similar device of the same quality. When differences in effectiveness or cost between the alternative treatments are substantial, however, gifts and incentives can lead to significant harm. Furthermore, some incentives (e.g., the lavish, all-expense-paid golf vacation) are so costly and so poorly justified that they can harm not only patients but the stature of the profession.

These considerations suggest at least one guideline that appears on neither the AMA's list nor that of the AAOS. Before accepting any industry-sponsored education or incentive, a physician should make a sincere effort to form an independent evaluation of the product. He or she should review the professional literature, examine a sample and consult colleagues. Only when a product appears to warrant further exploration and the information can only be obtained through a corporate-sponsored venue should a physician open the door to industry.

Clearly, the relationship between physicians and industry is controversial, the relative importance of the factors that have to be taken into account is uncertain, and thoughtful people can draw lines in different places. This conclusion should not be surprising precisely because judgment is critical to the analysis and because dilemmas require us to prioritize competing and important values that reasonable people may rank differently.

Notes and references

This paper draws on two previous articles:

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Journal discussion

Diagnostic tools and the hands-on physical examination

by Douglas P. Olson and Katalin E. Roth, JD, MD

Phoon CK. Must doctors still examine patients? *Perspect Biol Med.* 2000;43:548-561.

Technology is continually redefining the practice of medicine. From sophisticated tests in tertiary medical centers to the advanced technology now available daily in outpatient settings, there is no question that new discoveries, devices and laboratory tests have altered the way in which physicians diagnose, treat and palliate disease. Whether or not the introduction of new methods to improve health will alter the role of the physical exam in disease diagnosis—or the patient-doctor relationship itself—is an important topic to consider.

In “Must Doctors Still Examine Patients,” [1] Colin K. Phoon argues that technology threatens to alter the way physicians practice medicine. He defines physical examination as the physician’s routine assessment of a patient using the five senses and minimal invasiveness, using, for example, a stethoscope or ophthalmoscope but not a colonoscope. Phoon eloquently traces the physical exam back some 6,500 years to the Chinese, showing its evolution throughout the time of the Egyptians, Hippocrates, and up through the era of Osler and Taussig, declaring that the achievements of the latter two physicians are “[mostly] based on observation and physical examination...[and have formed] essentially the medicine of today” [2], and supporting this idea with a quote by Osler stating that “the whole art of medicine is in observation” [2].

Phoon goes on to assert that the physical exam serves functions beyond diagnosis, such as improving the patient-doctor relationship and maintaining the revered status of the physician in society. He believes that the physical exam is still the most effective and efficient means of diagnosis despite the high degree of specialization and the availability of so many tests. He acknowledges that, because of advances in technology, the physician’s reliance on physical touch to diagnose and interact with patients has decreased, which has distanced the physician from the patient, a point that another author, J.G. Bruhn, made more than 20 years earlier [3].

Playing devil’s advocate, Phoon presents several arguments in favor of the physical exam’s becoming obsolete, even citing an article in *Time* magazine entitled “Will Robots Make Housecalls?” [4] to bolster the argument from the lay press. Phoon suggests that an alternative to the psychiatric mental status exam may be an analysis of biochemical markers in the brain, and that the heart exam may be transformed into a single, all-powerful scan, before concluding that the physical exam “cannot hope to compete” [5].

If the aim of medicine were simply to diagnose, the physical exam might well lose out in competition against a “Star-Trek” scanner approach to medicine. But what of assessment, prognosis and the all-important physical connection between doctor and patient? Phoon himself, a proponent of advancing technology, concludes in his article that the “physical examination will remain an important part of the everyday practice of medicine” [6].

Technology and the practice of medicine have fused well at present. The careful history and physical examination remain the backbone of medical practice. There are a host of pragmatic and ethical reasons for this, a discussion of which follows.

The “physical”—a constant in medicine

The history and physical exam (H&P) are among the few commonalities in medicine, practiced by every physician trained in every country throughout the world. Indeed, anyone who has practiced or observed medicine in resource-poor settings knows that it is often the only method available for diagnosing a patient’s illness. While medical care has become increasingly specialty-oriented in the United States, the model of the general practitioner relying on the physical exam as the basis for diagnosis and treatment prevails. Because the majority of the world’s population resides in areas where physicians do not have consistent access to the latest available technology, physical examination continues to define the profession. The H&P has received renewed attention in medical schools [7] and forms an important part of the core curriculum for training future generations of healers. So every patient, whether afforded a technologically advanced scan or test, whether in the United States or the hinterland of a developing nation, whether presenting for a routine exam or being considered for hospice care, can be guaranteed a physical exam. As Phoon states, “If it is good for the patient, shouldn’t we use it?” [8] This is especially apt for the physical exam.

In today’s era of rapid global travel, where diseases such as avian flu and SARS (severe acute respiratory syndrome) know no boundaries, when malaria, dengue fever and other diseases are suspected in travelers or immigrants, it is often the physical exam that alerts the astute physician. Sometimes physical signs of the disease become recognizable to physicians before the disease is even understood, as was the case when physicians recognized the classical presentation of AIDS before a lab test was developed for the human immunodeficiency virus.

Legal aspects

There are reasons to perform a physical exam that go beyond the universality of the tradition. Current billing regulations by Medicare and Medicaid mandate that physicians perform key components of the physical examination [9]. Physicians who want to be paid must often confirm that they performed these parts of the exam. To simply complete the insurance form and not do the exam is not only unethical but unlawful.

While it is arguably a poor reason to perform medical procedures, the very litigious nature of medicine in the United States demands not only continuation of the

physical exam but competence in performing it. Studies have shown that the single best way to avoid legal proceedings against oneself is to have strong, trustful and well-developed relationships with one's patients [10]. The physical exam assists in this by emphasizing the physician's touch, listening ear and empathetic words of concern and advice.

While the litigiousness of U.S. society might demand a physical exam, and while time spent with patients might decrease the number of lawsuits, evidence abounds that patients simply like to spend time with their physicians and are willing to pay for it if they are able to [11]. The skillful performance of a physical examination is of considerable therapeutic importance. Through it, the patient acknowledges his trust by permitting the physician to touch his body, and the physician demonstrates fidelity to the relationship by taking the time to see, hear and feel what the patient's body reveals.

Is reliance on technology eroding skills?

Phoon's skepticism may arise, in part, from his background in cardiology, a field that has seen impressive advances in technologies for diagnosing and treating illness. Other fields still rely more upon skillful physical examination. Dermatology very much depends on human observation and palpation for the recognition of tumors, rashes and other skin conditions. Neurology, while enhanced greatly by noninvasive radiographic scans, depends on the physical exam to correlate pathology with functional changes. Rheumatology, which has been augmented by the development of specific tests for disease, must first rely on the history and physical exam to suggest disease. For example, while the physical exam cannot compete with the specificity of a positive test for the SCL-70 antigen, the test is not currently, nor in the foreseeable future will it be, ordered to diagnose scleroderma in the absence of symptoms identified on physical exam, false positives notwithstanding.

Someday a field like psychiatry, which depends heavily on the patient-doctor interaction, may indeed be altered if a physical test is identified that allows a physician to diagnose schizophrenia on laboratory data. Yet more definitive diagnostic tools will not solve the ethical dilemmas that often permeate the practice of psychiatry. For example, obtaining informed consent for a spinal tap from a schizophrenic patient will continue to be ethically problematic, even if there is a high probability of attaining diagnostic certainty.

How do these arguments fit with observations that the physical diagnosis skills of medical students, residents and fellows are declining? While we may insist that the physical exam remain an integral part of physician training, evidence suggests that trainees' evaluation (or promotion) is not always based on competency in these skills. Several investigators have identified "disturbingly low" levels of competence in bedside cardiac auscultation among physicians in training when compared with competency levels of more than ten years ago [12, 13].

It remains to be seen whether new methods of teaching and testing for the skills of physical examination (patient models, heart sound machines, etc.) will actually

improve diagnostic assessment. Skills are learned and practiced most during the training years and serve as a base for additional learning, refinement and experience. Skills not emphasized and honed during the training years are unlikely to improve later. Yet, although the physical exam remains a cornerstone of clinical medicine throughout the world, doctors actually touch patients less, and the mastery of examination skills at every level of training has decreased over the years. [13, 14].

No one knows whether the decrease in physical exam acuity has affected physicians' abilities as diagnosticians. From a strictly clinical sense, we would argue that it has not; physicians still diagnose disease as well as generations of physicians did before them. But with echocardiography readily available, few physicians would trade a certain diagnosis of a diastolic mitral murmur complete with flow velocities, leaflet visualizations and ejection fractions for a "highly likely" diagnosis by physical exam. Alternatively, a disease presentation "highly suggestive" of rheumatoid arthritis can sometime be both confirmed and followed by laboratory testing including anti-Smith, anti-dsDNA and RA antibodies. Technology aids advanced diagnosis, but determining what must be confirmed or ruled out depends on a proper H&P.

Improving differential diagnosis

This may be where advanced technology can and has helped best—in teasing out differential diagnoses. Initial diagnoses are still heavily observer dependent, and they flow from the physician's experience and clinical acumen. In today's U.S. medical environment, however, whether a cardiology attending physician or a third-year medical student hears a persistent murmur, the patient can be reasonably certain that he or she will be sent for an echocardiogram and EKG.

Ethical considerations

Is it ethical for technology to have this role in diagnosis? A knee-jerk response might be an emphatic "yes." A more thorough consideration of the question, however, challenges this initial response. In an environment of soaring health care costs, large numbers of uninsured patients and an ever-increasing gap between rich and poor in the United States, should we continue to spend money on advanced diagnostic tests when some of the information might be gleaned more economically from the physical? Unfortunately, unless the litigious nature of medical practice changes, this trend toward dependence on technology will probably continue in the U.S. The flip-side to this is the notion that more time spent listening, examining and physically touching a patient contributes to a decrease in the number of lawsuits [7]. This means that doctors must strike a balance between advanced technology and physical diagnosis, machine testing and bedside acumen.

International medical graduates must demonstrate proficiency in medicine by taking the USMLE Step exams before they are allowed to practice in the United States, even if they were already practicing medicine in their own country. Should the growing number of U.S. medical graduates who want to practice in resource-poor settings and areas that rely heavily on the physical exam be required to show that

they can perform one? The requirement for such a competency exam might draw more support from ethical than from legal arguments.

Conclusion

Phoon's take-home message is that technology has greatly influenced medicine and will continue to do so. He proposes several scenarios that might portend an ever-declining role for the physical exam as increased use of technology becomes more prominent in health care. We think, however, for the many reasons explored in this essay, that the physical exam is and will remain firmly entrenched as part of diagnosing disease and developing the patient-doctor relationship.

There is no doubt that the medicine of the last century is not the medicine of today. But one characteristic is constant: the human desire for trust and understanding, especially when one is sick and vulnerable. Upon this constant is established the efficacious and therapeutic patient-doctor relationship. Like the marriage of bench science to improved disease treatment and outcome, practiced by Sir William Osler and many before and after him, physical diagnosis must be fused with technology to diagnose and treat disease. As Osler himself said: "Learn to see, learn to hear, learn to feel, learn to smell and know that by practice alone can you become experts" [15]. Perhaps the fusion of the physical exam, technology and research can help physicians become more accurate, quicker diagnosticians and healers while maintaining the crucial human bond forged through personal interaction and improve patient care in the process: goals embraced by all.

Question for discussion

How should medical education address the convincing evidence that physician trainees of today are less astute at the physical exam than those who came before them?

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Clinical pearl

Imaging modalities for back pain

by Preeti A. Sukerkar

Back pain costs our society \$20 billion to \$50 billion annually, afflicts 80 percent of the U.S. population in one form or another, and disables 1 percent completely [1, 2].

Back pain can arise from any of the spinal structures, including the bone, muscle, ligaments, fascia, nerve roots and vessels [3]. The most common problems are musculoligamentous injuries or degenerative processes (disc herniation and osteoporotic fractures). But back pain can also result from spinal stenosis, infections, cancers and traumatic fractures and can be referred from visceral organs.

Unnecessary imaging leads to overdiagnosis and excessive expense [4, 5]. In about 85 percent of cases, imaging reveals only nonspecific findings [6]. Judicious use of imaging can be of great value, however, in discovering the cause of pain. The choice of imaging technique should be guided by the patient's history and the physical examination. Critical to the diagnosis is the proper assessment of the type of pain experienced (e.g., is it local, referred, muscle spasm). In referred back pain, physical examination should include the rectum and palpation of visceral organs in the abdomen. Neurological and musculoskeletal examination can pinpoint specific nerve root lesions or muscle spasms [1]. Once a working diagnosis has been established based on the history and physical, the following imaging techniques can be used to confirm it or rule it out.

Radiography

Radiography is useful for diagnosing skeletal lesions due to trauma, systemic disease or iatrogenic causes such as steroid use [3]. Radiographs (X-rays) can also give information about unstable or degenerating intervertebral discs by showing change in vertebral structure early in the disease [7]. Two orthogonal views are generally sufficient to characterize the nature and location of a lesion in bone, but soft tissue damage cannot be assessed [8]. Generally, X-ray is a good starting point and is best used as a screening test for misalignment or shape change of the vertebrae. The cause (osteoporotic fracture, tumor, infection, etc.) of such a finding may not be clear from the radiograph [9].

Computed tomography

Computed tomography (CT) can take the place of more invasive imaging techniques such as myelography, epidural venography and epidurography [7]. It is more helpful than radiographs because of the fast acquisition times, high resolution, and 2-

dimensional and 3-dimensional detail it provides, especially for complex vertebral fractures. It should be performed when radiography is inadequate [10]. CT is optimal for imaging of bony lesions and may catch problems that will be missed on traditional X-rays, which provide more limited views [1]. Imaging of soft tissue is better with CT than with radiography (although CT is inferior to MRI in this respect). CT may not distinguish symptomatic findings from incidental ones, however, leading to overdiagnosis. For example, herniated discs may show up on CT, but may not be the cause of pain [11]. CT subjects the patient to more radiation and is more expensive than a plain radiograph, but it gives more information than an X-ray and is a good alternative when MRI is contraindicated, as in the case of claustrophobic patients or those with pacemakers.

Magnetic resonance imaging

Magnetic resonance imaging (MRI) and CT myelography are comparable in diagnosing spinal stenosis or herniated discs. MRI may be somewhat more sensitive to and specific for herniated discs [10, 12]. It is superior in detecting infections like osteomyelitis and bone or soft tissue tumors, in terms of both sensitivity and specificity [3, 12]. It is also best for soft tissue imaging. In general, MRI is the best tool for diagnosing patients with lower back pain because it picks up a greater number of abnormalities than radiograph or CT [13]. MRI is the only imaging technique that allows direct visualization of the spinal cord and is therefore the best means for diagnosing congenital spinal lesions, myelopathies and metastatic cancers [10]. Because MRI does not use radiation, it is safer than X-ray and CT, but it is more expensive than they are, which may be a concern for some patients.

Ultrasound

Ultrasound is noninvasive, inexpensive and able to image soft tissues. Moreover, there are no contraindications for ultrasound as there are for MRI. Ultrasound scans have been able to provide structural information about intervertebral discs that can be related to their pathology [14]. This is not a common technique though, and while sensitivity in finding painful and degenerative discs is high, specificity is low [15]. More studies must be conducted to determine its value in diagnosing disc pathology. It is very helpful in determining whether pain may be due to visceral organs. For example, ovarian cysts are easily diagnosed this way and may be the cause of back pain.

Nuclear scan

Bone scans (skeletal scintigraphy) are informative in excluding tumor, fracture, metabolic or degenerative changes in the bone, necrosis or infection. Bone scans are more sensitive than radiographs and are able to determine various pathologies with high specificity by identifying areas of new bone growth or breakdown [16]. Positron emission tomography (PET) is also revealing, especially for finding cancers. While PET scans do not offer as much detail as CT or MRI, they can detect changes in metabolic activity and are highly sensitive for early detection of cancers that may be causing pain. It may even pick up on a cancer earlier than CT or MRI and therefore

may be the best imaging option if cancer is suspected [12] . Nuclear scans expose the patient to about the same amount of radiation as a radiograph.

Excessive imaging is costly and ineffective. Therefore, the imaging modality should be chosen based on the patient's history and physical. Generally, the best imaging option for determining a cause for back pain is MRI. Other imaging modalities can be advantageous in the specific situations outlined above.

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Health law

Waiver of consent in medical procedure research

by Matthew Stonecipher

The phase 3 clinical trial of a blood substitute called PolyHeme recently concluded, and its preliminary results boded a not-so-happy new year for developer Northfield Laboratories and its investors [1].

PolyHeme test subjects were individuals in hemorrhagic shock, to whom the oxygen-carrying blood substitute was administered in an ambulance and continued for 12 hours after arrival at a hospital [2]. Northfield CEO Steven Gould contends that the study data are susceptible to different interpretations, but it is not only the results that are controversial; many have criticized the trial design, claiming that certain stages violated federal regulations and were unethical [3].

Most of the scrutiny stems from the characteristics of the subject population—severely injured people who were incapable of consenting to or refusing the experimental treatment. The FDA allows for “waived consent” research under its provisions for protection of human subjects in 21 CFR sec. 50.24, but demands greater patient protections in such situations [4]. Its critics say that the PolyHeme trial, despite its FDA approval, was not in accordance with a plain reading of federal regulation of waived consent research because, once the patients-subjects reached the hospital, a standard and effective treatment—blood—was available but was not given to them. The Northfield case exposed ambiguity in interpretation of the FDA regulations that undermines the intent of that agency’s narrow waiver of informed consent in specific types of research.

Informed consent is the cornerstone of clinical medicine. Under American and common law, each person “is considered to be master of his own body,” and has the right to authorize or decline medical treatment [5]. Failure to obtain informed consent creates liability for medical battery, unless the treatment falls under the emergency care exception [6]. The emergency exception derives from two sources, the physician’s ethical obligation to provide care in life-threatening situations and the assumption that the patient would have consented to the medical treatment in the interest of self-preservation had he been competent to do so [7].

There is a heightened standard of care in clinical research because of the potential and historic abuse of test subjects [8]. While the Nuremberg Code calls for voluntary consent in all human experimentation, the American Medical Association (AMA) *Code of Medical Ethics* and the Declaration of Helsinki recognize that advancement of medical knowledge sometimes requires research involving patients who cannot

consent, for example, patients who are unconscious or incompetent [9, 10]. Both documents require investigators to obtain consent from the subject or a surrogate as soon as possible. The AMA guidelines require that the experimental treatment “have a realistic probability of benefit equal to or greater than standard care,” and that the risks of using the experimental treatment are “reasonable” compared to the risks associated with standard treatment [9]. The FDA regulations for waived consent research into new drugs or devices are an attempt to accommodate medical progress while respecting individual rights.

FDA regulations impose significantly greater obligations on researchers and institutional review boards (IRBs) than the AMA standards. The FDA endeavors to protect the rights of subjects by requiring investigators to consult with “representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn,” and to disclose the experiment’s risks and expected benefits [11]. In studies that have been granted the waiver of informed consent, test subjects must be in a life-threatening situation, available treatments must be unproven or unsatisfactory, the study must offer subjects a direct benefit for participating, and the risks and benefits of receiving the experimental treatment must outweigh those of receiving the standard care [12].

The FDA elaborated on its regulations in a 1998 information sheet explaining that an available treatment is considered “unproven or unsatisfactory” when clinical equipoise exists, that is, when “the relative benefits and risks of the proposed intervention, as compared to standard therapy, are unknown, or thought to be equivalent or better” [13]. The ethical principle of clinical equipoise underlies all medical research and obligates researchers to provide standard treatment unless there is uncertainty about the relative effectiveness of the standard and experimental treatments [14].

Based on the FDA’s interpretation of its regulations, the PolyHeme trial would be permissible if there were uncertainty about the superiority of the standard treatments at both the ambulance and hospital stages. There is little controversy about using PolyHeme in the field or in an ambulance because its oxygen-carrying capacity offers a benefit that saline solution, the current treatment, does not. When a patient arrives at a hospital, however, blood is available and is generally regarded as an acceptable treatment for severe blood loss [15]. According to 21 CFR sec. 50.24(a)(1), if blood is proven and satisfactory, then patients should receive blood and not experimental treatment.

The FDA’s construction of “unsatisfactory or unproven” as “maybe or maybe not inferior to an experimental treatment” expands the number of drugs and devices that may be tested without the patients’ consent. Even though blood is an effective treatment in 75 percent of cases [16], Northfield contends that blood is not satisfactory in some cases and that PolyHeme may be more effective. One commentator agreed, citing a correlation between blood transfusion and multiple organ failure [17]. Others dispute the claim of a causal relationship between blood

transfusion and multiple organ failure and argue that PolyHeme is not comparable because it lacks other characteristics of blood, such as clotting factors [3]. This difference of professional opinion may satisfy the FDA's clinical equipoise standard, but the widespread acceptance and success rate of blood transfusion does not fit comfortably with the formal rule that permits "waived-consent" experimental treatment when available treatments are "unsatisfactory."

Despite its high success rate, blood is not a perfect treatment for severe blood loss. In advocating for medical progress, the Declaration of Helsinki says that "[e]ven the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality" [18]. PolyHeme, which has a longer storage life and is less likely to trigger immunologic complications because it does not require blood-type matching, represents such a challenge.

If 21 CFR sec. 50.24 is read to permit experimentation without the consent of the test subjects for any drug or device that can be improved, then the requirement that existing treatments be "unproven or unsatisfactory" is hollow, and individual permission is unnecessary provided there are exigent circumstances and the community is aware of the experiment [19]. If PolyHeme is at least as safe as blood and prior research has demonstrated its potential superiority, then the trial operated within the ambit of federal guidance for waived consent emergency research, but not within a reasonable interpretation of the wording of the regulation.

On the other hand, exceptions to laws and ethical standards of conduct should be read as narrowly as possible to avoid encroachment on the rights and safety of individuals, especially those as vulnerable as accident victims suffering from severe blood loss. The FDA's permissive 1998 guidance increases the vagueness of 21 CFR sec. 50.24, with the result that an imprecise definition of "unsatisfactory" is interpreted to allow experimentation without consent in situations where proven and reliable treatments are available.

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Medicine and society

Ethical and social challenges of brain-computer interfaces

by Paul R. Wolpe, PhD

In John Donoghue's lab at Brown University sits Matthew Nagel, who is a quadriplegic. From the top of his head emerges a pedestal plug that is connected to a socket that runs to a computer. Hard-wired into that computer through a technology called BrainGate, Matthew can move the cursor entirely with his brain waves [1]. He has become so adept that he beat a *Wired* reporter in a video game when the reporter came to see the lab.

At Emory University, Drs. Roy Bakay and Phillip Kennedy treat J.R., a 53-year-old man who has locked-in syndrome because of a brain stem stroke. They have implanted J.R.'s brain with glass ampules containing electrodes and coated with neurotropic chemicals taken from his peripheral nerves. His neurons migrate into the ampules and connect themselves to the electrodes. Now this man, who could not communicate with the outside world, is hard-wired to a computer where he can move a cursor to spell out words and select phrases [2].

In the U.K. in 1998, Kevin Warwick, professor of cybernetics at the University of Reading, England, and as much a showman as a scientist, underwent an operation to surgically implant a silicon chip transponder in his forearm. The chip is connected wirelessly with his office; as he enters, computers fire up, lights turn on, heaters activate [3]. A 100-electrode array implanted in the median nerve of his arm in 2002 allows him to operate a remote prosthetic arm and to feel sensation sent to him by a less complex implant in his wife, Irena [4].

The integration of information technology into the human nervous system has been a relatively recent and quick development. While prosthetics have a long history, and the use of self-contained or feedback information technology in assist devices (like cochlear implants or pacemakers) is decades old, what is new about the types of developments listed above is that they try to integrate or translate neural processes into external outcomes. Not all brain-computer interface (BCI) technologies are implanted. A number of researchers are trying to explore how to translate brain waves or fMRI signals into real time external responses. Jonathan Wolpaw at Wadsworth Center, New York State Department of Health in Albany, for example, uses electrodes on the surface of the scalp to help those who are paralyzed or have movement disorders to control cursors or other electronic equipment using brain waves alone [5]. Along with BCIs, such as artificial vision technologies, we are for the first time beginning to treat the human brain as "wetware" that we can connect to

other information technology systems. The social and ethical implications of such a development are vast.

Clearly BCIs have the potential to help those whose injuries or diseases have left them with a functioning central nervous system that cannot control the actions of the peripheral nervous system. In that sense these technologies, particularly if they can be developed to use transcranial impulses robustly and specifically, can be low-impact ways to give such people an enhanced quality of life and control over their environment.

BCIs also raise some concerns, however. In cases like Matthew Nagel's (whose BrainGate device has since been removed), the computer that translates his brain waves into signals "learns"; it does increasingly well in understanding what Nagel is trying to do and translating it into action. But this computer is hard-wired into Nagel's brain. As it learns, its relation to Nagel's intentions changes. In other words, this extension of Nagel's brain is itself a developing intelligence of a sort, now integrated into Nagel's own brain processes.

Imagine a period in the near future where we have developed the interfaces between computer and brain to a degree where the information flows in both directions; the brain sends out information to the computer, and it also receives impulses from the computer, which learns and develops. Perhaps that computer is also connected to the Internet. Now we have the human brain hard-wired into the Internet, itself now a wetware node on that system.

Research is being done on brain prosthetics. Theodore Berger and his colleagues at the University of Southern California have designed a brain chip that could bypass lesions in the hippocampus [6]. The chip "reads" the signals entering the hippocampus, processes them just as the hippocampus would, and relays them to the tissue on the other side of the lesion. The USC researchers have tested the concept on rat brain slices with success.

So not only will BCIs connect us through wires to external information technologies, the information technology itself may be integrated into our neural tissue. For the first time, fundamental neural processes in the central nervous system will be part organic, part synthetic. A whole field of cyborgology has developed to try to understand the social, political and ethical implications of our becoming cyborgs, part organic and part synthetic, human/machine hybrids. Books like "Cyborg Citizen: Politics in the Posthuman Age" argue that the very nature of our relationships with each other, as well as with social institutions, will change as we integrate technologies into our physiology and as we integrate our physiologies into our environments [7].

We can expect that more and more types of injuries and diseases will be treated with BCIs. It is too early to know what ethical and social issues will emerge from these technologies. Clearly, however, they will pose challenges for privacy, as machines

are able to tap into our private brain processes. They will challenge personal autonomy, as experiments with other animals show how the brain can be conditioned or even disrupted with implanted technologies. And they will challenge our conceptions of selfhood, when computers are part of the very functioning of our thought processes. Psychiatry will have to develop new ways of understanding the cyborgian mind. A new breed of medical technologist will have to monitor, repair and fine-tune the complicated devices that are interacting with the human brain, and that may include an unprecedented amount of control over people's "minds." Psychopharmaceuticals are being developed now to try to control cognitive and affective traits, and it is likely that BCIs will be able to have similar effects. We already see the beginning of that process with the use of deep brain stimulation for psychiatric disorders.

Human beings have evolved for over 100,000 years with the brain isolated in the skull, inviolate. It is inviolate no more, with not only BCIs but brain imaging technologies revealing the detail of brain function, or with transcranial magnetic stimulation able to shut off discrete areas of the brain. The ability to access the brain, to understand its inner workings, to connect it to external devices, promises remarkable resources to aid the infirm as well as worrisome opportunities to cause harm. It is important to develop these technologies with a careful eye towards using them responsibly.

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Medicine and society

Neuroprosthetics and neuroenhancement: can we draw a line?

by Steffen K. Rosahl, MD, PhD

Electrical stimulation of neural tissue by surgically implanted neuroelectronic devices to restore lost neural function has become an integral part of today's medicine. Ethical issues and the current public debate about these implants precipitate around two major questions:

1. Does the benefit of the prosthetic implant justify the risk of adverse effects to the individual and to society?
2. Is it desirable to *enhance* human capabilities by neuroelectronic devices?

The objective of this paper is to provide both scientific and moral arguments in this ongoing debate. As with most public discussions, arguments about human-neuroelectronic interfaces are clouded by fears, hopes, market interests and academic endeavors, as well as by philosophical and religious differences of opinion.

The case of the cochlear implant helps to define both questions. There is no doubt that cochlear implants benefit thousands of people without major risk. Still, even the cochlear implant is not universally accepted as a *therapeutic intervention* by the profoundly deaf. Some see it as an intrusion into their way of life, claiming that the implant threatens to eliminate their standing as a culture and thus compromise their autonomy [1-4]. Moreover, some contend that, in a community of deaf people, (re)gaining hearing for a single individual could be considered an *enhancement*, an additional capability on top of what other members of the community have, gained by artificial means.

About neuroelectronic implants in general, it is argued that people may be transformed more radically or profoundly than with other techniques of intervention. And it is feared that neural prostheses directly coupled to the brain may threaten personal identity. It is not only among the deaf that this might separate an individual from the community.

Therapy: neural prostheses available today

Broadly defined, a neural prosthesis is a device implanted to restore a lost or altered neural function. Neural prostheses work in one of two ways, either (1) by delivering electrical stimulation that excites or inhibits neural tissue or (2) by picking up electricity generated by the brain and using it to control computer cursors, electromechanical devices or even paretic limbs. Until now, both methods have been

applied only after pharmacologic options have been exhausted. They have proven to be very effective, most prominently with respect to deep brain stimulation in Parkinson's disease where high-frequency stimulation causes inhibition of the subthalamic nucleus [5]. Despite ethical problems raised by sham surgeries conducted as placebo controls [6-8], the success of these techniques in improving the lives of several thousand patients makes it impossible to ignore the benefit of this option.

Restoring sensory pathways is one of the more classic applications of neural prosthetics. Cochlear implants, introduced into clinical practice in the early 1960s, have become a routine procedure today, especially in children. Multichannel cochlear implants have been provided to hundreds of thousands of patients today, making speech development possible and enabling a majority of them to use the telephone. Auditory brainstem implants with electrodes placed over the cochlear nucleus or even pushed into the brainstem have proven capable of restoring some residual hearing in a few hundred patients who had lost both hearing nerves.

Visual implants, on the other hand, are still investigational and have just entered phase 1 trials. More than 20 research groups worldwide are currently working on electronic implants to restore vision in blind patients. Methods include electrical stimulation at the receptor level (subretinal implants), at the origin of the optic nerve (epiretinal implants), at the optic nerve itself and at the visual cerebral cortex. Another line of research is the fabrication of hybrid implants—neurons cultured on photosensitive silicon chips—with the potential to form a biological connection that restores the whole visual pathway.

While premature enthusiasm with respect to clinical applications has inspired false expectations in the past, research in this field is now progressing more slowly and steadily. Currently, most researchers anticipate that an implant will probably not fully restore vision but may allow a blind person to move freely in a familiar environment, guided by visual perception of contours, outlines and shades of light.

Translating neuronal signals into actions. So-called "brain-computer interfaces" (BCIs) basically work the other way around: rather than stimulating neural structures, they pick up electrical potentials generated in the brain as a byproduct of neuronal activity. This term, as well as the terms "human computer interface" and "brain-machine interface" describe invasive or noninvasive devices that can restore lost motor or sensory-motor functions by translating raw neuronal signals into electrical impulses sufficient to control a computer cursor or reproduce arm and hand movements with artificial actuators [9, 10].

In principle, it is also possible to control computer cursors and artificial limbs by eye movements and noninvasive electrodes. But when the recording devices for brain signals are not fully implantable, the computational algorithms are not sophisticated enough to provide a wide range of subtle and distinct movement and there is no sensory feedback from the actuators, so the acceptance of these implants would

remain rather limited, even if the neurosurgical procedures were free of risks—which in fact they are not.

Safety

Neural prostheses have a general disadvantage over other methods employed to restore or even enhance neural function: they typically involve an invasive surgical procedure. Given that risk, why would anyone seriously choose surgical connection of artificial devices to the human brain? The answer, in large part, is that these implants restore neural function where all other methods fail, function continuously without the patient having to attend to them or interrupt or alter his or her normal behaviour, can be completely hidden under the skin, and can be turned off easily.

Surgical risks, such as hemorrhage and infection, are minimal with deep brain stimulation and less-than-minimal for vagal nerve stimulation like that used for control of epileptic seizures. The main difficulty with risk assessment in these medical technologies is our limited understanding of the physiological mechanisms involved and the neural circuitry upon which they act. Stimulating neural structures with an electrical current without knowing all the physiological mechanisms that may ultimately be turned on or off by this stimulation is bound to cause some unforeseeable effects, especially if the targets are small and located in brain regions with dense neuronal packing.

Patient satisfaction with the treatment result is often quite high, but relatives and friends sometimes complain of personality changes in the patient, ranging from transient confusion and bradyphrenia to euphoria or depression. These changes, however, occur in a minority of patients, and it is unclear whether the electrical stimulation per se directly causes them. It may be that when some symptoms are eliminated through electrical stimulation, other aspects of the disease are unmasked (e.g., depression is recognized only when movement disorder is improved). It is also possible that psychosocial changes (e.g., acting out) are epiphenomena related to the relief of the patient's symptoms.

Still, the vague fear that, due to the treatment, a patient may no longer be “who I used to be” could prevent individual patients from undergoing these medical procedures and lead to disapproval from the general public. During the research phase, therefore, any new central neural prosthesis should be monitored systematically for subtle side effects that affect personality and mental capacities related to personhood.

Ethics committees as well as official agencies like the FDA demand careful study designs to evaluate new technologies. These demands have been met in the past, and it is safe to say that, for sensory prosthesis like the cochlear implant, the risks and adverse effects are negligible today.

While placebo-controlled studies are hardly possible when surgery is involved, intelligent study designs like crossover paradigms, where a device is implanted but

not activated in half of the patients for a limited time, can make up for this drawback. As long as the risks and side effects are acceptable, the main question will always be whether the new treatment modality helps any better than other, less invasive or less risky measures.

Limitations and trends

As Hollywood's cyborgs and man-machine creations become more and more confused with reality in the public eye, it is worthwhile to consider some of the limitations of neural prostheses today.

- Sensory implants contact the neural tissue with a relatively small number of electrodes compared to the multitude of anatomical neurons involved in the sensory pathways.
- Implants are placed in sensory pathways that have been severed. With a lesion in the central nervous system there usually is little chance of natural regeneration. Other elements in the severed pathway may degenerate, too, when not in use.
- Electrodes contacting the neural tissue are prone to rejection and degradation. On the other hand, they may also damage the neural tissue that they are supposed to stimulate.
- The neural interfacing of electrodes is far from mimicking the anatomical and physiological connections in a neural network.
- Refractory properties limit the number of electrical impulses a neuron will respond to in a given time interval.
- Output functions of brain-computer interfaces tend to be rather slow. Even with a well-tuned 96-electrode, BCI speed is limited to 6.5 bits per second or approximately 15 words per minute typed with a key selection system [11].

Moreover, size, biocompatibility, durability and energy supply are basic problems for all neuroelectronic implants, but, considering recent developments, it does not appear these will remain critical in the long run.

Current research

Apart from improving and miniaturizing technical details, there are two promising lines of research aimed at improving the performance of neuroelectronic interfaces. The first approach is to obtain more information on the structural organization and the working principles of neuronal networks and their function. For example, with a technique they call “linear decoding,” researchers at the University California, Berkeley, were able to reconstruct actual moving images from electrophysiological recordings by means of electrodes placed in a cat's lateral geniculate ganglion, a neural structure connected to the cat's optic system [12]. They have also shown that it is possible to map non-linear neuronal responses to visual stimuli in the visual cortex.

A group in Germany has recorded electrical brain activity in response to rising and falling tones from the auditory cortex in gerbils. Interestingly, when the auditory

cortex itself was stimulated with similar electrical signals at the same location, the animals were able to discriminate rising and falling tones in the absence of any sound presentation [13].

Experiments like these lead to the second approach—attempts to model neurobiological structures based on their morphological and functional characteristics (“morphing”). One example from the University of Pennsylvania is the creation of an artificial retina, a silicon-based microchip that includes 3,600 output “cells,” simulating characteristic responses to light stimulation of the four major clusters of retinal ganglion cells [14]. With their axonal processes, these cells account for 90 percent of the fibres of the optic nerve. The “neuromorphic” chip consumes only one-thousandth of the power required by a regular PC.

One of the most ambitious projects in this respect combines methods of computational neuroscience with computer engineering to “morph” memory functions of the hippocampus with computer hardware and software at the University of Southern California [15]. At present, it is hard to see how such an artificial neural network could be functionally interfaced with the human brain. Moreover, human memory is based on continuous changes in the efficacy and qualities of cellular and molecular processes. A “memory chip” would have to adapt continuously to such changes. There is no way of knowing where research of this kind may take us in the future. Considering the complexity of the task, it comes as no surprise that the answers range from “nowhere” to a “superhuman race” and that these answers are based mostly on matters of belief rather than scientifically proven facts.

Where do we go from here?

Even if the restoration of lost or disturbed neural function by neural prosthesis is a temporary phase before better treatments are made available through biotechnology, neural prosthesis will be a dynamic and growing field in medicine for many years to come. Clinical indications will be extended, e.g., to electrical brain stimulation in epilepsy and in the treatment of migraine, depression and obsessive-compulsive disorder.

Microtechnology now makes it possible to minimize electrodes and enlarge their active surface by laser treatment. Coating of the electrodes with growth factors appears to improve the electrical contact to the neural structures, and conductive varnish with nanoparticles reduces the breakdown of electrodes by living tissue. Neurons cultured on nanofibres develop neurite extensions, and the artificial material employed counteracts astrocytic scar formation at the same time [16].

Neural cells can be grown onto silicon chips and promote fibre growth connecting the implant to the nervous system. “Artificial synapse chips” capable of communicating with the nervous system on a chemical (electro-osmosis) rather than electrical basis are being developed [17].

Microfluidic implants can serve both as neural prosthesis and as focal drug delivery systems. They are composed of electronic implants combined with mechanical actuators capable of releasing a variety of different chemicals, e.g., neurotransmitters or drugs, in a very small volume of biological tissue.

Treatment versus enhancement

The interventions that have just been described appear to be in line with the prevention and treatment goals of medicine, and society will probably not have major objections to neuroelectronic implants as therapeutic devices [18]. Use of technical intervention to improve the physical, cognitive or psychological aspect of an individual beyond what is considered “normal” may be different. While the distinction between treatment and enhancement may be difficult in borderline cases, it can safely be assumed that enhancing healthy human beings is not part of the responsibility of health care professionals, which is to treat and prevent diseases and to restore function that is normal for an individual of a given age and sex. Enhancement with neuroelectronic devices would not fall under the obligatory force of the principle of beneficence in medicine. Respect for autonomy—especially with regard to enhancement of children—and questions of distributive and social justice will undoubtedly clash in the debate over enhancing human beings with neural implants.

When we look ahead to possible enhancement with electronic devices directly coupled to the human brain, is the first question that comes to mind really whether there should be limits to enhancements in the interest of remaining human? Or is the first question: Do we really want to be enhanced with surgically implanted devices when it might be possible to achieve these gains by noninvasive devices or even by pharmacological means? Infrared vision, perception of radio-frequency signals, ultrasound hearing and even invisible communication can all be accomplished by small external devices today. Enhancing well-being, motivation and cognition by administering drugs—in other words “doping”—is well established.

Ethical analysis is essential

Finally, with every new step in the development of technologies, there will be a potential for abuse. To many, enhancement by connecting electronic devices to the human body and brain will appear, at least *prima facie*, morally suspect. Others have argued that these enhancement technologies offer an opportunity to make life more worthwhile, provided that society responds appropriately to the implicit social challenges, including that posed by distributing these technological interventions justly.

A variety of science fiction scenarios involving cyborgs and the imminent transformation of the human race into a semi-electronic species has left the public rather perplexed and provoked reactions against scientific progress in the field of neural prosthetics. Even though neuroelectronic technology is available, few human beings would choose to be permanently enhanced by implanted electronic devices. And as long as technology does not progress to the point where implants have

advantages unsurpassed by less-invasive means, concerns about an enhanced transhuman race can be put off until later.

Ethical analysis should strive to separate realistic forecasts from the more speculative ones. Still, we should be aware of the accelerating pace of implant technology, driven mainly by trends in microcomputing, neuroscience and medicine. While there is certainly no point in trying to stop the development of central neural implants, an early and thoughtful discussion of their potential benefits and risks must lay the groundwork for a responsible application of this very promising technology.

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Op-Ed

Must publicly funded research be culturally neutral?

by Neil Levy, PhD

Cochlear implants, so-called bionic ears, are surprisingly controversial. Most of us in the hearing community see them as medical miracles that restore the precious gift of hearing to the deaf. But many people within the Deaf community (where the capital letter signals the fact that this is community bound by a shared culture, and not merely by a shared deficit) see the implants as an attack upon them and their group. For them, deafness is not, or not only, a disability; it is also the necessary condition of belonging to a rich and ongoing culture, with its own language, its own art forms and its own values. The Deaf see the cochlear implant not as a cure for a disability, but as a means of cultural genocide [1].

Some philosophers have argued for this view. Writing in the *Journal of Political Philosophy*, for instance, Robert Sparrow argues that, given the fact that cochlear implants predictably lead to the destruction of Deaf culture, it is impermissible for governments to fund research into the implants. He believes that governments in multicultural societies have an obligation to be culturally neutral, and funding such research violates that obligation [2].

We might be forgiven for doubting the first premise of this argument, that there really is such a thing as Deaf culture. No doubt there are some differences in the values and practices of those who associate mainly with other deaf people, and no doubt, given the fact that the Deaf have a language of their own, these differences go deeper than the defining traits of the majority of subcultures that proliferate within Western countries. Still, there is little evidence that these differences are very deep. Because there is no clear answer to the question of when a subculture becomes a distinct culture in its own right, however, we do well to ponder Sparrow's argument on its merit, setting our doubts aside.

If cochlear implants represent a threat of cultural genocide, this is a threat that takes a form which is unique, because the means of transmission of Deaf culture is unique. In almost every other culture (gay culture, if there is one, is the only other exception), parents share and transmit their culture to their children. But only 10 percent of deafness is inherited. Hence, most children who join the Deaf culture leave their parental culture to do so. To that extent, there is a crucial difference between the Deaf culture and all others in which the urge for solidarity coincides with the desire of parents that their children follow in their footsteps. With the Deaf culture, parental desires can clash with community goals, for if there is a distinct

Deaf culture, parents can legitimately worry that, if their children join it, they risk becoming estranged, at least somewhat. Parents have a greater (although not absolute) claim to decide what culture their children belong to than do others. On those grounds, the wishes of hearing parents that their deaf children have the opportunity to share their culture by having cochlear implants ought to have a greater weight than the wishes of the Deaf culture to preserve its way of life.

There are hard cases in which the wishes of parents and the Deaf culture actually coincide. Consider the recent case in which a deaf lesbian couple deliberately sought to have a deaf child, using donor sperm from a deaf friend [3]. In this case, their wish to have a child who shared in their culture meant having a child who would be deaf. Here, the presumption in favor of parental choice concerning the values and culture of their children supports the wish deliberately to choose deafness in one's child.

Though there is a strong presumption in favor of a right of parental choice, this is not a choice with an unlimited scope. The scope of parental rights is limited by the child's right to an open future: a future that contains a range of incompatible and valuable choices. Deafness is a disability, even if it is a disability that (perhaps uniquely) carries with it the compensation of access to a rich culture. But not all aspects of life in the Deaf culture can be viewed as just as advantageous to life goals as those in the hearing majority. For example, the Deaf score badly on a variety of socioeconomic measures. To that extent, Deafness narrows the child's future too significantly for it to be legitimately included within the scope of the parents' right to choose their children's culture [4].

Note, moreover, that even if we thought that the parents' right to choose their children's culture was so significant that it outweighed the child's right to an open future, Sparrow's conclusion—that governments must not fund this research—does not follow. If the right of parents is so weighty, then we need a very good reason to deny hearing parents the means of exercising their right to bring their children into the hearing culture, and absence of government support for developing technology would deny hearing parents the exercise of that right.

There is every reason to think that cultural innovations, including technologies, have a profound impact on human cultures. Indeed, some thinkers believe that distinctively human thought, with its characteristic power and creativity, is due in very important part to technological enhancement [5, 6]. We are capable of systematic thought only because we are capable of using external devices to represent our ideas and to augment our brains. With the invention of writing and other forms of external representations, new cognitive landscapes became accessible. To the extent to which we only became properly human when we enhanced ourselves technologically, the fear that such technologies are somehow unnatural is baseless. If Deaf culture succumbs to the pressure of cochlear implants, this will be in some ways sad, but it will not be tragic, since the children who might have belonged to that culture can be expected to have a broader range of choices and opportunities in the mainstream. But the expansion of our technological capabilities

carries with it other risks, most pressingly of injustice and inequality. They are no less pressing for being so familiar.

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Medical humanities

Technology and the patient-physician relationship: a defining historic moment

by Stanley J. Reiser, MD, MPA, PhD

Those who appraise American health care as pre-eminent in the world invariably point to the widespread diffusion of technologies and the experts and health systems that use and house them as the foundation upon which the successes it claims rest. Centers that specialize in orthopedic, cardiac and cancer care and so forth, standing alone or embedded in hospitals, crowd the map of medical America. Specialties that govern such technologies now are the most sought after by medical students. But the ascendancy of technological medicine to the pinnacle of medical success has meant that nontechnological aspects of practice inevitably become less studied, valued and used. This consequence needs attention if we are to gain a wider and more realistic view of how American medicine should function and how to assess its quality. The best place to turn for this perspective is to medicine's past and to a moment in time when perhaps the most significant technological invention of the diagnostic part of medicine was introduced and applied.

Practice without technology

It is difficult for contemporary physicians and medical students to conceive of a period when technologies were not sought, and were even eschewed, by doctors. Yet this occurred in the medieval period, when medicine was eliding from an art taught by individual practitioners to novices who worked for them to a discipline within universities, whose founding accelerated in the 13th century when universities at which medicine was taught were created in Paris, Oxford, Padua, Cambridge, Montpellier and several other European cities [1]. As places devoted to conceptual study transmitted through discourse, lectures and texts, universities avoided those forms of practice involving the need for the manual skills and tools associated with trades. The most significant medical casualty of this viewpoint was surgery. Universities gradually excluded this subject from medical learning. This led to the creation of schools to train surgeons that were independent of universities and to the disciplinary separation of medicine from surgery. It was only in the 19th century, when developments that will be explored shortly ended this prejudice, that surgical studies were reintroduced into medical education.

In the second decade of the 19th century, just before a technology that would revolutionize medicine appeared, physicians learned about the illness of patients through three avenues. Most important was the recounting by patients of the symptoms from which they suffered and the events of their lives that were coincident with their ailments. A second realm of evaluation was the exercise of observation.

Physicians visually focused on things such as the posture, gait and appearance of patients. The third main sphere of inquiry was the use of touch, mainly to estimate the quality of the pulse and the coldness or warmth of the skin and to gently examine external disfigurements such as tumors. Physicians generally did not deeply probe the body of their patient with their hands, nor did they use tools in their examination, thus following the tradition established centuries earlier. At this time, however, a critical exception was made to this exclusion of manual and technological exploration: it now was permissible to apply such means to the patient's body after death. By the 19th century's start, dissecting the body to identify structural changes in its fabric that illuminated the etiology of the patient's symptoms was gaining increased attention.

The rise of technology

This was the medical environment in 1816 when a French doctor, Rene Laennec, was called to examine a young woman at the Necker Hospital in Paris with a puzzling heart disease. Laennec employed the traditional forms of evaluation, but found them not useful to elucidating her condition. He then thought of applying a technique to detect fluid in the chest recommended by Hippocrates, whose 2,500-year-old writings Laennec had explored as a medical student. It was called "immediate auscultation" and required physicians to place an ear directly on the patient's chest to listen for sounds that indicated a fluid's presence. Laennec and one of his colleagues occasionally used this technique, but it did not gain favor because it required close physical contact with the patient's body. In this case, Laennec quickly concluded that the youth and gender of his patient rendered its use by him infeasible. But in a moment of clinical revelation about how he might auscultate this patient, Laennec recalled a well-known fact of acoustics: that sound was augmented when it traveled through solid bodies, as when the scratch of a pen applied to the end of a piece of wood is heard at the other end. He spied a sheath of paper on a table next to his patient's bed, rolled it tightly into a tube, put an end on the patient's chest over her heart, and placed his ear to the remaining end. The sounds of her heart were heard. Laennec writes: "From this moment I imagined that the circumstance might furnish means of enabling us to ascertain the character, not only of the action of the heart, but of every species of sound produced by the motion of all the thoracic viscera" [2].

Laennec spent the next three years examining patients in this way. He experimented with many forms and sizes of material to replace the makeshift paper instrument through which he tested his revelation. The chosen instrument was constructed of a round piece of wood 1 foot long and 1-1/2 inches in diameter, perforated down its center by a hole to enhance the transmission of sound and separable in two parts to enhance ease of transport. He called his device the "cylinder" for its shape, or sometimes the "stethoscope," from the Greek words for "chest" and "I view." The latter was the name by which it became popularly known.

With this instrument Laennec explored the chest of patients at the Necker Hospital to discern and describe the sounds made normally by its organs and those produced

when disease altered their structure and function. Critically, he followed the examination of patients while they lived with an autopsy if they died. This allowed him to assert with security the connection between the sound an organ made during life and structural changes in the body that produced it. The work revealing these findings was published in 1819 under the title “A Treatise on the Diseases of the Chest” [3].

Laennec’s simple technology gave physicians a new set of accurate signs of disease that increased the precision of their diagnoses, but it had the unforeseen consequence of altering their relationship with patients. Why seek to inquire into the lives of patients to gain insights into their illness, which not only took time but was fraught with undependability stemming from forgetfulness, exaggeration, embarrassment and other contingencies that introduced error into their account, if a technique existed that gave doctors the ability to locate and evaluate significant signs of disease by themselves? The stethoscope and the technique of auscultation it furthered created a paradigm of examination that continues to be a major force in the medicine of today.

Medicine’s modern dilemma

Contemporary medicine is defined by a panoply of diagnostic technologies that follow the pattern set by the stethoscope. They permit accurate evaluation of the patient without personal input from the patient. It is a large challenge for today’s medicine to seek ways to understand who patients are and how this influences their illness. This realm of evidence has been and always will be central to treating their problems. Technology is not a substitute for engaging the life of the patient. Its evidence can be precise, but precision is not the only standard by which to judge the significance of evidence. Saliency of the evidence to the problem needing solution is equally critical. And nothing is more salient to helping patients than knowing what they feel, think and need.

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Suggested readings and resources

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