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Technological and Treatment Imperatives, Life-Sustaining Technologies, and Associated Ethical and Social Challenges

See also pages 658, 666, 674, and 761

In this issue of *Mayo Clinic Proceedings*, 4 articles[1-4] highlight the technological and treatment imperatives (defined subsequently) and ethical and social challenges associated with using life-sustaining technologies in clinical practice.

Tweet et al[1] describe the use of an extraordinary technology, extracorporeal membrane oxygenation (ECMO), in a 46-year-old woman who experienced cardiac arrest due to thrombosis of the left main coronary artery. The case is riveting: "Throughout the procedure, the patient required cardiopulmonary resuscitation (CPR) for recurrent cardiac arrest and received a total of 10 shocks for recurrent ventricular arrhythmias."[1] She was maintained on ECMO until hospital day 8, at which point it was discontinued. She was discharged on hospital day 30 and subsequently did well as an outpatient. Without the availability of CPR, ECMO, an expert care team, and an undoubtedly sophisticated support infrastructure, the patient certainly would have died shortly after her presentation. This case exemplifies how a sophisticated technology can be used to rescue a patient experiencing profound physiologic compromise. For the patient and her clinicians, the desired outcome was achieved: a life saved, and a future ensured. The case also highlights a broader issue related to novel treatments, the *technological imperative*—"giving the best care that is technically possible; the only legitimate and explicitly recognized constraint is the state of the art."[5]

Indeed, clinicians tend to embrace and use novel treatments even when evidence supporting their use is lacking. For example, use of robotically assisted hysterectomy for benign gynecologic disease, which was introduced into clinical practice less than 10 years ago, increased markedly between 2007 and 2010 despite limited data on outcomes and cost-effectiveness compared with laparoscopic hysterectomy. Just this year, the results of a study that compared the 2 procedures were published; this study, which involved more than 260,000 women, reported that robotically assisted hysterectomy had a similar morbidity profile, but higher cost (by about $2200 per case), compared with laparoscopic hysterectomy.[6]

If a novel treatment seems to be effective and is available, clinicians will likely use it. In this scenario, supply drives demand. Hence, the case reported by Tweet et al[1] also highlights the *treatment imperative*—"the almost inexorable momentum towards intervention that is experienced by physicians, patients, and family members alike."[7] In the setting of an acute, life-threatening illness in which decisions must be made quickly, it can be overwhelmingly compelling for clinicians to offer treatments—including those that are mechanistically plausible, yet unproven—to patients. Faced with impending mortality, it is extremely difficult for patients (or their loved ones) to refuse the offer. Furthermore, saying "no" and electing a palliative approach can be unattractive, particularly for young, previously healthy patients. The report by Tweet et al[1] also presents other challenges. On the basis of the favorable outcome of their case, must clinicians now use ECMO for future similar cases? Which patients should receive it? At which centers should it be

available—some or all? How do we assess its overall effectiveness?

Notably, clinician exposure to novel, yet unproven, treatments is facilitated partly by the US Food and Drug Administration approval process. A recent analysis showed that of 121 high-risk cardiovascular devices (eg, implantable cardioverter-defibrillator, endovascular graft) approved by the Food and Drug Administration during 2001-2011, only one-half of the devices were approved with active control data from at least one supporting study, and one-third of the devices were approved without any control data or objective performance criteria.[8] Although novel technologies can advance medical science, enthusiasm for broadly integrating them into routine clinical practice should be tempered until appropriate comparative effectiveness studies (eg, comparison with standard treatment) are done.

Barbara et al[2] describe 33 patients with left ventricular assist devices (LVADs) who safely underwent 67 noncardiac operations. Most of the patients received the device as "destination therapy" (LVAD-DT), ie, use of the device in patients with severe heart failure who are not heart transplant candidates and are supported by the device for the remainder of their lives. It is estimated that several hundred thousand Americans have end-stage heart failure.[9] Although heart transplant is a treatment option for some of these patients, only 2100 donor hearts are recovered and transplanted in the United States each year.[10] Left ventricular assist device destination therapy has emerged as a promising treatment for patients with end-stage heart failure. Indeed, trials have shown that survival is superior in patients treated with LVAD-DT compared with medical therapy.[9] Because the use of LVAD-DT and the number of patients supported with this treatment are increasing, it is not surprising that some of these patients experience noncardiac medical issues and need noncardiac surgery.

The article by Barbara et al[2] also highlights challenges that arise when new technologies become more widely used in practice. According to Entwistle et al,[11] "many patients [with end-stage heart failure] facing imminent death opt for VAD therapy without full realization of the effects that this technology will have on their daily lives," an attitude that is indicative of the treatment imperative. With the device, they live longer. However, for some of the patients described by Barbara et al,[2] the device appears to have contributed to the need for noncardiac surgery (eg, sternal wound incision and drainage). As pointed out by the authors, for surgery to be successful, the device mandates expert multidisciplinary care—an LVAD team working in concert with anesthesiologists and surgeons. Indeed, care coordination of these patients and associated costs are substantial,[11] and some (regulators, payers, and others) may question whether LVAD treatment is a good use of resources. Furthermore, caregiver burdens can be substantial.[12] Finally, the 2-year survival in patients with continuous-flow LVADs is only 70%.[13] As a result, clinicians may encounter daunting ethical dilemmas when caring for these patients, particularly those who are dying and have not engaged in advance care planning (eg, to establish the patient's views on whether withdrawal of LVAD-DT is assisted death[14]). Clinicians should be prepared to address not only clinical challenges associated with novel technologies but also social and ethical challenges and to develop and use preventive measures to ameliorate those challenges.

Jesus et al[3] describe the results of a survey of patients with do-not-resuscitate (DNR) and/or do-not-intubate (DNI) orders regarding preferences for CPR. They found that "most patients with DNR/DNI orders want CPR and/or [tracheal] intubation in specific hypothetical clinical scenarios, directly conflicting with their documented DNR/DNI status."[3] Because patients often base decisions about their resuscitation status ("code status") on potential outcomes rather than on specific interventions,[15] it is not surprising that even though nearly all of the patients in the study by Jesus et al knew they had a DNR/DNI code status, more than half "would want to be intubated in the face of a life-threatening but potentially reversible case of angioedema" and more than a quarter "wanted intubation in the case of severe pneumonia."[3] The study results also reflect the vagaries of decision making in the setting of medical illness. Ill and vulnerable patients may be especially willing to accept treatment—the treatment imperative—and countermand their DNR/DNI order.[16] In our view, when patients indicate a desire for a DNR/DNI order, what they really want is to avoid spending the last days of their lives attached to invasive technologies and separated from loved

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ones. Furthermore, a DNR/DNI order, like any order, should not be viewed as immutable. In many ways, a DNR/DNI order is a blunt instrument used in situations that require finesse. Patients' clinical situations and perspectives change. Hence, discussions of resuscitation status should occur often, especially whenever patients' clinical situations change.[15] Ironically, the reports by Tweet et al[1] and Jesus et al[3] highlight that CPR, in most cases, would be unsuccessful (and code status discussions irrelevant) in the absence of other lifesaving technologies such as mechanical ventilation.

Finally, Combs et al[4] describe the results of a survey of physicians regarding decision making for patients incapable of making their own decisions. Traditionally, a surrogate makes decisions for the patient who lacks decision-making capacity. Ethically and legally, the surrogate should make decisions based on "substituted judgment," ie, make decisions the patient would make if he or she were capable, on the basis of the patient's known health care–related values, goals, and preferences. If these values, goals, and preferences are unknown, the surrogate should make decisions based on the patient's "best interests," ie, make decisions that maximize benefits and minimize harms on the basis of the medical facts and the patient's prognosis.[17] Combs et al found that eight-tenths of physicians agreed with the statement, "Surrogates should make decisions based on the patient's prior wishes or advance directives, even if it contradicts what is in the patient's best interest." However, four-tenths of physicians also agreed with the statement, "Surrogates should make decisions based on what is in the patient's best interest, even if it contradicts the patient's prior wishes or advance directive."[4]

These seemingly contradictory findings reflect the reality of clinical practice. Physicians commonly encounter clinical situations in which substituted judgment conflicts with what seems to be in the patient's best interest, eg, a surrogate who requests that "everything be done" based on a decisionally incapable patient's previously expressed (yet often vague) preferences, even though recovery is unlikely and further treatment will harm and interfere with a natural and peaceful death. Health care professionals involved in these situations may perceive unnecessary prolongation of patient (and surrogate) suffering because of rigid adherence with substituted judgment and, as a result, experience moral conflict. Sulmasy and Snyder[18] offered an alternative approach, the "substituted interests and best judgments" model, in which:

> [Surrogates] provide knowledge of the patients' authentic values and interests…rather than guessing what the patient would have decided [for a specific clinical situation]. A 'best judgment' about what decision advances the good of each patient as a unique individual follows.

While respecting patients' values, this approach, which should be affirmed by research, may alleviate burdens and avoid conflicts associated with surrogate decision making.

Barger-Lux and Heaney[19] stated that:

> One cannot begin to understand the health care system in our society—let alone propose changes in it—without coming to grips with the influence of technology. Health care professionals, patients, and others have attached powerful, positive values to procedures and devices that affect illness and preserve life.

The 4 articles in this issue of *Mayo Clinic Proceedings* highlight this reality. Novel life-sustaining technologies, such as ECMO and LVAD-DT, offer hope to patients with serious illnesses. The technological and treatment imperatives compel healers to use them and patients and loved ones to accept them. Human ingenuity and the desire to save lives ensure that more life-sustaining technologies will be developed. Novel technologies, however, should be properly evaluated in clinical trials, and their overall efficacy and cost (financial, ethical, and social) should be determined before they are broadly introduced into routine practice. Even so, when introduced into practice, these technologies not only create clinical challenges (eg, LVAD management during noncardiac surgery) but also ethical and social challenges (eg, surrogate decision making). As a community of healers, we must anticipate these challenges and formulate responses to them (eg, "preparedness planning" in patients treated with LVAD-DT[20]) that respect patients' values and facilitate surrogates' decision making.

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