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ORGAN DONATION AND TRANSPLANTATION: CAN LAW RESOLVE THE DILEMMA OF SCARCITY?

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An Ethics of Scarcity

In May 2015, the national Organ Procurement and Transplantation Network (OPTN) reached an important milestone: since its establishment in 1987, it has coordinated 500,000 organ transplants from deceased donors, with an estimated 250,000 recipients still living.[1] Despite this achievement, the ethics of human organ donation and transplantation remains an ethics of scarcity: the number of patients awaiting transplants of vital organs increases by several thousand each year, while the number of donors (deceased and living) has flatlined. In 1988, 12,618 transplants were performed with organs from 5,901 donors; the waiting list was 15,029. Over the following 15 years, the number of donors more than doubled, to 13,284—but the reported wait list more than quintupled to almost 82,000.[2] Over the past 10 years, the reported wait list has grown to more than 123,000, while the number of donors has remained stable, between 14,000 and 15,000.[3] More than 80 percent of those on the waiting list seek a kidney transplant, and thus can receive an organ from a living donor. However, the number of living kidney donors peaked in 2004 at 6,647, and declined to 5,539 in 2014.

A comprehensive study published in 2003 reported significant increases over the previous decade in living and cadaveric donations;[4] that progress clearly has not continued. The deaths of those on the waiting lists serve as daily reminders of these trends: while an average of 79 people receive transplanted organs each day, another 22 waiting for an organ pass away.[5] The average wait for a donated kidney is now five years.[6]

For more than four decades, American law has attempted to address this problem of scarcity, and to ensure the equitable allocation of those organs made available and suitable for transplant. Several core ethical principles and conclusions have guided these legal developments: that affirmative consent of the deceased recorded prior to death, or the consent of the family at time of death, be required; that donation be wholly voluntary and altruistic; and that vital organs not be marketed or otherwise commoditized. Over the same period, the unresolved dilemma of scarcity has inspired proposals to depart from these principles. It is a debate worth having; as the recent half-million milestone reminds us, organ transplantation is not an exotic corner of medical practice, and its successes and failures—including the failure to find a suitable donor—touch thousands of lives each year. We offer here a brief summary of current law, the chief proposals for reform, and a legal and ethical appraisal of whether the gains from such proposals are worth compromising the principles that have heretofore guided the transplant system. Due to space limitations, proposals for ameliorating scarcity through the compensation of donors must be the subject of a future article.

Current Legal Structures

Federal and State governments play a distinct but complementary role in regulating the donation, procurement, and allocation of deceased donor organs suitable for transplant. Broadly speaking, federal law, commencing with the 1984 enactment of the National Organ Transplant Act (NOTA),[7] governs the process of procurement and allocation, while state law, reflected in the universal adoption of the Uniform Anatomical Gift Act (UAGA), governs the process of organ donation and donor registry. Pursuant to authority created by NOTA and HHS regulations,[8] the system for procuring and distributing vital organs is under the management of 58 regional Organ Procurement Organizations (OPO), which oversee the activities of 249 transplant centers.[9] An OPO must be a member of the national Organ Procurement and Transplantation Network (OPTN), administration of which has been contracted (since 1987) to the United Network for Organ Sharing (UNOS), based in Richmond, Virginia.[10] When an organ is donated within an OPO service area, the allocation matching system matches the donor with the database of waiting transplant candidates. The OPO evaluates the potential donor, checks the deceased's state donor registry, discusses the potential donation with the deceased's family members, and through the OPTN runs a match list to arrange for the recovery and transport of the donated organ.[11] The decision to accept or decline a matched donation is up to the transplant center, based on professional judgment.[12]

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from the director's desk

BY PAIGE C. CUNNINGHAM, JD
EXECUTIVE DIRECTOR

At CBHD, we have written and spoken about the need for biblical, theological, cultural, and ethical literacy. Today, I would like to encourage you to pursue scientific literacy.

If you have children or grandchildren in school, you have probably heard of the emphasis on STEM (science, technology, engineering, and math). STEM programs teach the four disciplines in an interdisciplinary, applied approach, rather than as separate classes. Backed with support from the Department of Education and thirteen agencies, the STEM goal is to move American students "from the middle of the pack in science and math to the top of the pack in the international arena."[1]

But STEM is not just for our children and grandchildren. We live in a scientifically and technologically advanced age, and the pace of innovation shows no sign of slowing down. Do we have a basic understanding of the science that is involved? Some of the innovations border on the miraculous, restoring sight to the blind, making the deaf hear, helping the paralyzed to walk again, and attaching prosthetic limbs that might be stronger than the original. The potential of medical and scientific technologies is boosted by massive increases in computational power. (The average car today has more computing power than the system that took the Apollo astronauts to the moon.[2])

Are we safe in assuming that every breakthrough is a benefit? An unmitigated good for society? Of course, we know that is not the case. The question then becomes, how do we evaluate this dizzying array of technologies? We must consider how to develop discernment and grow in wisdom about our use and refusal to use technology. We do not assume that technology is basically neutral. It has a direction or *telos*, a propensity to shape us, both overtly and covertly.

What Is 'Scientific Literacy'?

Here is one way of thinking about scientific literacy. One of Taylor University's foundational core requirements is scientific literacy, to "enable students to explore God's creation, investigate contemporary human challenges, and use technology thoughtfully in the context of human interaction.[3]" Although it is not feasible for us to conduct lab experiments and field observations as undergrad students do, it is possible to observe God's creation, to learn more about technology, and to think about how technology might—or might not—ethically solve human problems.

Why Scientific Literacy Matters to the Church

STEM is broader than bioethical concerns. Digital technologies affect not only electronic medical records and the doctor-patient relationship, they also have transformed communications. Think, for example, of the impact of smartphones on learning in the classroom, family meals, dating relationships, or even the safety of pedestrians.[4] On what grounds would we endorse or oppose smartphones, social media, or the internet? What is the trajectory of digital technologies? They are reshaping culture in seemingly dramatic ways. These ways can be positive or worrisome. The question for the church, then, is *how well do we interpret the signs of the times?*

Technology and Human Relationships

In *Alone Together*, Sherry Turkle writes, "We expect more from technology and less from each other."[5] An early advocate of how virtual technology could help us live better lives in the real world, Turkle now warns that "we're letting it take us places that we don't want to go."[6] Robots, computers, and smartphones of all kinds are driving us toward virtual, rather than real, intimacy. Our children are experts in texting, but not in speaking face to face. Actual people become an annoyance, while the incoming text message irresistibly demands our attention. Meanwhile, the technologies that promised to give us more

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leisure time make the boundaries between work and personal life increasingly porous.

Ignorance about how something works can lead to a distorted relationship with the technology. Turkle points out that unfamiliarity with how computer hardware works, or how software is coded, enables us to relate to the technology as human-like. This may explain why people confide in robots or computer-based therapists (with no actual person involved) even though the robot's or computer's responses are programmed, not human. Perhaps, like Riley's friend Bing Bong in the movie *Inside Out*, technology has become the adult version of an imaginary friend.

Medicine, Science, and Technology

One place to begin in evaluating new technologies is to ask what goal they serve. My colleague Michael Sleasman has observed that medicine and technology should always function in the service of human flourishing. Science can serve human flourishing, but also can be pursued simply in the "wonder of God" and his creation. Before buying the next wearable technology, you might ask if and how it will help you to flourish? Or will it make you more and more dependent upon the technology? And, before criticizing funding for basic research, we might consider that condensed-matter physics research linked with string theory gives us more insight into black holes.[7] For me, that is an awe-inspiring, wonder-of-God's-creation moment.

1 Elaine J. Hom, "What is STEM Education?" *LiveScience*, February 11, 2014, http://www.livescience.com/43296-what-is-stem-education.html (accessed July 23, 2015).

2 Institute of Physics, *Physics.org*, http://www.physics.org/facts/apollo-really.asp (accessed July 1, 2015).

3 Thomas G. Jones, "Foundational Core," Taylor University. See http://www.taylor.edu/academics/files/undergrad-catalog/current/FCC.pdf (accessed July 23, 2015).

4 Katherine Shaver, "Safety experts to pedestrians: Put the smartphones down and pay attention," *Washington Post*, September 20, 2014, http://www.washingtonpost.com/local/trafficandcommuting/safety-experts-to-pedestrians-put-the-smartphones-down-and-pay-attention/2014/09/19/278352d0-3f3a-11e4-9587-5dafd96295f0_story.html (accessed July 23, 2015).

5 Sherry Turkle, *Alone Together: Why We Expect More from Technology and Less from Each Other* (New York: Basic Books, 2011), xii.

6 Sherry Turkle, "Connected, but Alone?" *TED Talk*, April 2012, http://www.ted.com/talks/sherry_turkle_alone_together/transcript.

7 Zeeya Merali, "Collaborative Physics: String Theory Finds a Bench Mate," *Nature*, October 19, 2011, http://www.nature.com/news/2011/111019/full/478302a.html (accessed July 23, 2015); Perimeter Institute for Theoretical Physics, "Waiter, There's a Black Hole in My Condensed Matter," March 24, 2014, https://www.perimeterinstitute.ca/news/waiter-theres-black-hole-my-condensed-matter (accessed July 23, 2015).

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The process of becoming and being recognized as a donor is under the purview of state law. The UAGA, first drafted in 1968 and revised in 1987 and 2006, has been enacted in all states, although seven have not updated to the 2006 revision.[13] The UAGA respects the dominant ethos in the United States regarding organ donation: that it be the result of a free and voluntary decision made by the donor (or by a designated health-care proxy or close family member in the case of a permanently incapacitated patient). Its revisions conformed state laws to the system of organ procurement developed under NOTA to simplify the process of donation and expand the potential supply of donated organs. For example, the 2006 revision, now the law in most states, emphasizes the principle of first-person authorization; the donor's family thus has no legal right to override the deceased's prior decision to donate (although they suffer no legal penalty if they do so). Practices in response to this development vary. Some OPOs remain reluctant to oppose a family's effort to override the deceased's decision, but there also is evidence that the incidence of such objections has declined and that families of designated donors accept the principle of first-person authorization.[14] The UAGA also provides for the establishment of state organ donor registries (now adopted in all states), donor designations on driver licenses, and more efficient access by OPOs to such registries and records.

State and federal law reinforce each other on two salient points: the prohibition on financial incentives for organ donation, and the establishment of "routine inquiry" or "required consent" protocols, mandating that the families of donor-eligible patients be given the option to donate. Both sets of provisions merit further discussion, as the latter has been promoted (but largely failed)[15] to increase the supply of cadaveric organs, and the former criticized as an impediment to increasing both deceased and living organ donation—particularly of kidneys, which account for 80 percent of the current shortfall.[16]

Routine Inquiry to Presumed Consent?

Congress in 1986 required that hospitals participating in Medicare and Medicaid establish written protocols to identify potential organ donors and assure that families of such potential donors are made aware of their option to donate organs or tissue and their option to decline.[17] The following year, the Health Care Financing Administration (HCFA; now the Centers for Medicare & Medicaid Services or CMS) issued regulations, updated in 1998, requiring hospitals to incorporate an agreement with an OPO under which it must timely notify the OPO of individuals whose death is imminent or who have died in the hospital; OPO will then make a determination of medical suitability for organ donation. The hospital must collaborate with the OPO to ensure that a representative of the

OPO (not the hospital) inform the family of a potential donor of the option to donate or decline.[18] The UAGA includes parallel provisions;[19] in practical effect, these merely replicate the more specific federal requirements which, being tied to Medicare/Medicaid reimbursement and designation of OPOs, create a much stronger mandate. Even prior to the revision of the UAGA on this issue, virtually all state legislatures had enacted routine inquiry or required consent laws; these were subject to varying degrees of enforcement and regulatory implementation by State health departments.[20] In addition to these legal requirements, the transplant safety standards of the Joint Commission[21] require hospitals to have a written agreement with an OPO and to work with the OPO to develop a written donation policy for asystolic organ recovery.[22]

Under these schemes of regulation, the American system of organ donation remains an "opt-in" system—meaning that the donor beforehand, or the family at time of death, must affirmatively consent to the donation of organs. Because these measures have not appreciably increased the supply of cadaveric organs, some propose that the United States adopt a system of "presumed consent," under which the deceased is presumed to have consented to donation unless he or she has affirmatively "opted-out" before death,[23] or a system of "mandated choice" in which all adults would be required to express their preferences regarding organ donation, perhaps when obtaining a driver's license or filing a tax return.[24] A hybrid of these two systems could also be devised: the "mandated choice" aspect would require all adults to indicate their preference, and the "presumed consent" aspect would provide that those who do not reply are deemed to have consented to donation.[25] The American Medical Association (AMA) has recommended that pilot programs for each system be established to determine whether "ethically appropriate models of presumed consent or mandated choice for deceased donation would positively or negatively affect the number of organs transplanted."[26]

Proponents of presumed consent point to the fact that in continental Europe (as opposed to England, and with the exception of Germany), presumed consent laws are the norm.[27] Conceptually, presumed consent provides no role for family members in the decision to donate organs.[28] Under Austrian law, for example, relatives have no right even to be informed of organ removal, and the stricter notion of presumed consent has struck "deep roots."[29] In practice, however, some measure of affirmative consent endures, and is even required. Even in Austria, families are often consulted to confirm the intent of the deceased, and in Spain, which enjoys a high rate of organ donation, next of kin are routinely consulted even if the deceased has not opted-out of donation.[30]

Is Presumed Consent Effective?

The pivotal questions are whether presumed consent leads to higher rates of organ donation and if so, whether adoption of the system would lead to similar results in the U.S. Cadaveric donation rates in the U.S. are comparable to those of many "presumed consent" countries (Spain being a high-rate outlier, even among European nations); the medical literature often reflects that donation rates in presumed consent countries are not much higher relative to affirmative consent countries.[31] Abadie and Gay's 2006 study applied regression analysis to factors such as GDP, health expenditures, religious beliefs, and rates of death from motor vehicle accidents and cerebovascular disease.[32] They concluded that presumed consent countries have roughly 25–30 percent higher donation rates. However, the authors caution that adoption of presumed consent would not be a silver bullet to eliminate the shortage of donated organs in the U.S., that it may result in a reduction in the rate of living organ donation, and that it could generate an adverse response without first building sufficient social support for the policy.[33] Given the fractiousness of current U.S. debates over health care policy, the latter point is, if anything, understated.

It seems clear that when accounting for cultural factors, the reported success of presumed consent (which, to repeat, never exists in its "pure" form) is contingent on a society's receptiveness to what Richard Thaler and Cass Sunstein have described as the "nudge" factor.[34] In Europe, the specific history of presumed consent to necropsy and the general acceptance of communitarian obligations, often reinforced by law, create circumstances where presumed consent for organ donation will not only be accepted, but lead (or nudge) families to affirmatively agree when approached after the death of a loved one.[35] If the deceased has not opted out, the family will infer that the deceased had a desire to donate—even if the family has no specific knowledge on that point.[36] The law thus nudges families to consent, which, even though not strictly required by law, is likely to facilitate higher rates of donation.

Barriers to Presumed Consent in the U.S.

Adoption of presumed consent in the U.S. faces formidable legal barriers as well as related ethical objections, with the uncertain prospect that such reform would result in an appreciable net increase in available organs. Any such change would require coordinated efforts to overhaul the NOTA and its implementing regulations, as well as the laws of every state. The UAGA, now close to 50 years old and adopted in some form in every state, has always been based on the principle of affirmative consent, even

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as it has been revised to expand opportunities for persons to register their consent to donate, and ensure that such consent is known and given full legal effect. Thus, the principle of affirmative consent is as deeply imbedded in American legal culture as presumed consent is in most nations of continental Europe. A fundamental reorientation from affirmative to presumed consent would disrupt settled expectations and practice, and quite possibly result in a patchwork of state laws that could complicate the national organ procurement process.

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Under principles of federalism, Congress would have limited authority, if any, to impose a change from affirmative to presumed consent on the states; moreover, reforming NOTA in this manner would have the same disruptive effects. Although the AMA and others have suggested "pilot projects" to test the effectiveness of presumed consent, designing such a project to produce valid comparative data poses numerous difficulties. Laws would need to be changed in one or more jurisdictions, perhaps at the federal level as well, and a generous amount of time, at least a decade and probably more, would be needed to assess whether the change in law and practice increased the number of cadaveric organs suitable for transplant.

Proponents would likely point out that incremental legal change, even if disruptive, often leads to progress, and that on this issue, the lack of progress has become a matter of life and death for thousands of Americans. They also question the validity of the standard ethical objections to presumed consent—that it would infringe on autonomous decision-making making, undermine the principle of voluntariness, and result in procurement of organs from persons who, if asked, would not have consented. Noted bioethicist Arthur Caplan contends that a system of presumed consent, or "default to donation," is "completely consistent with the existing bioethical framework governing organ and tissue procurement. Respect for persons and voluntary altruistic consent remain the moral foundation for making organs available."[37] Citing the nudge factor, Caplan contends that society's familiarity with defaults in other areas might with increase comfort with this manner of procuring organs—thus replicating the experience in much of Europe.

The best that can be said of these arguments is that even if presumed consent were adopted, families would still likely be asked to ratify the process of donation, as they are to varying degrees in Europe, thus preserving in fact some element of affirmative consent. But the contention that the *design* of presumed consent serves equally well the principles of individual consent, voluntarism, and altruism that underlie U.S. law on organ donation is far less persuasive. The paths of affirmative and presumed consent diverge at critical ethical and jurisprudential points, and reflect different accounts of humankind's relationship to the state—which may explain Germany's adherence, along with the common-law countries, to the less coercive scheme of affirmative consent.

Whether or not it is coercive in practice, presumed consent is coercive in principle, even if the coercion is of the "soft" or "weak" variety that allows for an opt-out and ratification by family. It has been argued that no one has the right to say what should be done to their body after death, because the body "can only legitimately be regarded as on extended loan from the biomass."[38] On this view, no immoral coercion would exist because there is no moral claim to ownership of the body or expectation of its disposition. But the radical nature of the premise is unlikely to lead to any greater acceptance of presumed consent as a non-coercive means of increasing organ donation.

Mandated Choice: A Less Coercive Option?

Recognition of these barriers to a policy of presumed consent—whether of the "strong" (Austrian) or "weak" (Spanish) variety—has led to advocacy for, and limited adoption of, the policy of "mandated choice."[39] By requiring all adults to either opt-in, opt-out, or "defer to family wishes,"[40] mandated choice, according to its proponents, preserves the autonomy that is lost under a system of presumed consent. No one is required to make a particular decision for or against donation; all that is required is to register *some* decision.[41] In fact, one could say that a limited (and inconsistently applied) form of mandated choice already exists under the rubric of "routine inquiry." Mandated choice may be less coercive than presumed consent, and it may pass constitutional muster as violating no rights to privacy or free speech.[42] However, it still involves a measure of coercion that (particularly in practice) places at risk the principles of voluntarism and altruism underlying current legal norms on organ procurement and donation, all with uncertain effect on the rate of organ donation and procurement.

The current "model" for mandated choice is Illinois' First Person Consent Act (FPCA). The FPCA requires the Secretary of State to offer to each applicant for a new or renewed driver's license the opportunity to be included in a First Person Consent registry for organ or tissue donation; once placed on the registry, the donor's decision may not be overridden by family objections at the time of death.[43] Individuals can also join the registry by mail, phone, or online. In practice, those obtaining or renewing a license in person are required to answer the question: Do you want to be an organ donor?[44] Virginia also requires a choice to be made at the time of renewing a license, but offers the options of "yes," "no," and "undecided."[45]

For reasons not easily explained, the Illinois law has resulted in 60 percent of adults reportedly registered as organ donors, well above the national average, while Virginia's rate (31 percent) is actually below the national average (40 percent).[46] (Virginia's "undecided" option does not appear to be the cause, as 45 percent of respondents affirmatively choose not to donate). California more recently adopted legislation modeled on the FPCA, with a specific requirement that a motor vehicle employee verbally ask every registrant whether he or she wishes to join the registry.[47] An estimated 10 million Californians are currently on its donor registry.

Despite the inconsistent evidence from the few states that have adopted mandated choice, we can presume that the more people are asked—and required to answer—whether they wish to donate organs, the more organ donors will be recognized and registered. Public opinion polls show widespread support for donation, and for willingness to donate, even if current rates of affirmative consent donation do not reflect that level of support. Much will depend on how mandated choice is implemented—it is not difficult to imagine that if the same poll respondents were asked whether their state's motor vehicle department was the best venue in which to be compelled to make a decision, the approval numbers would decline significantly. But even if well-handled at the bureaucratic level, and successful in raising the number of registered donors, it is legitimate to question whether mandated choice compromises autonomy and to what effect.

Issues Regarding the "Non-Donor" and Autonomy

A chief feature of the Illinois and California laws, in contrast to the Virginia law, is that the names of those who decline to register as donors are not placed on a "non-donor" registry—meaning that the families of those who have affirmatively chosen not to donate may, at the time of death, nonetheless be asked to give approval to donate, thereby overriding the wishes of the deceased. Proponents of mandated choice assert that the state has a legitimate public health interest in compelling persons to make a decision one way or the other—even by the compulsive effect of withholding a driver's license renewal or a tax refund.[48]

But is the state acting even-handedly when it chooses to record the wishes only of those who select the state-preferred option of donation? Of course, it may be presumed that all who are not listed on the donor registry must have declined at some point in receiving or renewing their driver's license, but they are not given the option of affirmatively stating and having recorded their decision. The situation is different from that under a pure affirmative consent model—there, the state (and perhaps no one else) has never asked the deceased or near-decedent whether he or she wishes to donate, and it is fair to ask the family to fill the gap in the interests of altruism and beneficence to others. But if the state, under compulsion of law, has required one to make a decision, is it not incumbent on the state (under the principle of "first-person consent") to honor that choice, however it comes out?

Furthermore, simply increasing the number of registered donors is weak justification for this inversion of the principle of autonomy. Creating more registered donors does nothing to ameliorate the shortage of organs unless an appreciable number of those donors will be in a position, at some point, to actually donate. Odds are, happily, heavily against that eventuality. Of the two million who die in the U.S. each year, only a small fraction, around 12,000, do so under the unfortunate circumstances in which vital organs are amenable to donation.[49] Under the prevailing system—one of affirmative choice, first-person authorization, and required inquiry—family consent is available where no first-person decision has been made. Evidence is lacking that family refusal in such cases is a systemic impediment to increasing the number of transplantable organs (as opposed to merely increasing the numbers of people who are registered to donate, and in all likelihood will never be in a position to do so). The consent rate for donation from eligible deceased donors is 75 percent; up from 50 percent in the early years of this century.[50] First-person consent is already the law in most states; in practice, families are still consulted and it is likely they will continue to be consulted even if the first-person authorization has been obtained through a system of mandated choice. Even if Illinois and California lead a broader trend toward mandated choice, it is doubtful that a significant increase in transplantable organs will result.

Conclusion

> *"I am profoundly skeptical whether any change of legislation in and of itself could modify a social reality which is supported by the majority. The sequence of events goes the other way around. Laws are good laws when they conform with that which has been accepted by society and when they do not try to modify society by coercion."*[51]

Decades of legal initiatives have supported the progress of a world-class organ transplantation system in the United States, saving and prolonging hundreds of thousands of lives, and allowing new technologies to develop and flourish. Under critical federal oversight and coordination, the system incorporates a strong "local" component, with a variety of OPOs and an even greater number of transplant centers implementing protocols for procurement and allocation with substantial flexibility. Furthermore, the states have the dominant role in governing the process of consent for donation.

Yet this system of laws and procedures has not bridged the increasing gap between donated organ needs and organ availability from deceased donors. As the preceding discussion suggests, there may be inevitable limits to the law's capacity to do so, even if it departed from some of the bedrock principles under the current system. More radical departures from those principles, including the compensation of living donors (chiefly of kidneys and livers) and expanding the concept of who may be considered a "dead donor,"

are subjects for a future essay.

1 United Network for Organ Sharing, "Transplant Network Reaches Milestone of 500,000 Deceased Donor Organ Transplants," May 19, 2015, https://www.unos.org/transplant-network-reaches-milestone-of-500000-deceased-donor-organ-transplants/ (accessed May 28, 2015). Half of these transplants have involved kidneys, one-quarter liver, and one-eighth heart.

2 It is widely recognized that the "reported" wait list is inflated by as much as one-third through inclusion of inactive and medically-ineligible patients. The United Network for Organ Sharing admits, and defends, its practice of including inactive and ineligible potential recipients on the reported wait list. However, prominent bioethicists such as Arthur Caplan and other experts have sharply criticized the practice. Rob Stein, "A Third of Patients On Transplant List Are Not Eligible," *Washington Post*, March 22, 2008, http://www.washingtonpost.com/wp-dyn/content/article/2008/03/21/AR2008032102981.html?sid=ST2011022308018 (accessed August 20, 2015). The wait list is further inflated by "multiple listing" of patients who register at more than one transplant center. Arthur Caplan, "Organ Transplantation," in *From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns*, ed. Mary Crowley, 129-132 (Garrison, NY: The Hastings Center, 2008), http://www.thehastingscenter.org/uploadedFiles/Publications/Briefing_Book/organ%20transplantation%20chapter.pdf (accessed August 20, 2015).

3 Organ Procurement and Transplantation Network, "Need Continues to Grow," Health Resources and Services Administration, U.S. Department of Health and Human Services, http://optn.transplant.hrsa.gov/need-continues-to-grow (accessed May 28, 2015).

4 Howard M. Nathan et al., "Organ Donation in the United States," *American Journal of Transplantation 3*, suppl. 4 (2003): 29.

5 OrganDonor.gov, "The Need Is Real: Data," Health Resources and Services Administration, U.S. Department of Health and Human Services, http://www.organdonor.gov/about/data.html (accessed May 28, 2015).

6 Sally Satel, Joshua Morrison, and Rick Jones, "State Organ-Donation Incentives Under the National Organ Transplant Act," *Law & Contemporary Problems* 77, no. 3 (2014): 17.

7 Public Law 98–507, 98 Statute 2339 (Oct. 19, 1984), codified, as amended, at U.S. Code 42 §§ 273–274 (hereafter referred to as "NOTA").

8 The Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA) is responsible for HHS regulations in this area, including the certification of transplant centers and organ procurement organizations. A different branch of HHS, the Health Resources and Services Administration, provides oversight of the OPTN. See *Code of Federal Regulations*, title 42 Part 121.

9 Nathan et al., "Organ Donation in the United States," 29–30. The phenomenon is not limited to the United States. Cf. Nereo Zamperetti et al., "Reflection on Transplant Waiting Lists," *The Lancet* 378, no. 9791 (August 13, 2011): 632-635.

10 Ibid., 29–30. See also documentation published at OPTN's web site: http://optn.transplant.hrsa.gov/converge/members (accessed May 28, 2015).

11 Nathan et al., "Organ Donation in the United States," 29–30. The list can be accessed at http://organdonor.gov/materialsresources/materialsopolist.html (accessed May 28, 2015).

12 Nathan et al., "Organ Donation in the United States," 33–34. Rates for non-recovery of donated organs vary greatly depending on the organ involved—as low as 7 percent for kidneys and livers, up to about 50 percent for hearts and over 80 percent for lungs.

13 For detailed information see the table at http://www.organdonor.gov/legislation_micro (accessed May 28, 2015). The Anatomical Gift Act (2006) is available at http://www.uniformlaws.org/ActSummary.aspx?title=Anatomical%20Gift%20Act%20(2006) (accessed May 28, 2015).

14 Heather M. Traino and Laura A. Siminoff, "Attitudes and Acceptance of First Person Authorization: A National Comparison of Donor and Nondonor Families," *Journal of Trauma Acute Care Surgery* 74, no. 1 (2013): 294.

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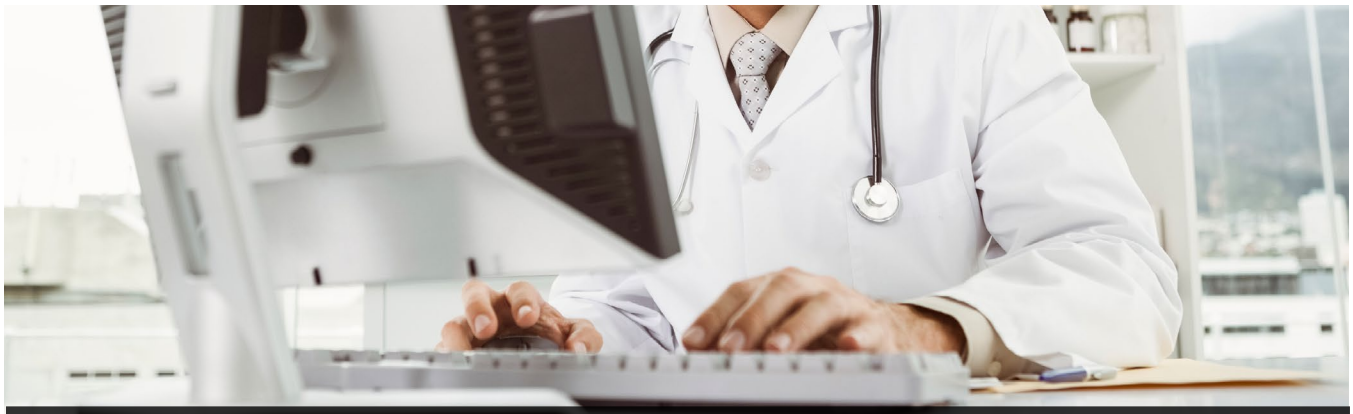

ELECTRONIC MEDICAL RECORDS:
A STORY OF TECHNIQUE AND MEDICINE

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"Men have always sensed that the more they forged and the more machines they built, the more they were forced to know, to love, and to serve these devices." –Edmund Pellegrino, MD [1]

Among the numerous advances of technology in the practice of medicine, the electronic medical record (EMR) is unique, because it insinuates itself into a fundamental aspect of the patient-physician relationship: the clinical encounter. In an increasingly common scenario, there is a "third person" in the room with the patient and physician, represented by a screen and keyboard into which the physician enters and from which she retrieves information. The widespread adoption of the EMR introduces new ethical considerations into the practice of medicine, some of which are common to any extension of technique into medicine, and some of which are unique to the EMR.

Technique

One way of analyzing the EMR or any technology is to take a step back and examine the category of *technique*. This category is perhaps not one with which many of us are familiar. It is not equivalent to technology, with which it is easily confused, although what we commonly think of as technology—gizmos and gadgets such as dishwashers, smart phones, and MRI scanners—is a subset of technique. Lewis Mumford defined technique (he used the word *technics*) as "a translation into appropriate, practical forms of the theoretic truths, implicit or formulated, anticipated or discovered, of science."[2]

Of course, people have always employed technique; but the contemporary situation, in which technique has taken over our environment, is unique in history. In his *Technics and Civilization,* Mumford recounts how, during the 17th and 18th centuries, the close link between scientific research and technological invention developed, radically altering the relations between technique and civilization. The amazing successes of science applied to invention led to the widespread acceptance of the notion that applying the principles of scientific research to all domains of life would therefore be a beneficial practice. Thus, those qualities that make scientific research successful—objectivity, reductionism, standardization, the reduction of all characteristics to quantitative measurement (and the corollary classification of anything that cannot be quantified as "subjective," and therefore less valid)—were, and are being, firmly established and extended into all domains of human life. In short, technique is our environment.

Technique as All-Encompassing

The 20th-century French sociologist Jacques Ellul emphasized this all-encompassing aspect when he wrote that technique "does not mean machines, technology, or this or that procedure for attaining an end. In our technological society, *technique* is the *totality of methods rationally arrived at and having absolute efficiency* (for a given stage of development) in every field of human activity."[3] Technique is about making everything rational, so that every human activity is analyzed and reshaped in such a way as to eliminate spontaneity or intuition. "Man's traditional, spontaneous activities are now subjected to analysis in all their aspects—objects, modes, duration, quantities, results."[4] Technique is also about "absolute efficiency." In our technological society, efficiency is the "universally applicable criterion of social choice."[5] Seeking the single most efficient means is the "main preoccupation of our time."[6] Efficiency becomes the standard for all decisions, overriding any other competing standard, such as aesthetics or ethics. Certainly

we see this at work today; one has only to defend a particular choice by saying, "This way is more efficient," to get all heads in the room nodding in agreement.[7] Technique is not just our environment, but our mindset as well.

So technique is not about machines, per se, but the subjugating of all of human activity to the methods of the machine. And yet, the machine provides the best metaphor for technique, for as Ellul wrote, technique "transforms everything it touches into a machine."[8] Now we may use the expression, "He's a machine!" as a compliment, meaning that a person does something particularly well, tirelessly, and consistently. However, Ellul uses the word "machine" in a sense that is decidedly *not* complimentary. He understands that "machine-ization" or "technicization" is opposed to characteristically human modes of living, and thus leads to "dehumanization." Or as Mumford expressed it, "the calculus of energies...takes precedence over the calculus of life."[9]

Technique and the Transformation of Practice

To provide evidence that introducing a technique into a field alters the meaning of that field, consider the following experience from my work as an attending physician in a Family Medicine residency program. When I am attending on the inpatient service, I still like to go on bedside rounds with the residents. My residents enjoy seeing patients as well (otherwise they would not have chosen Family Medicine as their specialty!), but, like all residents these days, they are required in the course of their work to spend hours in front of the EMR's computer screen attending to what Abraham Verghese calls the "iPatient"[12]—many more hours, in fact, than they can spend in the presence of their patients. On one particular day I was rounding with my residents, and I could feel the tension rising in one of them as we went from room to room, taking our time to listen to patients and examine them. Finally she burst out, "Can we hurry up and get through with this so we can get back and do our work?" By "our work," she meant "getting back to the computers in our resident room," as opposed to "listening to and examining patients." It is not difficult to see how the technique of the EMR is redefining just what the work of a doctor is, and that it is redefining it in technical terms. It is an ecological change, not merely an additive one.

> ***The development of technique inevitably creates technical problems, unforeseen consequences which can only be resolved by the elaboration of another technique, thus assuring technique's increase.***

A significant aspect of technique is that each new individual technique or technology carries within it an idea, an ideology.[10] Techniques are often portrayed as value-neutral: it is not the technique that carries moral content, rather, it is how we use it (or as is commonly claimed "Guns don't kill people; people kill people."). But each new technique changes, sometimes imperceptibly, our assumptions about the world and our function in it, and it does so based on qualities inherent in the technique itself. Thus each new technique carries within it the seed of an idea, and change of technique is therefore not merely additive but ecological.[11] Applying these concepts to healthcare, when one adds the EMR into medical practice, one does not have merely "medical practice + EMR"; one has *a different medicine*—a different idea about medicine, a different practice of medicine, a different concept of what makes up medical practice.

Another salient aspect of technique is that in the technical system, we are compelled to use our techniques. Ellul used a few different terms to describe this aspect of technique: it is *monistic, self-augmenting,* and *autonomous.* Monism, as Ellul uses the term, means that a technique tends to be applied everywhere it *can* be applied, without regard to whether it is a "good" or "bad" use. Self-augmentation describes how technique "is being transformed and is progressing almost without decisive intervention by man."[13] Humans catalyze rather than control the augmentation of technique. We are "so enthusiastic about technique, so assured of its superiority, so immersed in the technical milieu,"[14] that we simply assume that more technology is inherently good, and we automatically apply it everywhere it can be applied, whether or not the occasion demands it.[15] There are certainly occasions that demand technique, and medicine is rife with them: by technique medicine has achieved astonishing victories over many of mankind's most terrible scourges. But technique takes on a very fertile life of its own, for which Ellul used the term autonomy. The development of technique inevitably creates technical problems, unforeseen consequences which can only be resolved by the elaboration of another technique, thus assuring technique's increase.

So we gradually relinquish increasing domains of life to technique, seemingly unable or unwilling to put appropriate limits on it. As our freedom to choose anything outside of the technical system is diminished, we see all that we gain from technique; but we rarely if ever pause to consider what we lose. Technique, for all the good it offers, is a double-edged sword; to use a medical analogy, it has a very narrow therapeutic range. When unchecked, it is a force that naturally dehumanizes whatever it touches; applied indiscriminately, it acts to diminish the nature of medicine as a human profession, transforming it instead into a machine-like activity, driven by efficiency, and maladjusted to the human beings who practice it and whom it is meant to serve.

Technique and the EMR

How might the concept of technique help us evaluate the use of EMRs in medical practice? The EMR has gained momentum since the 1960s when Lawrence L. Weed first introduced the concept.[16] In the 1970s, academic and research centers began to implement EMR-like systems in the inpatient setting. In the late 1980s, low-cost PCs became available and started to appear in physicians' offices, used mostly for billing and coding. In 1996, the Veterans Health Administration mandated the use of EMRs in all of its facilities. In 1999, the Institute of Medicine (IOM) published its landmark report, "To Err is Human: Building a Safer Health System," in which it stated that between 48,000 and 98,000 people in America die annually as a result of preventable medical errors. In 2001, the IOM followed up with a report entitled, "Crossing the Quality Chasm: A New Health System for the 21st Century." Both reports promoted EMRs as a way to reduce medical errors, improve patient safety, and increase the quality of medical care.

In 2004, President Bush called for widespread adoption of EMRs by 2014. In 2009, the Health Information Technology for Economic and Clinical Health Act was passed, authorizing the use of $26 billion to promote the adoption of health information technology, including incentive payments to those who demonstrate "meaningful use" of an EMR system. In 2011, the IOM published the report, "Health IT and Patient Safety: Building Safer Systems for Better Care." This report called for the establishment of an independent federal body to investigate patient deaths and other adverse events *caused* by EMRs and other health information technology. By 2013, 78% of office-based physicians were using some type of EMR.

Consequences of EMR Adoption

This rapid adoption of the EMR is unremarkable on one hand, given the broader societal trends in the proliferation of digital technologies and rising interest in Big Data. Furthermore, the government directly incentivized the transition, and, beginning this year, entities that do not demonstrate "meaningful use" of an EMR will start facing financial penalties. On the other hand, however, it is quite remarkable; because in a medical field that has adopted the mantra of evidence-based medicine, which is the idea that medical treatment should be guided by the best statistical data derived from the study of populations, there is remarkably little evidence that EMRs either reduce medical errors, improve patient safety, or increase the quality of medical care—the very goals that the IOM reports averred would be achieved through EMRs.

> ***"The EMR, as currently implemented, introduces a rival for the physician's attention directly into the exam room.***

So why the push from the government to adopt EMRs? And why the headlong rush of medical care providers to adopt them? One response may be that EMRs will contribute greater pools of statistical data sets, but the value of such data remains to be seen. Absent actual evidence that it makes a positive difference, does the answer lie in the nature of technique? The computer *can* be used in medicine; therefore it *must* be (Ellul's monism). The computer is an advanced technology; therefore it *must* advance the practice of medicine, make it better, because we believe that more technology, particularly the latest technology, is always better. The computer promises greater efficiency (even if it has yet to deliver on that promise); therefore, it is the obvious choice.

But the EMR, like all techniques, carries within it an idea, or multiple ideas. One of those ideas can be expressed by a variation on the old maxim, "To a man with a hammer, everything looks like a nail"; that is, "To a person with a computer, everything looks like data." Medicine is rapidly embracing the idea that it should be data-driven; it is supposed that the more data we can amass about patients and diseases and treatments, the better able we will be to treat patients' diseases. Computers are absolutely necessary for the recording and manipulating of that data. This will almost certainly be a positive thing for medical practice in many ways. We will have gained much. But will we lose anything? This is the question that is rarely, if ever, asked. What, if anything, do we lose by adoption of the EMR?

What is Gained? What is Lost?

For a very long time, the basic economy of medicine has been a relationship between two people: one person with a problem, and another person with some skills and a professional duty to act in the first person's best interest. That relationship necessarily involves careful listening and observation—full attention—by the professional in order to diagnose and treat correctly. In many cases the relationship itself has been efficacious for healing, not only in times past when effective treatments were rare, but even today, when a vast armamentarium of powerful treatments and medicines lies at our fingertips. The EMR, as currently implemented, introduces a rival for the physician's attention directly into the exam room. The EMR, as currently implemented in most places, requires a physician to spend large portions of the patient visit focusing attention on data entry, attending to the screen instead of the patient, attending to the needs of the computer for data in preference to the needs of the person in front of him for his full presence.

What is potentially lost by the adoption of the EMR? The primacy of the physician-patient relationship in medical practice. The careful observation of the patient. Presence. Things basic to relationship, like eye contact and body language that says, "For this period of time, you are most important to me." The common courtesy of giving full attention; with our ubiquitous computers, we are at risk of "legitimizing rudeness."[17]

But EMR vendors and proponents will never mention these potential drawbacks; we hear only of the great things that we will gain by adopting the EMR.

Some of the effects of introducing the EMR into the exam room have been studied and documented. These studies have shown that doctors find EMR a limitation to their practice and, ultimately, that the needs of the machine take precedence over the importance of the human relationship. On average, physician visits take longer when an EMR is used in the exam room; however, this lengthening is not attributed to increased time in conversation, but to time spent logging data on the computer or tablet. The data entry activities are noted to contribute to inhibition of physician engagement in psychosocial question asking, eye-to-eye contact, focusing

> ***Technique, for all the good it offers, is a double-edged sword***

on patients, and emotional responsiveness, although there is the positive effect of increased exchange about biomedical and therapeutic matters. The physician using the EMR tends to efficiently structure the patient visit around data-gathering rather than around patients' own narratives, methodically pointing-and-clicking their way through the patient interview.[18]

Attitudes of physicians towards EMRs were examined in a 2013 mixed-methods study of professional satisfaction sponsored by the American Medical Association (AMA). The study notes that "the most novel and important findings concerned how physicians' perceptions of quality of care and use of electronic health records affected professional satisfaction."[19] Physicians noted positive aspects of EMR use: for the most part, they approve of the *concept* of the EMR. They appreciate the ability for remote access and the ability to communicate via e-mail with other providers and patients. They appreciate its potential to improve care quality and patient satisfaction as user interfaces and health information exchange improve.

On the negative side, physicians note the poor usability of EMRs and time-consuming data-entry, finding that it interferes with face-to-face patient care, and leads to less-fulfilling work content. They are frustrated by the inability to exchange information between EMRs and the degradation of clinical documentation. They feel the burden of information overload, and that they are doing clerical work, rather than working "at the top of their license." Interestingly, having more EMR functions, such as reminders, alerts, and messaging capabilities, was associated with *lower* professional satisfaction. Apparently, where the EMR can enhance communication, physicians are in favor of it. Where the EMR is a hindrance to communication and displaces the patient-physician relationship in favor of mechanical exercises, physicians sense the degradation of their profession.

As with any technique, the EMR brings with it a host of unintended consequences, some of which are detailed above. Among others that have been documented include the introduction of new work for physicians; things that were once done by other people, such as typing, coding, and billing, are now done by physicians, which necessarily takes time from other activities, such as being with patients.[20] There is the never-ending presence of new demands. The forms for paper charts remained unchanged for decades without significant upgrades. EMRs, however, are constantly being tinkered with and "improved," leading to the need for continuous upgrades to hardware and software, and the need for continuous physician training to become familiar with new or changed system features. Whereas the EMR is supposed to facilitate communication between different team members, another unintended consequence has been the introduction of new types of communication errors. For instance, without the EMR, one might have to call or otherwise directly contact another person participating in the care of a particular patient; the EMR, however, can create "the illusion of communication," that is, the false belief that if I enter information into the chart, the right person will automatically see it.

Other Ethical Considerations: Accuracy and Privacy

Apart from the particular issues raised by the EMR's extension of technique into the physician-patient relationship, there are other ethically important consequences of EMR adoption. One has to do with the accuracy of the information in the EMR, and relates to the widespread usage of templated notes and "copy-and-paste" functionality. Much of the documentation in EMRs is in the form of standardized templates, in which the physician points-and-clicks and/or the computer automatically fills in information from the patient's database. Many times documentation is copied-and-pasted from previous entries,[21] without any way to tell which information in the note was actually obtained from the patient and what was blithely copied from a previous note or automatically "blown in" by the computer. This can generate massive notes, loaded with extraneous data that is never actually read or reviewed, because nobody actually has the time to review it. (It can also lead to absurdities that I have personally observed, such as a detailed description of male genitalia documented on a female patient!) In this way, a single error in documentation propagates and is preserved in subsequent documentation—documentation that is used not only for patient care, potentially endangering a single patient, but also for research, in which the error potentially affects the treatment of whole populations of patients. Here the concern is not the collection of data as such, but the accuracy of the data itself.

Templated EMRs also undermine patient individuality and life narrative. Within the confines of an EMR's templated documentation, patient particulars can and often do get lost, and in the chart all patients start to look the same.[22]

> *much of the work of EMRs appears to be characterized by humans adapting to the machine.*

Another serious and growing concern with the EMR is the frequency of privacy breaches. Stolen medical records, containing details such as social security numbers and credit card information, sell at a high price on the black market. According to a report published in May, the health records of at least 88.4 million people were breached last year (although security experts say there were probably far more that have gone undetected), and the numbers are already higher for 2015.[23] Cyber-attacks are costing the U.S. healthcare system $6 billion annually; more worrisome than the money, however, is the breach of the trust and privacy which have been enshrined in medical practice since Hippocrates.

Another potential source of privacy breaches comes from those with legitimate access to the EMR. One of the drawbacks of current EMR systems is that different EMRs often cannot communicate with each other. If a patient is seen in the emergency department of a hospital outside of my system, I have no access to the record of that visit. This has led to the effort to create Health Information Exchanges (HIEs), central repositories for the sharing of data between systems. However, the access to such data will be extremely difficult to control. In my own hospital system, access to the EMR is automatically monitored to make sure that people are not inappropriately accessing the charts of family members or celebrity patients. However, if data from multiple systems is collected in a central HIE, there is nothing to stop "a meddlesome pharmacist in Alaska" who "looks up the urine toxicology on his daughter's fiancé in Florida, to check if the fellow has a cocaine habit."[24]

Another privacy issue involves EMR vendors' use of patient data. Several EHR vendors (among them Cerner, GE, and Allscripts) sell de-identified copies of patient databases in their systems to pharmaceutical companies, medical device makers, and health services researchers. It has proven easy, using the Internet, to "re-identify" the data.[25]

Conclusion

The story of the EMR is one of good intentions and unintended consequences. Some of the negative consequences are amenable to technical solutions. The integrity of documentation can be protected by removing the functionalities that automatically write notes in the chart; the privacy and safety of patient data can and must be protected by the elaboration of better computer security; and the selling of de-identified patient data must be discontinued. It is untenable that patients must risk privacy invasion and identity theft every time they see their physician.

However, some of the negative consequences of the EMR are not so amenable to technical innovations, since they arise from the essential nature of the EMR as part of the system of technique. The EMR, by its presence in the midst of the patient-physician relationship, brings the most intimate and personal aspect of the practice of medicine into the harsh glare of the system of technique. Its intrinsic tendency is to introduce the "spirit of machineness" into a human activity or relationship characterized by intuition, empathy, and spontaneity. The move toward using scribes, people in the exam room who attend to the computer so that the physician can attend to the patient, is one way physicians are countering the negative effects of the EMR on this relationship. Even so, much of the work of EMRs appears to be characterized by humans adapting to the machine. Instead of the physician laboring to conform to the requirements of the EMR, programmers must labor to adapt the technology to the needs of the humans using it.

In the education of medical students and residents, the centrality of the patient-physician relationship must be continuously reasserted. Students from a generation immersed in computer technology and virtual worlds must repeatedly be reminded and shown by example that important clinical information is lost when physicians fail to observe the patient in front of them. Instead, they must learn that the most important information is not found in computer databases but in the eyes and faces and bodies and stories of their actual patients.[26]

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1 Edmund Pellegrino, *Humanism and the Physician* (Knoxville: University of Tennessee Press, 1979), 10.

2 Lewis Mumford, *Technics and Civilization* (Chicago: University of Chicago Press, 2010), 52.

3 Jacques Ellul, *The Technological Society* (New York: Vintage, 1964), xxv (Emphasis in original).

4 Ibid., 395.

5 Langdon Winner, "Foreward," in Mumford, *Technics and Civilization*, xii.

6 Ellul, *The Technological Society*, 21.

7 This facet of technique raises the question of human freedom in making choices. Efficiency is determined by mathematical calculation. If the sole standard in the technological society for making choices is efficiency, then when we "choose" between one course of action and another, all we are really doing is measuring which option is most efficient and taking the inevitable course laid out for us by calculation. We become tabulators rather than choosers. Ellul described this as the "automatism of technical choice."

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22 Ventres et al., "Physicians, Patients, and the Electronic Health Record," 129.

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48 Cotter, "Increasing Consent for Organ Donation," 621.

49 Francis Delmonico, "Organ Donation and Utilization in the United States, 2004," *American Journal of Transplantation* 5, no. 4p2 (2005): 863, 872. See the link to the spreadsheet at Association of Organ Procurement Organizations, "Data on Donation and Transplantation," http://www.aopo.org/related-links-data-on-donation-and-transplantation/ (accessed June 8, 2015).

50 Association of Organ Procurement Organizations, "Data on Donation and Transplantation."

51 Matesanz, "Cadaveric Organ Donation," 1633.

TOP BIOETHICS NEWS STORIES: MARCH – MAY 2015

BY HEATHER ZEIGER, MS, MA
RESEARCH ANALYST

"More States Consider 'Death with Dignity' Laws" by Michael Ollove, *The Pew Charitable Trusts*, March 9, 2015

> The advocacy group Compassion & Choices says that bills on aid-in-dying have been introduced this year in Alaska, California, Colorado, Connecticut, the District of Columbia, Hawaii, Iowa, Kansas, Maryland, Massachusetts, Missouri, New Jersey, New York, Oklahoma, Wisconsin, Wyoming and Utah. Court cases have surfaced in New York and California. (http://tinyurl.com/pu4cz8x)

This year has seen an uptick in the number of physician-assisted suicide (PAS) bills in the U.S. Several states presented bills, including California, where the bill passed in the Senate, but eventually failed in committee. Internationally, France passed a law that allows physicians to place terminally-ill patients under sedation, but in Scotland, a bill to legalize physician-assisted suicide failed. Furthermore, reports show that euthanasia cases in Belgium, which has some of the most permissive laws, have doubled over the past six years.

"Terri Schiavo: 10 Years after Her Death 'End of Life' Debate Rages On" by Liz Neporent, *ABC News*, March 31, 2015

> Ten years after the death of Terri Schiavo, the debate over when to end the life of someone catastrophically ill rages on. (http://tinyurl.com/ls4l3tc)

"Kara Tippetts, Who Wrote an Open Letter to Brittany Maynard, Has Died" by Sarah Pulliam Bailey, *Washington Post*, March 22, 2015

> A Christian author and blogger with terminal cancer who tried to persuade Brittany Maynard to reconsider her November decision to die through doctor-assisted suicide, has died. (http://tinyurl.com/obeet5l)

March 31, 2015 marked the ten-year anniversary of Terri Schiavo's death a week after her feeding tube was removed. Her high-profile case spurred a national debate about patients in persistent vegetative state and who decides whether they live or die. In the same month as the Schiavo anniversary, Kara Tippetts, who courageously responded to physician-assisted suicide (PAS) proponents, passed away. Tippets offered a life-affirming message despite her terminal prognosis, in response to the more publicized message of Brittany Maynard (who died in November 2014 through the use of PAS in Oregon). Maynard famously advocated for PAS after being diagnosed with terminal brain cancer, while Tippetts advocated for life after being diagnosed with terminal breast cancer. CBHD recently published an article on CBHD.org by Advisory Board member Edward Grant, JD, reflecting on the anniversaries of the Nancy Cruzan and Terri Schiavo cases. The article can be accessed at http://tinyurl.com/nqopz3q.

"30 New Ebola Cases, Lowest Weekly Figure in Nearly a Year" by Reuters Staff, *Scientific American*, April 8, 2015

> Thirty confirmed cases of Ebola were reported in West Africa in the past week, the smallest number in nearly a year of the worst ever outbreak of the deadly fever, the World Health Organization said on Wednesday. (http://tinyurl.com/oljm2w9)

Ebola ravaged the countries of Guinea, Sierra Leone, and Liberia, prompting a world-wide effort to provide resources and contain the disease. Finally, after over a year, the Ebola epidemic seems to be receding. April marked a steady decrease in the number of new cases. However, after having no new cases for several weeks, Liberia, reported six new cases this summer. These cases have since cleared, and now Liberia is waiting to be declared Ebola-free. New cases in Guinea and Sierra Leone continue to decline.

"Are Human Head Transplants Coming Soon?" by Debra Goldschmidt, *CNN*, April 10, 2015

> As crazy as this sounds, to put an entire head on a new body, a human body, Italian physician Dr. Sergio Canavero says we are approaching HEAVEN (an acronym for head anastomosis venture; anastomosis is surgically connecting two parts). The pieces are coming together but there are still many hurdles to jump. (http://tinyurl.com/q4j4lx4)

In the area of weird science that is fraught with ethical issues, Dr. Sergio Canavero made headlines for giving a TED talk theorizing a head transplant in the next few years. He claims to have heard from several patients who are willing to be guinea pigs when he is ready to try the transplant. CBHD Executive Director Paige Cunningham published a commentary on this news item in Summer 2015 issue of *Salvo* magazine, which can be accessed online at http://tinyurl.com/o39x2pz.

"Chinese Scientists Genetically Modify Human Embryos" by David Cyranoski and Sara Reardon, *Nature*, April 22, 2015

> In a world first, Chinese scientists have reported editing the genomes of human embryos. The results are published in the online journal *Protein & Cell* and confirm widespread rumours that such experiments had been conducted—rumours that sparked a high-profile

> debate last month about the ethical implications of such work. (http://tinyurl.com/n8eenl7)

Using non-viable embryos, Chinese scientists edited the genome of a human embryo. They used CRISPR/Cas9, a robust gene editing technique, to edit the gene that is known to cause beta-thalassaemia. The research has prompted many scientists, ethicists, and organizations, including the NIH, to call for a moratorium on germ-line editing. The authors of the paper point out that their research shows this technique has a long way to go before it could be feasible in a clinical setting. CBHD staff Paige Cunningham and Michael Sleasman co-authored an essay on this, which is posted on http://everydaybioethics.org/editing-human-beings. The piece was also posted in a modified format on DesiringGod.org.

"WHO Coordinating the Health Response to Nepal Earthquake; Working to Prevent Spread of Disease" News Release, *World Health Organization*, April 29, 2015

> At present, 11 districts in Nepal have been deemed "severely affected" by the quake measuring 7.8 on the Richter scale, while many more districts have sustained significant loss of life and property, and face the challenges that these bring. The current death toll from the quake stands at just over 5000 and an estimated 8 million people have been affected in some way. (http://tinyurl.com/nwxofr8)

In the area of disaster ethics, the April 25th earthquake in Nepal wreaked havoc in the area, causing avalanches in the Himalayas, leaving many homeless, thousands injured, and eventually (after the time of this article) resulting in the death of about 9,000 people. Controversially, the media highlighted rescue efforts of surrogate babies in Nepal who were commissioned by Israeli couples. Nepal is a popular place for same-sex couples in Israel to hire a surrogate.

"Psychologists Met in Secret with Bush Officials to Help Justify Torture – Report" by Raya Jalabi, *The Guardian*, April 30, 2015

> Based on an analysis of more than 600 newly disclosed emails, the report found that the APA coordinated with Bush-era government officials—namely in the CIA White House and Department of Defense—to help ethically justify the interrogation policy in 2004 and 2005, when the program came under increased scrutiny for prisoner abuse by US military personnel at the Abu Ghraib prison in Iraq. (http://tinyurl.com/nrj68j8)

A watchdog organization filed a report showing that the American Psychological Association (APA) coordinated with the CIA and the U.S. Department of Defense to create an enhanced post 9-11 torture program. Since the time of this article, the APA conducted its own review and found several ranking members of the APA were involved, standing in direct conflict with the APA's explicitly stated position on torture. A timeline of the APA's official policy and response to the report has been chronicled at http://tinyurl.com/oxplsjs.

"U.S. Introduces New DNA Standard for Ensuring Accuracy of Genetic Tests" by Robert Pear, *The New York Times*, May 14, 2015

> Scientists have identified hundreds of genetic mutations that appear to increase the risk of diseases, including cancer, Alzheimer's and cystic fibrosis. But laboratories often report different results when they analyze genes obtained from samples of the same blood or tissue, because of variations in their testing equipment and methods. (http://tinyurl.com/nat3tob)

Genetic tests are becoming more widespread as sequencing becomes faster and cheaper. However, there is often a wide disparity in results obtained from different companies using the same sample. This calls into question the validity of DNA test results, which is particularly problematic when they are used to identify genetic markers for devastating diseases. This study comes out only two months after 23andMe announced that it will begin a medical research program using their genetic database. The new standard allows laboratories to determine whether their machines and software for genetic analysis are accurate.

"Drugs: Regulate 'Home-Brew' Opiates" by Kenneth A. Oye, J. Chappell H. Lawson, and Tania Bubela, *Nature*, May 18, 2015

> Currently, morphine is produced from the opium poppy (*Papaver somniferum*). By providing a simpler—and more manipulable—means of producing opiates, the yeast research could ultimately lead to cheaper, less addictive, safer and more-effective analgesics. And in generating a drug source that is self-replicating and easy to grow, conceal and distribute, the work could also transform the illicit opiate marketplace to decentralized, localized production. In so doing, it could dramatically increase people's access to opiates. (http://tinyurl.com/kzvbuck)

In the field of synthetic biology, researchers were able to replicate the first half of the process that a poppy uses to make morphine. In light of the opiate drug addiction epidemic, this ethics article was published in *Nature* concurrently with the original research paper. Given possible use of this process among the DIY community, the paper calls for proactive consideration and coordination among "public-health experts, scientists, regulators and law-enforcement agencies."

PREMIUM CONTENT UPDATE

Over the summer months CBHD staff worked with Emilee Tullar, an undergraduate student from Trinity International University, to upload over 600 audio addresses (including plenaries and paper sessions) from the Center's annual summer conferences from 1994–2013. These resources are available to all active members of the Center through our website www.cbhd.org. (To become a member, sign up at https://cbhd.org/membership.)

STAFF TRANSITIONS
WITH GRATITUDE

Without the assistance of our part-time office, event, and research staff, many of the things that CBHD does would not be possible. All of us at the Center wish to extend special thanks to the following staff for their contributions to the work of the Center under their respective tenures. We wish them well in their future endeavors.

Tyler Chernesky (Event & Education Assistant)
R. Daniel Dake, MA (Research Assistant)
Jenna Perrine (Office Assistant)

CBHD also saw Glory Diaz, MPM (Communications Manager & Executive Assistant) leave in early July after four years with the Center, due to her family relocating across the country. Amongst many other things, Glory was instrumental in raising the aesthetic quality of the Center's various print and electronic resources including this publication. Her joyous presence will be greatly missed among the staff.

NEW STAFF

CBHD welcomed two new part-time staff over the summer: Lindsay Callaway (Office Assistant) and Ryan Silhavy (Event & Education Assistant). Both are incoming graduate students in Trinity Evangelical Divinity School. Efforts to fill the remaining positions are in process.

COMING SOON: TECHNOLOGICAL PROGRESS IN HEALTHCARE

ON THE CBHD BOOKSHELF

For those interested in knowing what books and articles the Center staff have been reading and thought worth highlighting. **Notes that the resource includes material by members of the Center's Academy of Fellows

On the Bookshelf:

Agamben, Giorgio. *Homo Sacer: Sovereign Power and Bare Life.* (Stanford University Press, 1998).

Keane, Philip S. *Christian Ethics and Imagination: A Theological Inquiry.* (Paulist Press, 1984).

Rhodes, Rosamond, Magaret Battin, and Anita Silvers, eds. *Medicine and Social Justice: Essays on the Distribution of Health Care*, 2nd ed. (Oxford University Press, 2012).

Riskin, Jessica, ed. *Genesis Redux: Essays in the History and Philosophy of Artificial Life.* (University of Chicago Press, 2007).

Russell, Cathriona. *Autonomy and Food Biotechnology in Theological Ethics.* (Peter Lang International Academic Publishers, 2009).

Stump, Eleonore. *Wandering in Darkness: Narrative and the Problem of Suffering.* (Oxford University Press, 2010).

Articles of Note:

Adler, Nancy, and William Stead. "Patients in Context: EHR Capture of Social and Behavioral Determinants of Health." *New England Journal of Medicine* 372, no. 8 (2015): 698-701.

**Cusveller, Bart, René van Leeuwen, and Annemiek Schep-Akkerman. "Being the Minority: Christian Healthcare Professionals in the Netherlands." *Journal of Christian Nursing* 32, no. 1 (2015): 26-30.

Demertzi, Athena, Ralf Jox, Eric Racine, and Steve Laureys. " A European Survey on Attitudes towards Pain and End-of-Life Issues in Locked-in Syndrome." *Brain Injury* 28, no. 9 (2014): 1209-1215.

Grady, Christine. "Enduring and Emerging Challenges of Informed Consent." *New England Journal of Medicine* 372, no. 9 (2015): 855-862.

Gragert, Loren, Mary Eapen, Eric Williams, John Freeman, Stephen Spellman, Robert Baitty, Robert Hartzmann, J. Douglas Rizzo, Mary Horowitz, Dennis Confer, and Martin Maiers. "HLA Match Likelihoods for Hematopoietic Stem-Cell Grafts in the U.S. Registry." *New England Journal of Medicine* 371, no. 4 (2014): 339-348.

Green, Robert C., Denise Lautenbach, and Amy McGuire. "GINA, Genetic Discrimination, and Genomic Medicine." *New England Journal of Medicine* 372, no. 5 (2015): 397-399.

Haffajee, Rebecca, Wendy Parmet, and Michelle Mello. "What Is a Public Health 'Emergency'?" *New England Journal of Medicine* 371, no. 11 (2014): 986-988.

STAFF

PAIGE CUNNINGHAM, JD

- In mid-March was interviewed by *WORLD* magazine and "Chris Fabry Live" on two-dad embryos and IVF for same sex couples.
- In April presented "Why the Ethics of Science, Medicine, and Technology Matter More to the Church than Bioethics" to faculty at Talbot School of Theology, and "'Two-Dad' and Three-Parent Embryos: Constructing Persons in the 21st Century," to law students and faculty at Trinity Law School.
- In late April was interviewed by "Karl and June Morning" (Moody radio) on the proposal for head transplants.
- In late May was interviewed on "Let's Talk with Mark Elfstrand" (WYLL Chicago) on the Chinese report of gene editing of embryos, and on "Karl and June Morning" (Moody radio) discussing scientific literacy.

MICHAEL SLEASMAN, PHD

- In April his essay on "Nanotechnology" was published online as an entry to the *Encyclopedia of Global Bioethics* edited by Henk ten Have (Springer).
- Was featured in the article "The Science of Life" by Jesse Carey, which appeared in the May/June 2015 issue of *Relevant* magazine.

MEDIA RESOURCES

CBHD.org on Twitter: @bioethicscenter

Bioethics.com on Twitter: @bioethicsdotcom

The Bioethics Podcast at thebioethicspodcast.com

Facebook Page at facebook.com/bioethicscenter

Linked-In Group at linkd.in/thecbhd

YouTube at youtube.com/bioethicscenter

The Christian BioWiki christianbiowiki.org