

Health Care Law

Mid-Atlantic Ethics Committee Newsletter

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Newsletter, Spring 2016

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MID-ATLANTIC ETHICS COMMITTEE

NEWSLETTER

A Newsletter for Ethics Committee Members in Maryland, The District of Columbia and Virginia
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The *Mid-Atlantic Ethics Committee Newsletter* is a publication of the Maryland Health Care Ethics Committee Network, an initiative of the University of Maryland Francis King Carey School of Law’s Law & Health Care Program. The Newsletter combines educational articles with timely information about bioethics activities. Each issue includes a feature article, a Calendar of upcoming events, and a case presentation and commentary by local experts in bioethics, law, medicine, nursing, or related disciplines.

Diane E. Hoffmann, JD, MS - Editor

TRENDS IN MEDICAL DECISION-MAKING FOR UNREPRESENTED ADULTS

A homeless patient with no identified surrogate who lacks decision-making capacity is admitted to the hospital with dry gangrene of the foot. Initial treatments are provided based on the “emergency exception” for consent. Lower limb amputation is recommended to avoid life-threatening septic infection. However, because the patient is not yet septic, the amputation cannot be done without consent based on the emergency exception. Emergency petition to appoint a guardian to consent to the amputation will likely take too long to avoid the septic infection that would qualify the surgery as emergent. Is there an alternative to appointing a guardian to represent this patient’s preferences or best interests in medical decision-making? (Colorado Public Guardianship Advisory Committee, 2014)



It’s estimated that, overall, 5.5% of patients in U.S. intensive care units (ICUs) are unrepresented [meaning there is not an appropriate method in place for representing their medical treatment preferences when they lack decision-making capacity (DMC)] (White, et al., 2007). Most unrepresented adults live in hospitals, in nursing homes, or are homeless (Pope, 2012a). However, changing demographics (e.g., more aging childless persons who have smaller social support networks) point to increasing

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numbers of cognitively impaired individuals whose medical care will be impacted by delayed decisions related to lack of available surrogates to consent on their behalf. Often, this results in overtreatment and extended stays in acute care settings that expose such individuals to iatrogenic harms and unnecessary discomforts (Pope, 2012a, 2012b, 2013).

Current substitute decision-making practices for patients whose recommended treatment is not considered emergent include consulting an advance directive (i.e., a valid living will, verbal advance directive, or appointed health care agent) or following a valid Physicians Orders for Life-Sustaining Treatment (POLST) order. However, advance directives and POLST orders would need to be completed before the patient's admission in order to be useful. Furthermore, most living will language provides guidance on treatments to provide or withhold if a patient is in a terminal or end-stage condition, or permanently unconscious, so this wouldn't address decision-making for unrepresented patients who are not in these conditions. Regarding POLST forms (or Maryland's MOLST – Medical Orders for Life-Sustaining Treatment – form), even if one was completed prior to the patient's admission, it is likely that the patient's condition has changed, which warrants a reconsideration of the POLST/MOLST orders. Thus, health care facilities are left with figuring out whether a surrogate can be designated, and if not, whether applying for guardianship is necessary.

The American Thoracic Society, in collaboration with the American Geriatric Society, has assembled a project committee to develop a position statement on medical decision-making for unrepresented

incapacitated patients. At a recent meeting, the committee considered a number of proposed solutions (Pope, 2012a), including:

- Promoting preventive measures such as having advance care planning (ACP) conversations with at-risk individuals and documenting their health care preferences (i.e., in a state advance directive registry and a patient's medical record), and focusing on appointing a surrogate decision-maker, if one is available, rather than completing the more complex living will document. Reimbursement now available through Medicare for ACP conversations may help in this area.
- Conducting thorough searches for a surrogate before concluding that there is no one available to serve in this role. Some facilities employ a private detective agency to conduct such searches, offsetting the cost by money saved due to avoiding guardianship petitions and extended stays in the hospital caused by lack of an available surrogate decision-maker. In Maryland, an individual may sign an affidavit asserting to being a close friend who has maintained regular contact with the patient sufficient to be familiar with the patient's activities, health, and personal beliefs. Some contend that emphasizing the person's role as representing the patient's preferences (i.e. "substituted decision-making") rather than serving as a medical decision maker may assuage concerns that such a friend or distant relative lacks appropriate authority to make medical decisions for the patient.

- Conducting careful decision-making capacity assessments to identify the patient's preferences, to identify an appropriate surrogate (if one is available), and to determine whether the patient is able to make his or her own medical treatment decisions. As Pope pointed out (2012a, p. 88), “[w]ith support, time, and good communication, seemingly unbefriended individuals may be able to make decisions that at first blush appear not to be possible.”

Assuming these approaches have already been implemented, and that the number of remaining patients who need but lack others' input for medical decision-making is minimized, the question remains: how should decisions for non-emergent medical treatment or medical transfer be made for the remaining unrepresented patients? Currently, practices vary widely from institution to institution and from state to state. Alabama, Arizona, Connecticut, and North Carolina allow the patient's attending physician (often with input from the hospital's ethics committee) to make medical decisions (Pope, 2015). This has raised concerns about the physician's bias and potential conflict of interest. Having ethics committees (or multi-disciplinary ad hoc committees) weigh in may increase logistical burdens but is generally favored over an individual clinician making decisions for a patient. Pope has also suggested involving committees external to the institution where the patient is receiving care, to

avoid potential conflicts of interest.

Individual states have explored their own solutions. For example, Florida permits a social worker external to an institution to serve in this role, with oversight from an ethics committee. In California, long-term care facilities can establish inter-disciplinary teams comprised of an attending physician, registered nurse with responsibility for a resident, a patient representative (if available), and other appropriate staff to make decisions for unrepresented residents (Pope, 2012b). Oregon and Nebraska have initiated public guardianship programs to address widespread concerns with time delays and lack of training when petitioning for guardians. New York recently passed legislation allowing an attending physician, with a concurring opinion from another physician and the facility ethics committee, to elect hospice for an unrepresented patient (before that, New York statute allowed for this mechanism to make decisions about “routine medical treatment,” “major medical treatment,” and “withholding/withdrawal of life-sustaining therapy,” but hospice care did not fit in these categories) (Pope, 2012b). In Maryland, clinicians could petition for emergency protective services under Rule 10-210, granting guardianship for decision-making in as quickly as one day. As with other guardianship appointment systems, turn-around times may vary based on region and case loads.

Those caring for patients who cannot make their own medical decisions and have no one to represent them are charged with a great responsibility. Unfortunately, current laws and regulations have not always served the best interests of these individuals, and at times leave hospitals as de facto homeless shelters. The American Thoracic Society position statement on medical decision-making for

unrepresented incapacitated patients is expected to address this disparity. It is anticipated that this position statement will complement the joint policy statement on responding to requests for potentially inappropriate treatment in intensive care units (Bosslet et al., 2015).

REFERENCES

- Bosslet, G.G., et al. (2015). An official ATS/AACN/ACCP/ESICM/SCCM policy statement: Responding to requests for potentially inappropriate treatments in intensive care units. *American Journal of Respiratory and Critical Care Medicine*, 191(11), 1318-1330.
- Colorado Public Guardianship Advisory Committee (2014). The Public Guardianship Advisory Committee's Report to the Chief Justice of the Colorado Supreme Court. Available at https://www.courts.state.co.us/userfiles/file/Court_Probation/Supreme_Court/Committees/Public_Guardian/OfficeofPublicGuardianshipFinalReportandRecommendationsJuly312.pdf.
- Pope, T.M. (2015). Legal briefing: Adult orphans and the unbefriended: Making medical decisions for unrepresented patients without surrogates. *Journal of Clinical Ethics*, 26(2), 180-8.
- Pope, T.M. (2013). Making medical decisions for patients without surrogates. *N Engl J Med*, 369, 1976-1978.
- Pope, T.M. (2012a). Legal briefing: The unbefriended: Making healthcare decisions for patients without proxies (Part 1). *Journal of Clinical Ethics*, 23(1), 84-96.
- Pope, T.M. (2012b). Legal briefing: The unbefriended: Making healthcare decisions for patients without proxies (Part 2). *Journal of Clinical Ethics*, 23(2), 177-192.
- White DB, Curtis JR, Wolf LE, et al. (2007). Life support for patients without a surrogate decision maker: who decides? *Ann Intern Med*, 147, 34-40.



PHYSICIAN ASSISTED DYING LEGISLATION: FARES WELL IN CALIFORNIA BUT FAILS IN MARYLAND

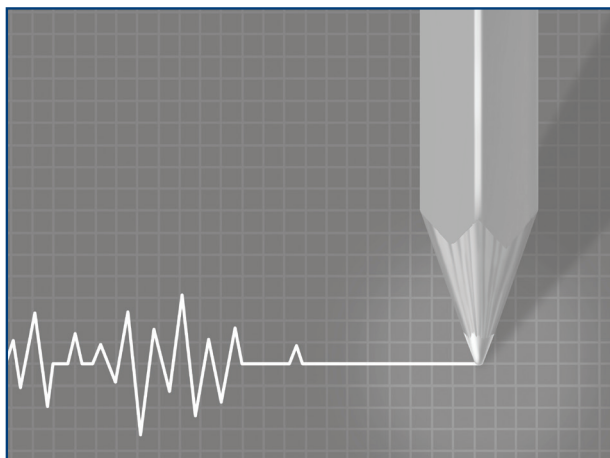
Physician Assisted Dying (PAD) legislation continues to be proposed in a number of states around the country with varying degrees of success in terms of passage. These laws permit physicians to prescribe medication to a terminally ill adult to use to end his or her life. Most recently, California passed such legislation. Called the End of Life Option Act, the bill took effect on June 9, 2016. As a result, California will join four other states that have legalized PAD including Washington, Oregon, Vermont and Montana. The California law, as is the case in most other states, closely follows the contours of the Oregon law. Oregon was the first state to pass PAD legislation and it has been in effect now for over 18 years. Features of the Oregon law adopted by California include the following eligibility requirements: the patient must be a resident of the state, 18 years of age or older, diagnosed with a terminal illness that will lead to death within 6 months, and mentally competent to make and communicate health care decisions. The patient's diagnosis and mental capacity must be certified by the patient's physician and a consulting physician. In addition, both laws require that the patient make two oral requests at least 15 days apart, and a written request to his or her physician. Patients must also be able to self-administer the medication. While California's law is substantially similar to Oregon's, the California law differs in a few ways, including that:

1. it explicitly permits people who do not speak English to use an interpreter when interacting with their physician;
2. it requires the attending physician to "discuss the request for medications with the patient... alone" (in order to be sure the

patient is not being coerced);

3. "there is no waiting period between the patient's written request and the writing of the prescription";
4. "the attending physician must provide a separate form for the patient to complete within 48 hours prior to taking the medications";
5. any unused medications must be properly disposed of;
6. the law includes forms that the physician or patient must complete in the statute whereas in Oregon the forms are created by a state agency; and
7. the law in California has a sunset provision of January 1, 2026 and will expire at that time unless renewed by the legislature. (DWD National Center, 2016)

This last provision indicates that the California legislature wanted the opportunity to evaluate the law after it has been in effect for ten years. Since the law passed, the California Medical Association has prepared a question and answer sheet about the law for physicians. The Q&A sheet can be found at: https://www.deathwithdignity.org/wp-content/uploads/2015/10/CMA_EOLOptionAct_Guidelines.pdf.



This past year approximately 18 additional states considered or are considering passage of PAD legislation. The surge in interest in the legislation is thought to be a result of the highly publicized Youtube video of Brittany Maynard who, at the age of 29 and diagnosed with an aggressive form of brain cancer, moved to Oregon so that she could take advantage of that state's PAD law. Among the many states that considered PAD legislation this year was Maryland. This was the fourth time such legislation had been introduced into the Maryland General Assembly. The first two were in 1995 and 1996, during the highly controversial actions of Dr. Jack Kevorkian in Michigan, the third was in 2015. The most recent bill, the Richard E. Israel and Roger "Pip" Moyer End-of-Life Option Act, was introduced in both the House and the Senate in the 2016 legislative session by Maryland Senator Ronald Young (S.B. 418) and state Delegate Shane Pendergrass (HB 404). The bill was modeled after the Oregon law and includes the same eligibility and physician oversight requirements as the Oregon legislation.

A joint hearing by the House Health and Government Operations and Judiciary Committees was held on the House bill on Feb. 19, 2016, and a hearing by the Senate Judicial Proceedings Committee on SB 418 was held on Feb. 25, 2016. Hearings on both bills were packed with emotional testimony by those both for and against the legislation. Shortly after the hearings, Senator Young withdrew the Senate bill from consideration by the Judicial Proceedings

Committee due to a lack of support. At about the same time Del. Pendergrass indicated that she would not bring the House bill up for a vote. According to news stories about the legislative process, the bill was strongly opposed by the Catholic church and disability rights advocates. They testified that the law did not provide sufficient protections for the disabled and vulnerable who often do not have enough resources for good medical care and may be coerced into asking doctors to help them end their lives prematurely. Others argued that such legislation does not go far enough in ensuring access to effective palliative care that would obviate a terminally ill individual accessing lethal medication to hasten his or her death. Advocates for PAD argued that it will allow patients to avoid the pain and suffering that often accompany the last few months or weeks of life and will likely push to have the bill introduced again next year.

REFERENCES

Death With Dignity National Center, The California End of Life Option Act and Death with Dignity, available at <https://www.deathwithdignity.org/news/2016/01/california-end-of-life-option-act/>.

Ovetta Wiggins, "Effort to legalize assisted suicide fails – again—in Maryland," *The Washington Post* (March 3, 2016).

CORRECTION

In the Fall 2015 issue of The Newsletter, we included a link to Dr. Shahid Aziz's blog, "You Deserve a Good Death." That link was incomplete. The full link is: <http://youdeserveagooddeath.blogspot.com/>

PHILOSOPHER'S CORNER: REASONS AND THE MESSINESS OF MORALITY

On a common, simplistic picture of morality, there is really only one large class of moral considerations that need to be understood. This class includes things like duties, obligations, rights, virtues and vices, right and wrong, goodness and badness, and likely some others I'm forgetting. And these concepts are related to one another in a fairly straightforward way: If I have a duty or obligation to do something, then someone else has a right that I do it, it's right to do, wrong not to do, it's what the virtuous person would do, and is morally good. Call this view "moral monism."

It would be very nice if moral monism were true. It would make the world of morality clean, understandable, and straightforward. Unfortunately, it's almost certainly false. The moral world is messy, and we have to deal with it. That's why I want to discuss a concept that contemporary philosophers are particularly keen on, but in a way that I think is helpful for those of us who regularly deal with the difficult, messy world of real moral problems: this concept is that of a "reason."

We use the language of something's "being a reason" in both a *normative*, justificatory sense, as well as a descriptive, motivational sense. In moral philosophy, though, we are mostly concerned with the former: we want to know what considerations justify some action or attitude, and are less concerned with what considerations actually motivate an action. What we are concerned with when we focus on normative reasons, then, are those "considerations that count in favor of a thing." Reasons, then, come cheap: that my coffee is tasty is a reason to drink it, that the sunshine is lovely is a reason to go outside, and that it would save her life is a reason to intubate a patient.

Notice, though, that not all of these reasons are of the same general kind. That last one, in particular, seems more important, and it is: while coffee- and sunshine-based reasons are merely prudential, rescue-reasons are *moral*. And moral reasons, we think, play a particular kind of special role in our deliberation.

Thus far, this may all seem like the philosopher's ivory-tower specification of something painfully obvious: considerations count in favor of and against doing things, and some of these considerations are moral. What is important, though, is that really embracing the reality of a world full of reasons to act, be or feel certain things makes clear how truly messy the moral world must be. Let's look first at a common philosopher's thought-experiment to see how this is so, before turning to the medical context.

In Introduction to Ethics classes, many philosophers will present students with "Trolley Problems," designed to elicit intuitions that place them into moral theoretic camps. In the basic case, a runaway trolley is barreling down a track, on which five innocent strangers have been tied. However, *you* happen to see this and happen to be standing at a switch, which would divert the train to a sidetrack. On the sidetrack, a single innocent stranger is tied. So, you must either throw the switch, which will result in a single person's death, or let the train go, which will result in the death of five people.

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In this simple case, most people say that you morally ought to throw the switch, or at least that it would be permissible to do so, which is evidence (so says the philosopher) that many of us believe that consequences matter – perhaps quite a lot – which is something like saying that there is a general principle of beneficence which commands promoting good consequences, even if that involves causing specific harms. However, a minority of students in every class does dissent against the prevailing opinion, arguing that one must not actively kill someone (and throwing the switch constitutes killing), even when failing to do so requires letting more people die.

There are lots of arguments about how we should reason in the Trolley Case, but I'm not going to discuss them here. I'm less worried about the right answer, and more worried about the general push so many people seem to feel toward figuring out "the right answer" regarding what to do, so that we can call it a day. If I were an ethics advisor, and the person from the Trolley Case came to me – distressed – for advice about whether to pull the lever, coming back with a straightforward judgment about what he should do would not seem appropriate. Suppose I told the advisee, "Your reluctance to throw the switch stems from your recognition that one generally ought not to harm another – we generally ought to be nonmaleficent. However, we also ought to promote the good, especially in rescue cases, and so ought to be beneficent. Since the good you could promote is so much greater than the harm you would cause in doing so, you clearly ought to throw the switch in this case, and you should not feel bad about doing so." I think that, even if I were right about how to weigh the relevant moral principles, this would be fairly bad advice. And that's because it takes what is, in reality, a difficult case, and pretends away the difficulty.

Any morally interesting case will be difficult, which means that there will be competing goods, principles and reasons involved. Even in the Trolley Case, there *is* a good reason not to throw the switch – and that reason can be variously described in terms of our duty not to harm another, or a basic right of all people not to be seen as expendable in pursuit of the greater good, or likely in yet other ways. And the fact that throwing the switch harms another for the sake of the greater good is a genuine moral consideration that doesn't disappear, even if it is defeated in moral deliberation. What's more is that such a reason demands a particular kind of response, which may be sadness or even guilt on the part of the one who acts against it; and it may even be a mark of good character to see an overridden reason as requiring certain reactions.

All of this complication was able to be raised in the artificial (and frankly, silly) case of the trolley, so we can only imagine how complicated genuinely difficult moral problems are. But we don't have to imagine, do we? As hospital ethics committee members, you likely have seen more than your fair share of genuine moral dilemmas, moral tragedy, and the general havoc reaped by unresponded-to reasons.

A case-type that regularly haunts me, and that has received attention in this very publication, is that of the very sick, extremely preterm infant, who will not survive, but whose parents are demanding that "everything be done." This sort of case likely often ends up in front of the ethics committee, and I am sure that most committee members do not believe that there will be an easy, "tidy" solution. They may, however, feel the need to *genuinely solve* the problem, and what I want to do here is provide permission to back away from a strong reading of that phrase. A committee can provide action guidance without giving the impression that the answer is obvious, or that doing the right thing is all that matters. For every interesting case, there will be a multitude of very real moral reasons in favor of competing actions and attitudes, which means that not all reasons can be responded to. Suppose that, after extensive deliberation, your committee decides that the parents' wishes must, for now, be honored, despite the infant's suffering and the lack of any indication that it will survive: this decision, even if correct, does not mean that there aren't very strong reasons to withdraw life-sustaining treatment. And even in "normative defeat," these reasons may do real work: they can explain the pain and moral residue felt by the health care team; perhaps they might demand certain attitudes toward the child, the parents, and the decision; and it may well be a mark of good character if members of the health care team find the situation difficult and emotional.

In this case and any other, such an admission does not mean that the ethics committee shouldn't recommend what it does; what it means is that the recommendation doesn't solve the problem in a complete sense that should make everyone perfectly comfortable. It provides a way forward, but that way – even if correct – may yet be difficult and morally messy. Being sensitive to this messiness may help committees and other ethics consultants to provide their judgment in a way that doesn't imply clarity or obviousness, and which makes way for a variety of responses to the extant reasons, including sadness, reluctance, and even grief.

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HIPAA RULING'S IMPACT ON FILMING PATIENTS FOR PUBLIC BROADCAST

On April 21, 2016, the Department of Health and Human Services' (DHHS) Office for Civil Rights (OCR) announced that they had reached a 2.2 million dollar settlement with New York Presbyterian Hospital (NYP) as a penalty for allowing the film crew of ABC's "NY Med" television series to access patients' protected health information (PHI) without prior authorization. One of those patients was Mark Chanko, who died at NYP after being hit by a sanitation truck while trying to cross the street. Unbeknownst to Mr. Chanko's family during his hospitalization in 2011, his care was filmed, including scenes of his attempted resuscitation, and he was featured in an episode of NY Med that aired sixteen months later, in August 2012. Although his face was blurred to mask his identity to viewers, Mr. Chanko's widow viewed a recorded version of the program months after her husband's death and recognized him by his words and the interactions with the clinicians caring for him. One of the physicians wore a microphone that captured dialogue, including Mr. Chanko asking if his wife had been notified, and excerpts of the conversation in which the doctor informed the Chanko family about the unsuccessful resuscitation attempts preceding Mr. Chanko's death. Describing her reaction to the NY Med episode, Mrs. Chanko told a New York Times reporter: "I hear them saying his blood pressure is falling. I hear them getting out the paddles and then I hear them saying, 'O.K., are you ready to pronounce him?' ... I saw my husband die before my eyes" (Ornstein, January 2, 2015).

The Chanko family filed a complaint with DHHS three years ago, culminating in the recent settlement with NYP, in which OCR determined that NYP committed an

"egregious" violation of the Privacy Rule (Ornstein, April 21, 2016). In addition to the monetary penalty, the hospital will undergo staff training and be subject to audit. The Chanko family also sued ABC, the hospital, and the chief surgical resident in charge at the time for intentional infliction of emotional distress, and they sued the surgical resident for breach of doctor-patient confidentiality. The New York State Court of Appeals dismissed the claim of intentional infliction of emotional distress but allowed the suit for doctor-patient confidentiality breach to proceed.

The Chanko family and opponents to programs that allow patient filming without prior consent and privacy release (i.e., HIPAA authorization) argue that privacy violations like these threaten the trust patients place in their health care providers, a trust that is central to the patient-provider relationship. Some argue that filming in the ER should not be permitted at all given that requiring permission prior to filming does not go far enough to protect vulnerable patients because patients who are seriously ill or injured often lack the capacity to provide informed consent. They are concerned that the rule permitting filming only after consent may perpetuate ethically problematic behavior to seek consent from patients who are not in a position to give such permission. (Typically, patients featured in such programming can withdraw content to be featured but are not offered the right to review content and consent or object to its inclusion, for logistical and editorial control reasons).

Proponents of the status quo (i.e., allowing filming in health care settings for the purpose of creating public broadcasts, documentaries, or films, with the prior consent of the patient or surrogate or blurring the

identity of those who don't provide consent) maintain that there is important educational value in such programming.

The OCR has issued a "Q&A" about this topic (FAQ 2023, <http://www.hhs.gov/>), clarifying that members of the media (including film crews) may only enter into patient treatment areas if prior authorization is obtained from patients whose PHI will be accessible, or, if the filming is being done on behalf of the provider (such as for internal training or public relations purposes), certain protections are in place, such as having a HIPAA business associate agreement in place with the film crew. Dr. Joel Geiderman of Cedars-Sinai Medical Center in Los Angeles told NYT reporter Charles Ornstein (April 21, 2016) that this could signal the end of real-life medical programming: "I think this will have a chilling effect on hospitals going forward ... Any hospital legal counsel worth his salt or any P.R. director would be committing malpractice in order to allow it to occur. It's now embodied in a federal directive."

REFERENCES

Ornstein, C. (April 21, 2016). New York Hospital to Pay \$2.2 Million Over Unauthorized Filming of 2 Patients. New York Times, available at http://www.nytimes.com/2016/04/22/nyregion/new-york-hospital-to-pay-fine-over-unauthorized-filming-of-2-patients.html?_r=0.

Ornstein, C. (January 2, 2015). Dying in the E.R., and on TV Without His Family's Consent. New York Times, available at http://www.nytimes.com/2015/01/04/nyregion/dying-in-the-er-and-on-tv-without-his-family-consent.html?_r=0.

CASE PRESENTATION

One of the regular features of this Newsletter is the presentation of a case considered by an ethics committee and an analysis of the ethical issues involved. Readers are both encouraged to comment on the case or analysis and to submit other cases that their ethics committee has dealt with. In all cases, identifying information about patients and others in the case should only be provided with the permission of the patient. Unless otherwise indicated, our policy is not to identify the submitter or institution. We may also change facts to protect confidentiality. Cases and comments should be sent to MHECN@law.umaryland.edu, or MHECN, Law & Health Care Program, University of Maryland Francis King Carey School of Law, 500 W. Baltimore St., Baltimore, MD 21201.

ORGANIZATIONAL ETHICS QUESTION FROM A MID-ATLANTIC HOSPITAL

A large, Mid-Atlantic non-profit teaching hospital is considering offering optional testing (at no charge) to all infants born at the hospital to test for specific cytochrome P450 enzyme and other pharmacogenetically relevant variants (that is, genetic changes that have to do with how individuals metabolize certain medications). The test would be done via a buccal swab shortly after birth after obtaining parental consent, and would be separate from newborn screening or any related tests. No other testing and no research would be done with these samples. These genetic variants are known to alter medication metabolism in ways that place individuals at risk for adverse drug reactions or lack of efficacy. In this analysis, specific variants with the strongest scientific and clinical evidence related to the metabolism of codeine, some Selective Serotonin Reuptake Inhibitors (SSRIs), and several other medications would be tested. By offering such preemptive testing to newborns, it's hoped that significant future adverse drug events or lack of treatment efficacy could be avoided. The rationale for offering the pharmacogenetic screening test to infants born at the hospital at no cost is that more infants would be tested, as fewer parents would consent if they had to pay for the screening out of pocket, and insurance would not likely cover the test. The rationale involves democratizing this type of screening, as such tests are typically only available to those with means and education. Some clinicians at the hospital raise questions about whether offering this optional testing is ethically justified. One concern is if, unlike in this case, it were to be included as part of the universal newborn screening process. The Recommended Uniform Screening Panel (RUSP) of the American College of Medical Genetics does not currently include these tests as part of their recommended newborn screening panel, though many states include tests that are not part of RUSP. They query the ethics committee to weigh in on the pros and cons in this hypothetical case.

COMMENTS FROM AN ECONOMIST & BIOETHICIST

This case asks the overall question: *Is the hospital ethically justified in offering this genetic test free to infants born in the hospital?* To address it, we begin by asking several prior questions.

First, what is the benefit to the newborn from the test?

The benefit is the information that the child *might* have an adverse reaction to certain drugs that might be administered sometime in the future.

Second, why give the test at birth?

Childbirth is a stressful event, and the newborn period is a bad time to ask parents to make decisions about genetic screening tests. Public health newborn screening (NBS) programs

understand this; they test all newborns in the hospital only because they must quickly identify children who will suffer harm if not diagnosed and treated soon after birth. In the case at hand, we aren't given much information about the drugs involved, the nature of the adverse reactions, and the probability they will occur in a person with a positive test result. But the two specific drugs mentioned should not be given to infants and young children (codeine, SSRIs). Why do the test in the birthing hospital if there is no urgency? The test can be offered later as part of normal pediatric or adult care if it is worth doing. This is the reason why this genetic test is not a suitable candidate for a public health newborn screening program; it would definitely not meet the criteria for addition to

the RUSP and is also very unlikely to be added by any individual state. The case description states that the test will be separate from other NBS tests, but doing the test during the same period may still cause confusion; a positive result on a public health NBS test requires immediate parental action to avoid harm, whereas a positive result on this test does not.

Third, why test at all?

The test's potential benefit is only realized if its results are *available and used to make the right clinical decision if and when the person who tests positive needs a problematic drug*. This is quite likely to fail to happen, especially if the test is done in childhood. Today's medical record-keeping systems don't provide seamless access to patient information

across providers and throughout a lifetime. It would be a challenge for any parent to keep track of this type of information; the low-income parents who are of concern in this case are especially likely to face more urgent challenges. Moreover, even if the critical moment actually arrives and the information is available, in today's health care system there is no guarantee that the clinician will know what to do with it.

In my opinion, there isn't a good case for routinely screening healthy people – especially newborns – for this genetic trait. It may make sense to screen population subgroups, however. For example, children and teens being treated for depression might be tested before being prescribed an SSRI. Children facing surgery might be tested if it is thought that avoiding codeine would complicate pain relief. People with chronic conditions might be tested if they are likely to need a problematic drug on an emergency basis, with no time to wait for test results. It might even make sense to test some newborns in the hospital, if they are born with symptoms that are likely to trigger the use of such drugs in the very near future. In these situations, the test would meet the usual requirement that tests only be recommended in clinical practice if the results have immediate clinical significance.

It doesn't necessarily follow that the testing should be actively discouraged for people who want it and can pay for it, but at this time the benefits are too contingent for it to be promoted as standard of care for everyone.

Fourth, even so, can it actually be unethical to offer the test to people at no charge?

The benefit may be small or nonexistent, but what's the harm, if the test is voluntary and free?

My first reaction in reviewing this case was surprise that a proposal for free testing could get far enough for

this question to arise. When many hospitals are struggling to provide care that meets basic quality standards without going bankrupt, wouldn't the administration say "Do genetic testing for free? With our operating deficit? You're kidding, right?" After all, the newborn's family may not be paying for the testing, but someone is, and there is always something else that money could be used for.

The distribution of a hospital's resources – where they come from and how they are used in caring for patients – is an organizational ethics issue. Hospital decision-makers should always be attentive to their stewardship obligations when making resource allocation decisions. Thus it is certainly appropriate to ask whether it is ethical to use the resources provided to the hospital by public and private insurance programs, self-paying patients, and charitable donors to fund a free service. We aren't given information about the cost of the testing but genetic testing is not cheap. A test of this type could cost \$50 or more per infant just for the test kit and processing, and there would be other staff costs for administering the test program. In this case, the stated rationale of "democratizing access to the test" does not seem compelling, since the benefit to the recipients isn't very great. It seems likely that there are other health-related services that could be provided to low-income families of newborns, or to other deserving patient categories, that would be of greater benefit – or the hospital could simply reduce its charges.

*Mary Ann Baily, PhD
Hastings Center Fellow*

COMMENTS FROM A PEDIATRICIAN, LAWYER, & BIOETHICIST

The proposed genetic testing that would occur in the newborn

period and would be available to all babies born in this institution raises many of the same issues currently faced by state newborn screening programs: what types of screening should be offered, what results should be returned to parents, and should parental consent be obtained prior to newborn screening? Another issue that has presented a significant challenge for state newborn screening programs in recent years has been whether parental consent should be required for the retention and secondary use of residual newborn screening dried blood samples (DBS). Rather than address points made by Mary Ann Baily about this case, I am opting to comment, instead, on this broader issue of newborn screening and implications for research.

The purpose of newborn screening is to identify infants with certain heritable conditions, such as phenylketonuria, sickle cell disease, and cystic fibrosis, so that appropriate treatment can be initiated, and the effects of the condition can be ameliorated, thereby preventing disability and/or death. An estimated 1 in 300 babies born in the United States has one of the newborn screening conditions, and it has been estimated that 12,500 children with serious metabolic, endocrine, hematologic, or functional disorders are identified through newborn screening each year in this country.

Shortly after birth, almost all of the 4 million babies born each year in the United States, whether born at home or in a hospital, have several drops of blood drawn from their heels. This blood is collected on a newborn screening card, and when the blood has dried, the card is sent to the state newborn screening laboratory for testing. In order to ensure that a sufficient amount of blood is available for testing, more blood is collected than is necessary for newborn screening testing, and therefore, after

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Case Presentation

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newborn screening testing has been completed, residual dried blood remains.

DBS have a broad range of potential secondary uses, including newborn screening program quality assurance and quality improvement activities, test validation, and the development of new newborn screening tests. They also can be used for other types of public health surveillance, such as the evaluation of prenatal exposure to environmental toxins, and biomedical research unrelated to newborn screening. Most importantly, DBS are a vital component of the continued successful operation of state newborn screening programs.

Historically, parental consent was not required for the retention and secondary use of DBS. However, the research use of de-identified DBS without parental permission has been controversial in some states and led to litigation against the state departments of health in Texas, Minnesota, and Indiana as well as the destruction of millions of archived DBS. In the past, under federal human subjects research protection regulations (the Common Rule), de-identified blood and tissue samples, including DBS, were not considered human subjects research, and the federal regulations governing human subjects research, including the requirement to obtain informed consent prior to participation in biomedical research, did not apply.

In 2014, however, the Newborn Screening Saves Lives Reauthorization Act was enacted. Section 12 of this law created an exception to the definition of human subjects under the Common Rule and determined that for purposes of federally funded research, research conducted using DBS would be considered human subjects research,

whether or not the samples were de-identified. This change in the definition of human subjects is significant because it means that the human subjects research protections, including the requirement to obtain informed consent, will apply to the research use of de-identified DBS. In 2015, sweeping changes to the Common Rule were proposed that would require informed consent for the research use of all blood and tissue samples, regardless of their identifiability. At the time of this writing, final rules have not yet been promulgated.

Prior to the passage of the Newborn Screening Saves Lives Reauthorization Act, there were serious questions about how well parents were being informed about state policies related to the retention and secondary use of their children's DBS and whether the option to opt-out of participation was a meaningful one. Nevertheless, the previous practice of retaining DBS for secondary use in a de-identified manner made DBS available for important public health and biomedical research that may not be possible going forward and with no demonstrated harm to the research participants.

The requirement to obtain parental consent to use de-identified DBS for research will have a profound impact on newborn screening. Most importantly, this definition will hinder the development of new newborn screening tests. Although it may increase perceived parent autonomy over the use of their children's DBS, it will strike an improper balance between autonomy and the facilitation of valuable research. Although respect for persons will be enhanced if parental autonomy over the use of the samples is increased, there have been no demonstrated harms to infants or their families from the secondary research use of DBS, and the increased autonomy will come at significant cost in that

the development of new newborn screening tests will be hampered. The increase in autonomy will not lead to decreased harm since there has been no harm demonstrated with the historical practices and will jeopardize important public health activities.

Rather than require parental consent for the secondary research use of all DBS, regardless of their identifiability, a better option would have been to require that parents be informed about state policies related to the retention and secondary use of DBS and that parents be given meaningful options to decline to participate. In this way, parental autonomy could be respected without such a significant cost to the research enterprise, and a better balance between autonomy and the value of research could be struck.

Note: This commentary is adapted from Public Comments I submitted in response to the NPRM for Revisions to the Common Rule.

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REFERENCES

- Centers for Disease Control and Prevention (CDC), "CDC Grand Rounds: Newborn Screening and Improved Outcomes," *Morbidity and Mortality Weekly Report* 61, no. 21 (2012): 390-393.
- P. McCann, Minnesota Dept. of Health, "Mercury Levels in Blood from Newborns in the Lake Superior Basin, Final Report to the EPA," November 30, 2011, GLNPO ID 2007-942, available at <http://www.health.state.mn.us/divs/eh/hazardous/topics/studies/glnpo.pdf>.
- 45 C.F.R. 46 (2009).
- The Newborn Screening Saves Lives Reauthorization Act, Pub. L. 113-2401 (2014).

CALENDAR OF EVENTS

JUNE

21 (12N-1:15P)

"Ethics for Lunch" Panel Discussion: Bias Towards Patients in Pain, sponsored by The Johns Hopkins Hospital Ethics Committee & Consultation Service, Sheik Zayed Tower room 2117 (the Arcade), Johns Hopkins Hospital, Baltimore, MD <http://www.bioethicsinstitute.org/efl> 15-16 Ethics.

JULY

11-12

International Bioethics Summer School, sponsored by the New York Society for Ethical Culture, New York, NY. Website: <http://summerschool.globalbioethics.org/>.

22-23

Pediatric Bioethics Conference: Autism Re-examined: Ethical Challenges in Care, Support, Research and Inclusion, sponsored by Treuman Katz Center for Pediatric Bioethics, Seattle, WA. Website: <http://www.seattlechildrens.org/research/initiatives/bioethics/events/pediatric-bioethics-conference/>.

28-30

Conflict Resolution and Clinical-Setting Mediation for Healthcare, Sponsored by the Center for Conflict Resolution in Healthcare, LLC, Memphis, TN. Website: <http://www.healthcare-mediation.net>.

AUGUST

1-5

2016 Annual Meeting, International Neuroethics Society, Seattle, WA. Website: <https://uw.cloud-cme.com/Ap2.aspx?EID=3390&P=5#>.

28-September 3

2016 Penn State Medical Humanities Scholars Colloquium, sponsored by the Department of Humanities of Penn State College of Medicine, Hershey, PA. For more information, e-mail kienlecenter@hmc.psu.edu.

SEPTEMBER

15-16

Sixth Annual Western Michigan University Medical Humanities Conference, sponsored by the Medical Humanities Workgroup at Western Michigan University. Website: <http://www.wmich.edu/medicalhumanities/events/conference>.

16 (8A-12N)

Cultivating an Ethical and Equity Lens in Clinical Care, sponsored by Social Work at Kennedy Krieger Institute, Conference center at Sheppard Pratt, Baltimore, MD. For more information, e-mail friend@kennedykrieger.org.

OCTOBER

6-9

American Society for Bioethics and Humanities' 18th Annual Meeting, Washington, DC. Website: <http://www.asbh.org>.

14-15

Hastening Death by Voluntarily Stopping Eating and Drinking: Clinical, Legal, Ethical, Religious and Family Perspectives, co-sponsored by Seattle University School of Law, Seattle, WA. Website: <http://law.seattleu.edu/continuing-legal-education/upcoming-programs/perspectives-on-vsed>.

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- Fostering communication and information sharing among Network members;
- Providing educational programs for ethics committee members, other healthcare providers, and members of the general public on ethical issues in health care; and
- Conducting research to improve the functioning of ethics committees and ultimately the care of patients in Maryland.

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