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Bed to Bench: Medicine and the Law

From the Editor

Health Law and Medical Practice 197
Arina Evgenievna Chesnokova

Ethics Cases

Ethical Challenges for the Medical Expert Witness 201
Commentary by Joseph S. Kass and Rachel V. Rose

**Managing Care of an Intrapartum Patient with Agitation
and Psychosis: Ethical and Legal Implications** 209
Commentary by Laurence B. McCullough, Frank A. Chervenak,
and John H Coverdale

**Expedited Partner Therapy: Clinical Considerations
and Public Health Explorations** 215
Commentary by Barry DeCoster, Lisa Campo-Engelstein,
and Hilary E. Fairbrother

How Should Clinicians Treat Patients Who Might Be Undocumented? 229
Commentary by Jeff Sconyers and Tyler Tate

Podcast

**Medical-Legal Partnerships and the Promise and Challenge of Physician
Advocacy: An Interview with Megan Sandel**

Medical Education

**One Model of Collaborative Learning for Medical and Law Students
at the University of Baltimore and Johns Hopkins University** 237
Gregory Dolin and Natalie Ram

State of the Art and Science

- Enabling Individualized Criminal Sentencing While Reducing Subjectivity: A Tablet-Based Assessment of Recidivism Risk** 243
Pablo A. Ormachea, Sasha Davenport, Gabe Haarsma, Anna Jarman, Howard Henderson, and David M. Eagleman

Health Law

- Needle Exchange Programs' Status in US Politics** 252
Richard Weinmeyer

Policy Forum

- Graduate Medical Education Specialty Mix and Geographic Residency Program Distribution: Is There a Role for the ACGME?** 258
Thomas J. Nasca and Douglas Carlson

- Shedding Privacy Along with our Genetic Material: What Constitutes Adequate Legal Protection against Surreptitious Genetic Testing?** 264
Nicolle K. Strand

- State Oversight of Hospital Consolidation: Inadequate to Protect Patients' Rights and Community Access to Care** 272
Christine Khaikin and Lois Uttley

- Privacy Protection in Billing and Health Insurance Communications** 279
Abigail English and Julie Lewis

- Federal Privacy Protections: Ethical Foundations, Sources of Confusion in Clinical Medicine, and Controversies in Biomedical Research** 288
Mary Anderlik Majumder and Christi J. Guerrini

- Medical Malpractice Reform—Historical Approaches, Alternative Models, and Communication and Resolution Programs** 299
Joseph S. Kass and Rachel V. Rose

Second Thoughts

- Undocumented Immigrants Face a Unique Set of Risks from Tuberculosis Treatment: Is This Just?** 311
Kelly A. Kyanko, Jun-Chieh James Tsay, Katherine Yun, and Brendan Parent

Resources

- Suggested Readings and Resources** 319
About the Contributors 347

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FROM THE EDITOR

Health Law and Medical Practice

The history of health law stretches back more than 200 years, when medical practice first became regulated and matters of medical expertise began to be used in court proceedings, such as forensic psychiatry and pathology [1]. Medical malpractice is, perhaps, the most well-known area of health law to students and clinicians. The English case *Slater v. Baker and Stapleton*, which is frequently cited as foundational precedent for American malpractice law [2], was decided in 1767 in favor of the patient, who, without proper consent, underwent a failed experimental treatment to mend a fracture [1]. Similarly, literature on health jurisprudence from that era, such as John J. Elwell's seminal text *Medico-Legal Treatise on Malpractice and Medical Evidence: Comprising the Elements of Medical Jurisprudence* [3], focused primarily on medical malpractice.

Health law has since evolved, but some physicians' fears of malpractice litigation still arise upon hearing the word "law" or "lawyer." In fact, 93 percent of surveyed physicians in high-liability specialties reported practicing "defensive medicine" as a result of their fear of litigation [4]. However, physicians' fear of malpractice litigation has been shown to be disproportionate to the risk of such litigation in certain states [5, 6]. Does this data suggest general confusion among physicians about health law and its impact on their clinical lives?

This theme issue of the *AMA Journal of Ethics* was born of my desire to address some physicians' emotional negativity and confusion about law and to highlight opportunities for collaboration by examining the nature of interactions between law and medicine. This issue presents practical information and thoughtful perspectives on some pressing legal issues and suggests ways in which law can become a useful tool for clinicians.

Two case commentaries respond to the ethical dilemma of whether to employ expedited partner therapy (EPT), which enables clinicians in 46 states [7] to treat their patients' sexual partner or partners—whom they have not met or examined—for a sexually transmitted infection. In their [commentary](#), Barry DeCoster and Lisa Campo-Engelstein foreground the need to assess the patient's reliability as a messenger, while Hilary E. Fairbrother analyzes the case in light of core ethical principles. Both commentaries also discuss the legal situation of EPT and conclude that the law in this case does indeed have helpful answers, as long as limitations are acknowledged and addressed.

Three pieces take up the participation of members of the medical profession in legal and policy matters. Joseph S. Kass and Rachel V. Rose [discuss](#) ethical issues a physician might consider when faced with an offer to serve as an expert witness when he or she is undecided about whether the content under analysis meets an evidentiary standard. Pablo A. Ormachea, Sasha Davenport, Gabe Haarsma, Anna Jarman, Howard Henderson, and David M. Eagleman [present](#) a new neuroscience-based technique for predicting recidivism that they hope will eventually be used in tailoring sentencing. Thomas J. Nasca and Douglas Carlson [consider](#) the role of the Accreditation Council for Graduate Medical Education (ACGME) in distributing residency programs and slots.

Although this theme issue of the *AMA Journal of Ethics* tries to dispel the idea that health law starts and ends with malpractice, it does consider how to minimize malpractice liability. Acknowledging the limited scope of medical students' knowledge of legal rules and problems, Gregory Dolin and Natalie Ram [discuss](#) an innovative, hands-on course offered to both medical and law students that introduces the process of litigating a medical malpractice case. Two other articles speak to minimizing liability. Laurence B. McCullough, Frank A. Chervenak, and John H. Coverdale [discuss](#) a stepwise process for ethical decision making that minimizes liability risk in a case in which a patient with psychosis who is in labor comes to the emergency department. In a second contribution, Kass and Rose [examine](#) the evolution of malpractice reform and the emergence of alternative dispute resolution (ADR) programs that can enable disclosure of harm and facilitate restitution.

Privacy law is another key theme of this issue. Mary Majumder and Christi Guerrini [identify](#) misbeliefs that privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA) obstruct good clinical care. Nicolle K. Strand [examines](#)—and reveals loopholes in—current state protections against surreptitious genomic testing. These two articles offer insights into privacy dilemmas as they relate to biological specimens in the era of genetic research and testing. Abigail English and Julie Lewis [unmask](#) a tension between fundamental ethical requirements of protecting patient confidentiality and the need for transparency in billing and insurance communications, which can lead some organizations to forgo payment to protect patients' confidentiality. They highlight state laws related to insurance communications that would increase privacy protections and thus obviate the need for this practice.

Knowledge is key to encouraging and enabling clinicians to participate in the legal system for the benefit of patients. This theme is developed in this issue's [podcast](#) with Megan Sandel, who highlights ways that medical-legal partnerships can help address some health issues more effectively than medicine alone. In their [commentary](#) on a case in which a physician doubts whether she has an obligation to report a patient suspected of not being a legal resident, Jeff Sconyers and Tyler Tate affirm that the current law is in line with the physician's inclination not to report.

Kelly A. Kyanko, Jun-Chieh James Tsay, Katherine Yun, and Brendan Parent [challenge](#) us to think beyond immediate clinical encounters in considering possible repercussions of patients' limited access to health care. For undocumented immigrants, risks of latent tuberculosis treatment—which can include permanent, lethal liver damage—are uniquely dire, because these patients are not eligible for insurance, and therefore unlikely to be listed for potentially life-saving liver transplants. Christine Khaikin and Lois Uttley [examine](#) how limited access to health care services can result from hospital mergers without adequate oversight or input from clinician employees and patients. Finally, in this issue's health law section, Richard Weinmeyer [reviews](#) the lengthy and politicized history of needle exchange programs (NEPs) that prepared the way for their (mostly) legal and funded status following a recent major outbreak of HIV in Indiana.

My hope is for readers to approach this theme issue with curiosity and emerge with a sense of confidence, a trust in their ability to seek counsel from the law and more ably discern its intersections with ethics. Developing the content of this issue has prompted me to appreciate that physicians have obligations not only to follow the law, but also to draw upon it for the good of their patients. Physicians' engagement with law should not be confined to malpractice reform, but should instead be central to their clinical goals and communications with patients. May this issue be a start for many on that journey.

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Arina Evgenievna Chesnokova, MPH

MS-3

Baylor College of Medicine

Houston, Texas

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ETHICS CASE

Ethical Challenges for the Medical Expert Witness

Commentary by Joseph S. Kass, MD, JD, and Rachel V. Rose, JD, MBA

Dr. Lopez is a well-respected, board-certified academic behavioral neurologist who primarily treats patients with cognitive dysfunction and has a special interest in traumatic brain injury (TBI). On rare occasions she has served as an expert witness but, as a rule, does not testify against physicians in her community in malpractice cases. Now a plaintiff's attorney, Mr. Sewell, has contacted her to engage her services in a case brought against a cross-country trucking company. One year ago the plaintiff, Ms. Dewey, was pulling out of a parking lot when her car was hit by a truck from the defendant's fleet. She alleged a variety of injuries sustained as a result of the accident, including chronic headaches and residual cognitive dysfunction from a mild traumatic brain injury (TBI). The mild TBI category, which is the most prevalent type of TBI, includes concussions and other brain trauma that have initial symptoms such as loss of consciousness and/or "a state of being dazed, confused or disoriented" [1].

Mr. Sewell told Dr. Lopez that she would be given an opportunity to review the documents and would then be asked whether she could testify that it was more likely than not that the mild traumatic brain injury sustained during the motor vehicle accident was the proximate cause of Ms. Dewey's cognitive dysfunction. Intrigued by the facts and interested in serving as an expert witness for a case not involving malpractice, Dr. Lopez agreed to review the documents once Mr. Sewell agreed to the terms of her fee schedule and she received her retainer fee for document review.

Upon reviewing the documents—including the plaintiff's and defendant's depositions; the police report from the accident; and Ms. Dewey's medical records from the emergency medical services, the emergency center, and the treating neurologist—a number of facts struck Dr. Lopez as potentially problematic. In both the police report and the EMS documents, there was no mention of Ms. Dewey's being confused or disoriented, and it was unclear whether she actually lost consciousness. The EC records were vague and contradictory, although the neurologist's evaluation did seem to meet the standard of care. After her document review, Dr. Lopez remained interested in helping Ms. Dewey receive just compensation, but she also knew that, at some point, she would be asked to reveal that Ms. Dewey's records did not definitively document a loss of consciousness, a fact that would likely put the severity of her injuries in question and possibly substantially undermine her claims to compensation. The evidentiary standard in civil litigation is "the preponderance of the evidence," which essentially requires 51

percent certainty that the facts are as the plaintiff claims them to be [2]. Dr. Lopez is undecided about whether she believes the evidence meets this evidentiary threshold.

Accordingly, Dr. Lopez is faced with deciding whether to continue to work on Ms. Dewey's behalf in the role of expert witness or to decline further engagement with her case. She wonders whether she has an obligation to tell Ms. Dewey's attorney about her impressions of the records she reviewed.

Commentary

The ethical principles that guide clinicians in their relationships with patients continue to guide them when they assume the mantle of medical expert witness, but with a nonclinical twist. Physicians in the role of medical expert witness must consider a number of ethical appeals to reach an ethically justifiable course of action. These appeals can be divided into the following broad categories: (1) consequences for the parties concerned; (2) established legal, ethical, and professional standards; (3) respect for the rights of all parties; (4) professional virtues; and (5) fiduciary duties and special professional obligations, such as beneficence and nonmaleficence [3]. If Dr. Lopez were to analyze her ethical dilemma through the lens of each of these appeals, she would be able to determine an ethically compelling way to act.

Bioethical Appeals

Appeal to consequences. Offering testimony in a case based on the theory that the plaintiff suffered a mild TBI—when, on the expert's assessment, the medical facts call that theory into serious doubt—may have far-reaching and irreversible consequences for all the parties to the litigation.

Providing less than honest testimony could ultimately undermine the case. Dr. Lopez must consider whether the plaintiff would be dragged into prolonged and unsuccessful litigation that burns both financial and emotional resources. Choosing not to litigate an unsubstantiated case saves time and emotional energy and considers the financial resources of all parties involved, including the plaintiff.

If she provided dishonest testimony, Dr. Lopez could also be subject to sanction by the state medical board and any professional societies of which she may be a member. The *AMA Code of Ethics* also calls on medical professional societies and state licensing boards to sanction those who give false or misleading testimony [4]. Thus, to do so could lead to disciplinary sanctions for Dr. Lopez from professional organizations and state medical boards [5].

Dr. Lopez could also be at risk of a lawsuit by the defendant for providing misleading testimony. She could also be subject to sanction by the court or at risk of a lawsuit by the defendant for providing misleading testimony. As RJ Kohlman notes, "The concept of

medicolegal malpractice liability has been recognized by courts; this means an expert hired to testify for a lawyer in medical litigation can become the target of litigation arising from this activity" [6]. Dr. Lopez has a legal obligation to the party she is aiding and to the legal process to ensure that her testimony does not perpetuate falsehoods.

Dr. Lopez could also certainly suffer serious consequences if she failed to follow the legal requirement that expert witnesses give honest testimony. Information on state and federal legal standards follows.

In response to the need for physicians to proffer expert testimony in medical malpractice cases, a majority of states promulgated legislation "to reduce fraudulent, misleading, or deceptive testimony of expert witnesses in medical malpractice cases" [7]. The fundamental requirements are that the expert witness actually possess relevant expertise and that the testimony be honest. For example, Florida's expert witness statute requires that physicians have expertise in the same field as the injury at issue [8]. Hence, an orthopedic surgeon could not opine on an obstetric issue. Since Dr. Lopez's specialty is neurology, and she holds a valid license, she could present expert testimony in this case that involves neurologic injury.

Furthermore, there are federal legal requirements that expert testimony be honest. Federal Rule of Evidence (FRE) 702 offers important direction because it governs the qualifications and testimony of an expert witness in federal court. Specifically,

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case [9].

Dr. Lopez would be breaking the latter three parts of this rule if she testified in a way that did not accord with her expert understanding of the medical facts.

In 1993, the United States Supreme Court issued a landmark opinion that established standards for expert testimony. *Daubert v. Merrell Dow Pharmaceuticals, Inc.* requires a "reliability of proof" and relevance [10]. These notions, along with the "Daubert Test" were upheld in *Kuhmo Tire Company, Ltd. v. Carmichael* [11]. According to this standard, commonly referred to as "[the Daubert test](#)," four factors must be considered when

evaluating expert testimony, whether technical or scientific in nature. The four factors include:

1. Whether a “theory or technique...can be (and has been) tested”;
2. Whether the theory or technique “has been subjected to peer review and publication”;
3. Whether, in respect to a particular technique, there is a high “known or potential rate of error” and whether there are “standards controlling the technique’s operation”; and
4. Whether the theory or technique enjoys “general acceptance” within a “relevant scientific community” [12].

The Daubert test’s four factors are required by the United States Supreme Court and all other federal courts in all expert testimony. Failure to meet [the requisite standards](#) may render a physician ineligible to testify. Dr. Lopez needs to be cognizant of her legally required duty to discuss and disclose the unfavorable findings from the police report and emergency medical services.

Appeal to respect for the rights of all parties. In the clinic, physicians demonstrate respect for their patients’ right to self-determination by allowing those patients with intact decision-making capacity to choose whether to accept the risks and benefits of a medical intervention. In the medicolegal context, respect for rights entails presenting the medical facts as accurately as possible to allow the litigants to make decisions that best advance their individual interests. Respect for rights also entails respecting each litigant’s right to a fair trial.

According to this appeal, if Dr. Lopez has any reservations about the theory of the case—whether the plaintiff suffered a mild TBI—and believes the evidence does not support the plaintiff’s story, she must discuss it with the plaintiff’s legal counsel. By being forthcoming with this information, Dr. Lopez allows the attorney to create, if possible, a stronger case that is less vulnerable to the opposing expert’s rebuttal testimony or to decide that the case is no longer worth pursuing.

Appeal to virtues. “Virtues” are attitudes, dispositions, or character traits that enable us to be and to act in ways that develop our potential as human beings. Edmund Pellegrino considers the following virtues as the mark of a good physician: fidelity to trust and promise, benevolence, effacement of self-interest, compassion and caring, intellectual honesty, justice, and prudence [13]. These virtues should guide Dr. Lopez’s actions as an expert witness just as they guide her actions as a clinician, since it is her clinical expertise and her standing as a medical professional that allow her to offer an expert opinion in this case.

Appeal to fiduciary duties. Physicians and attorneys alike have a fiduciary duty to the parties they serve. This duty requires the professional to prioritize the interests of the patient or client above all else. In medical ethics, the concepts of beneficence and nonmaleficence (promoting the patient's best interest and avoiding harm to the patient) are part of fulfilling the relevant fiduciary duty. Beneficence requires maximizing good to the patient, and nonmaleficence requires minimizing harm. Because medical interventions have both risks and benefits, beneficence and nonmaleficence must be balanced. In the context of providing expert medical testimony, although the decisions under review are not medical interventions but rather legal testimony, the duty is the same: it may either benefit or harm a litigant. Acting out of self-interest (e.g., to obtain financial remuneration) may have negative consequences for the patient. If Dr. Lopez is not convinced that the preponderance of the evidence supports the theory that the plaintiff suffered a TBI, the entire basis of the testimony is called into question. Lending her medical expertise under such circumstances benefits no one and harms the plaintiff, the plaintiff's counsel, the legal system, and Dr. Lopez herself because all parties could be sanctioned, the judge could dismiss the case with prejudice (i.e., the inability to refile the case), and the requisite parties could be reported to professional licensing boards.

Appeals to professional guidance. An important source of information for ethical analysis is the guidance that established professional and legal standards may offer. Professional medical organizations have promulgated ethical standards for member physicians serving as medical expert witnesses. The American Medical Association (AMA), which established the *Code of Medical Ethics* nearly 165 years ago [14], is an excellent starting point for professional guidance. The *AMA Code of Medical Ethics* Opinion 9.07 expressly states that physicians who serve as expert witnesses must deliver honest testimony grounded in "recent and substantive experience or knowledge in the area in which they testify, and be committed to evaluating cases objectively and to providing an independent opinion." The proffered opinions should be based on generally accepted scientific theories or, if the theory is "not widely accepted in the profession, the witness should characterize the theory as such" [6]. The opinion also states that physicians cannot let financial concerns drive the nature of testimony, and it calls on medical professional societies and state licensing board to sanction those who give false or misleading testimony.

A number of medical specialty societies have issued their own standards for expert testimony that are in line with those of the *AMA Code of Medical Ethics*. For example, the American College of Physicians (ACP) recognizes that "[p]hysicians, as members of society and as professionals, have a duty to testify in court as expert witnesses" and thereby participate "in the administration of justice" [15], and it has set forth recommended qualifications and general guidelines. These guidelines require that experts actually have the expertise they allege to have and require them to testify honestly about their credentials and about the medical facts of the case. Similarly, the

American Academy of Neurology's "Qualifications and Guidelines for the Physician Expert Witness" [16] requires the physician expert witness to have adequate qualifications (e.g., education, training, and experience) and to provide honest, accurate testimony grounded in evidence. According to the American Academy of Pediatrics guidelines, "the pivotal factor in the medical tort process is the integrity of the expert witness testimony. It should be reliable, objective, and accurate and provide a truthful analysis of the standard of care" [17]. In Dr. Lopez's case, she is a qualified expert and has doubts about the evidence.

Conclusion

All the ethical appeals and guidance from authoritative sources point to one conclusion: Dr. Lopez, whose qualifications meet both professional and legal requirements, must analyze the case for all points of vulnerability and report her conclusions honestly. She should continue working as an expert witness if she concludes the facts support the theory of the case within the requirements of the evidentiary standard. However, if she does not believe that the preponderance of the evidence shows the plaintiff suffered a mild TBI, she is ethically and legally obligated to educate the plaintiff's counsel about the weaknesses of the case and decline further engagement. To do so would manifest professional virtue, accord professional guidelines, and respect her fiduciary duty to the plaintiff and the rights of all parties. Although Dr. Lopez might feel sympathetic to a vulnerable plaintiff and the plaintiff's interest in compensation, she must not allow this sympathy for the plaintiff's plight to obscure the fact that even a vulnerable plaintiff does not have a right to untruthful testimony.

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Joseph S. Kass, MD, JD, is an associate professor of neurology, psychiatry, and medical ethics at Baylor College of Medicine in Houston, Texas, where he also serves as the assistant dean of students and the vice chair for education in the Department of Neurology. He is the chief of neurology at Ben Taub General Hospital.

Rachel V. Rose, JD, MBA, is a principal with Rachel V. Rose—Attorney at Law, PLLC and teaches bioethics in Baylor College of Medicine’s Center for Medical Ethics and Health Policy in Houston, Texas. She is co-editor (with Roberta L. Carroll and Peggy Nakamura) of the second edition of *Enterprise Risk Management Handbook for Healthcare Entities* (American Health Lawyers Association, 2013) and co-author (with Raymund C. King) of *The ABCs of ACOs: A Practical Handbook on Accountable Care Organizations* (American Bar Association, 2015) and (with Jonathan P. Tomes) *What Are...International HIPAA Considerations?* (American Bar Association, 2015).

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Related in the *AMA Journal of Ethics*

[Professional Oversight of Expert Testimony *Austin v American Association of Neurological Surgeons*](#), April 2005

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[The Role of Practice Guidelines in Medical Malpractice Litigation](#), January 2011

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[The Future of Neuroimaging in Witness Testimony](#), November 2010

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

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ETHICS CASE

Managing Care of an Intrapartum Patient with Agitation and Psychosis: Ethical and Legal Implications

Commentary by Laurence B. McCullough, PhD, Frank A. Chervenak, MD, and John H. Coverdale, MD, MEd

Ms. S arrived, unaccompanied, at the emergency department of an urban academic hospital in the early evening. She was disheveled and delusional, exclaiming that she had been invaded by an alien force. Because she was obviously pregnant and apparently in labor, she was seen by the obstetrician on call. No useful history could be obtained, and Ms. S did not cooperate with attempts to evaluate the status of her pregnancy.

Review of the limited electronic health record at the hospital indicates that Ms. S, 27 years of age, was diagnosed with schizoaffective disorder six years earlier and has been relatively stable on haloperidol in the intervening period. She was hospitalized once during this period for a week, during which time her medication regimen was adjusted and she was discharged. At that time, Ms. S lived alone and worked part-time as an archivist at a local museum. She took her medication regularly and kept her regular appointments with her psychiatrist. The electronic health record's last entry was a year ago; it contains reports of four unsuccessful attempts over a period of three months to contact her through her family and her job.

The obstetrician considers how to fulfill his professional responsibility with respect to both the patient's mental health needs and her pregnancy. In particular, he wonders how best to gain her trust to enable fuller and more comprehensive examination for the sake of the developing child, too.

Commentary

Pregnant patients with major mental disorders, including psychotic disorders, pose significant ethical challenges to obstetricians, the obstetric team, and sometimes hospital administration [1, 2]. The intrapartum period—the duration of labor and delivery—poses particular challenges for ethics consultation processes and deliberations. For example, a patient's labor process creates urgency that can be difficult for hospital ethics and legal consultants to respond to in a timely way when they do not have advance warning. This case illustrates the ethical and legal challenges that arise when a woman presents for the first time for obstetric care, apparently in labor and also experiencing an acute exacerbation of her chronic mental illness.

Assessing Decision-Making Capacity

Presumption in medical ethics and health law. Ethical analysis of this case can begin by gathering clinical facts, so the obstetrician's request for a psychiatrist colleague's [assessment](#) of Ms. S's decision-making capacity would likely be helpful. It is important to note that all adult patients are presumed both in medical ethics and in health law to have decision-making capacity. Clinicians should therefore regard their adult patients as having capacity unless they have evidence warranting further assessment of it. Ms. S's psychotic symptoms certainly constitute such evidence in this particular case.

Components of decision-making capacity. Major mental disorders chronically but variably impair patients' decision-making capacity. These impairments include diminished ability to pay attention, to absorb and retain information, to cognitively understand and reason from present events to their consequences, to appreciate the impact those consequences might have for oneself, to evaluate whether those consequences are desirable, and to communicate a decision based on the above factors [2]. The urgency of labor and its many demands on the patient make it an especially difficult time for the obstetrician or the consultant psychiatrist to assess these components of decision-making capacity.

Respect for patient autonomy should guide assessment of Ms. S's decision-making capacity and the process of facilitating her informed consent, if she is capable of it, during the labor process. Expressing respect for Ms. S's autonomy is essential because professional medical management of her high-risk pregnancy (since she had no prenatal care), labor, and delivery requires collaboration; gaining her trust and cooperation will be essential to care well for her and her newborn. For example, the obstetrician will need to request Ms. S's permission to perform a physical examination and ultrasound and initiate fetal monitoring.

Types of Decision Making

Assisted decision making. Given Ms. S's history, both the obstetrician and psychiatrist should be particularly attentive to deficits in the aforementioned components of decision-making capacity [2]. Their shared goal should be to identify impairments to which they can respond, to restore as much of her decision-making capacity as possible so that she can make decisions in light of her long-standing values and beliefs. Both physicians can try to help Ms. S make prudent decisions by supporting her psychologically and focusing on the shared goal of a good outcome for her and her soon-to-be-born child, a process called assisted decision making [2]. Assisted decision making can be augmented as necessary by respectful persuasion, i.e., an appeal to the shared goal of a good outcome and the clinical recommendations based on it [3].

Surrogate decision making. If attempts at assisted decision making and respectful persuasion are defeated by Ms. S's mental illness symptoms' undermining her decision-making capacity, then surrogate decision making is required from ethics and legal perspectives. A first step is to consult hospital policy, which should be informed by applicable state law, and hospital records to identify and prioritize potential surrogate decision makers—a list that usually begins with the adult patient's spouse, adult children, parents, or other family members and also usually includes a surrogate of last resort. In Texas, for example, a surrogate of last resort for patients who lack decision-making capacity and have neither a terminal nor irreversible condition is a member of the clergy [4]. Any doubts about who should serve as a patient's surrogate decision maker should be conveyed immediately to hospital counsel, who has the expertise to identify applicable law.

The next step is to apply one or both types of ethical and legal standards of surrogate decision making in a given case [5]. The first is known as the substituted judgment standard. This autonomy-based standard calls for the surrogate to identify the patient's relevant values and beliefs and make a decision on that basis. The standard for the replication of what the patient would decide if the patient could make a decision is not certainty (i.e., 100 percent accuracy) but only reliability (i.e., sufficient evidence for the replication as defined in applicable law). Texas law, for example, states that the decision "must be based on knowledge of what the patient would desire, if known" [4]. Other jurisdictions, such as Missouri, set a higher standard, e.g., requiring clear and convincing evidence that a surrogate's decision expresses a patient's preference [6]. This variation among jurisdictions should not be a problem, because the applicable legal standard should be stated in hospital policy and any questions about its interpretation can be addressed by hospital counsel.

In cases in which a surrogate decision maker does not know what a patient would prefer, which thus would not meet states' and health care organizations' legal standard for substituted judgment, then he or she should make decisions for the patient based on that patient's best interests. This beneficence-based standard calls for a surrogate to make decisions that will protect and promote the patient's health and well-being. In obstetric ethics, during labor a physician actually has obligations to two patients: the pregnant woman and the fetus or neonate. Beneficence-based obligations to both patients must be taken into account in applying either standard of surrogate decision making. Typically, when a surrogate authorizes clinical intervention, it should be implemented, and there is no need for the surrogate's decision to be reviewed by a court.

Responding to Refusal of Treatment by Patients with Impaired Decision-Making Capacity

In our experience, in very rare circumstances, even after surrogate authorization, a patient with seriously impaired decision-making capacity might persist in verbal or

physical [refusal](#) of the authorized treatment. Serious impairment means that verbal expressions of refusal do not reflect intact cognitive understanding, appreciation, or evaluative understanding. Respect for autonomy is not applicable in such clinical circumstances, because such [impaired decision making is not autonomous](#). The physician and health care team should therefore not mistake this patient's verbal or physical refusal as autonomous or as authoritatively expressive of their clinical judgment in planning intrapartum management. Respectful persuasion, as explained above, and beneficence-based clinical obstetric judgment should guide the physicians and health care team in cases in which a patient whose decision-making capacity is seriously impaired is expressing verbal refusal of intervention [7]. The first response to an impaired refusal is therefore to engage the patient in a respectful fashion with the goals of [treating the pregnant patient with respect](#) and [protecting](#) the [health-related interests](#) of both the pregnant and fetal or neonatal patients. Resorting immediately to force is not ethically justified. We address below how the team should respond if the patient, whose decision-making capacity is impaired, physically resists.

First, legal counsel should be immediately notified as soon as the patient expresses impaired refusal, as well as clinical ethics consultation, if the hospital has this service, so the consultation team has advance warning. The goal, if feasible, is to have legal and ethics resources ready to hand, to address ethical and legal challenges in a rapid fashion, should they subsequently arise.

Second, it should be ascertained whether evidence-based fetal complications that are indications for cesarean delivery are present. Isolated fetal heart rate deceleration with category 2 fetal heart rate tracing does not meet the threshold for an evidence-based fetal indication that would justify a cesarean delivery, because outcomes for newborns vary widely, making a poor outcome not reliably predictable. Conditions such as complete placenta previa—which happens when the placenta completely covers the cervical opening and can result in death of the laboring woman and her newborn—or various forms of placenta accreta—which happens when the placenta has grown into the uterine wall and, if inappropriately managed, can result in life-threatening hemorrhage—however, do, because their risks are well established in obstetric clinical judgment [8].

Third, a pregnant woman has a beneficence-based obligation to take only reasonable risks to herself when there are fetal indications for cesarean delivery [8]. This central tenet of professional ethics in obstetrics requires that evidence-based maternal indications be identified as reliably as possible and balanced carefully against potential benefits for the fetal and neonatal patient. When the evidence for fetal or maternal benefit is strong, the risks of cesarean delivery become reasonable in order to increase the probability of clinical benefit for the pregnant, fetal, and neonatal patients.

Fourth, if there are maternal or fetal indications for cesarean delivery, and the surrogate decision maker has authorized it, then preparations should begin. If organizational policy requires a court order and if there is time to seek a court order for cesarean delivery over the phone within the very short time needed to prepare the patient for surgery, this should be done. The judge's decision should be documented in the patient's record and the judge's instructions, whether to perform cesarean delivery or to prohibit it, should be followed, because doing so is a strict legal duty, unless the physician and the hospital are prepared to engage in civil disobedience. If cesarean delivery is to be performed, the obstetrician should clearly and concisely explain the indications for cesarean delivery and their evidence base to the patient, to show respect for her as a person, to gain her cooperation, and to reduce the risk of adverse psychological responses.

If the pregnant patient who lacks decision-making capacity physically resists and this resistance cannot be overcome safely for the pregnant woman, there is increased risk that clinically unacceptable outcomes could occur, including perinatal or neonatal death or a live-born infant who could have significant and irreversible morbidity and long-term disabilities. Beneficence-based clinical judgment would not support taking these risks.

Conclusion

Reasoning carefully through this clinically and ethically disciplined, step-wise process is essential for the fulfillment of the obstetric team's professional responsibility to the pregnant and the fetal and neonatal patients. This reasoning process and actions based on it should be thoroughly documented in the patient's record. Such cases should be routinely reviewed at patient safety and quality conferences, which use the results of retrospective review to improve the processes of clinical and ethical reasoning that can then be applied to cases in the future to make obstetric management safer. Improved safety clearly benefits patients clinically. The resultant patient care should be better, and that care, its documentation, and its routine review should be protected against any subsequent legal review, which constitutes a legitimate individual and organizational self-interest.

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Laurence B. McCullough, PhD, holds the Dalton Tomlin Chair in Medical Ethics and Health Policy in the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, Texas. He is writing (with Frank A. Chervenak and John H. Coverdale) a book titled *Professional Ethics in Obstetrics and Gynecology*.

Frank A. Chervenak, MD, is the Given Foundation Professor and chair of the Department of Obstetrics and Gynecology at Weill Cornell Medical College in New York City. He is writing (with Laurence B. McCullough and John H. Coverdale) a book titled *Professional Ethics in Obstetrics and Gynecology*.

John H. Coverdale, MD, MEd, is a professor of psychiatry and behavior sciences in the Menninger Department of Psychiatry and Behavioral Sciences at Baylor College of Medicine in Houston, Texas. He is writing (with Frank A. Chervenak and Laurence B. McCullough) a book titled *Professional Ethics in Obstetrics and Gynecology*.

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ETHICS CASE

Expedited Partner Therapy: Clinical Considerations and Public Health Explorations

Commentary by Barry DeCoster, PhD, Lisa Campo-Engelstein, PhD, and Hilary E. Fairbrother, MD, MPH

Dr. Eptor is facing Nick, an adolescent in the community emergency department (ED). Nick is 16, has been sexually active for about a year, has had three partners in the last six months, and has now noticed green penile discharge for about a week. Nick is otherwise healthy and has no other symptoms. Embarrassed about his symptoms, he drove alone for over two hours to Dr. Eptor's ED out of fear of being recognized. Based on Nick's clinical symptoms, Dr. Eptor is fairly confident of a diagnosis of *Neisseria gonorrhoea* urethritis and prescribes 250 mg intramuscular (IM) ceftriaxone plus 1g azithromycin by mouth. He sends off Nick's specimen for Gram stain and culture.

Dr. Eptor is also concerned about Nick's partners. He recently overheard fellow physicians talk about prescribing a double dose of an antibiotic to cover a potential infection in a partner, something they called "expedited partner therapy." Dr. Eptor practices in a rural area and mostly deals with members of the local farming community. He has not seen an adolescent with a sexually transmitted infection (STI) in almost five years and generally feels uncomfortable working with this population of patients. Coincidentally, he is currently being sued for misdiagnosing acute coronary syndrome (ACS) as gastric reflux three months ago, so he is feeling uneasy and on edge about making a misstep.

Dr. Eptor struggles as he thinks about Nick and his three female partners. "How could I prescribe something to a person I have never met? What if one has an adverse reaction or doesn't respond to the medication? Is it ethically justifiable for me to prescribe ceftriaxone, an IM medication?" Dr. Eptor knows that resistance to gonorrhea treatment has been increasing but he doesn't know the specific resistance profile for the area where Nick lives.

After some reflection, Dr. Eptor also becomes concerned that if he doesn't provide Nick with additional prescriptions, Nick's potentially asymptomatic partners might not ever seek care and could develop complications. Dr. Eptor doesn't want to be responsible for missing an opportunity to treat a subclinical infection in a young woman and risk her developing pelvic inflammatory disease (PID), which could compromise her fertility. He wonders about the scope of his public health role in this case and isn't sure whether the

decision he makes will be compliant with his state's regulations and institution's guidelines and protected from a legal standpoint.

Commentary 1

by Barry DeCoster, PhD, and Lisa Campo-Engelstein, PhD

This case raises important ethical complexities, even in the relatively straightforward example of a sexually transmitted infection. Dr. Eptor has a clear duty to care for Nick, but this case raises ethical concerns about STI care as part of the broader scope of physicians' public health roles. Dr. Eptor knows that Nick's three female sexual partners are at a high risk of being infected. Does he have a duty to these women directly, even if they are not his patients? Do Dr. Eptor's duties to treat extend to the community at large?

Goals of Care and Ethical Responsibilities

These questions suggest different—possibly conflicting—goals of clinical bioethics and public health ethics. Clinical bioethics has traditionally focused on the ethical complexities at the micro level of primary care (i.e., the doctor-patient relationship) rather than at the macro level. Yet these dialogues are only partially helpful here for understanding what Dr. Eptor owes to Nick and Nick's sexual partners. Public health ethics can be defined as "the principles and values that help guide actions designed to promote health and prevent injury and disease in the population" [1]. One way public health ethics differs from clinical ethics, then, is by prompting physicians to think about the needs of populations, not just individual patients, as ethically relevant to their decisions. In other words, from a public health perspective, physicians need to think about the problems facing populations, including social determinants of health; to think about prevention in addition to treatments and cures; and to seek ethically defensible responses that improve the health and well-being of populations [2]. In this case, Dr. Eptor is considering not only Nick's health, but also the needs of his sexual partners. Dr. Eptor might consider expanding his goals of care to include not only Nick's partners, but also the greater rural community. Acknowledging this broader goal helps us to better frame the ethical questions that Dr. Eptor should consider.

Furthermore, although Dr. Eptor expresses discomfort about prescribing EPT, he might have a strong ethical obligation to do so, since male-to-female transmission of STIs is greater than female-to-male transmission [3]. Thus, Nick's female partners are at greater risk than if Dr. Eptor's patient were a female with male partners.

A challenge that Dr. Eptor faces in this case is the tension between the view that medicine's duties are only or primarily clinical and the view that medicine also has public health duties. On the one hand, Dr. Eptor has clear and immediate clinical duties to Nick to do what is in Nick's best interests. On the other hand, his duties, framed from a public health ethics perspective, suggest that his responsibilities extend to protecting the

health and well-being of other members of the community, some of whom would be Nick's sexual partners, the three women with whom he has recently had sex and who might be infected. Given that Dr. Eptor (likely) has not met these women, we can ask two important questions. First, what is the nature of Dr. Eptor's ethical obligations to these women? Second, what is the scope of his duty to reach out to and treat them? One response might be to say that Dr. Eptor has no duty except to his patient, Nick. Yet, even if we take this view, we must acknowledge that Nick faces a high likelihood of reinfection if he has sex again with any of these women before they are treated. So, Dr. Eptor's treatment of Nick's sexual partners could be an indirect way of providing *preventive* care to Nick [4, 5].

Expedited Partner Therapy

One way to handle this situation is via [expedited partner therapy](#) (EPT), in which a physician prescribes treatment for a patient's sexual partners without seeing them. If Dr. Eptor were to follow his colleagues' lead by prescribing a "double dose" or multiple doses of antibiotics, he would have to make sure that Nick understands that the additional pills are to be shared with his partners. Prescribing this double dose with the expectation that it is to be shared with a partner has a clinical history [6]. This kind of semi-clandestine approach to treatment via double dosing has been common historically, albeit "not traditionally condoned" [7]. This subterfuge becomes unnecessary if Dr. Eptor practices in a state that has legalized anonymous prescriptions via EPT [8]. In fact, only four states prohibit EPT [9]. In states where anonymous prescriptions via EPT are legal, Dr. Eptor could write a prescription to Nick directly and to multiple unnamed prescription recipients to whom Nick could deliver the antibiotic. The CDC recommends EPT for all sexual partners in the last 60 days [10]. This means EPT prescriptions can be written for as many partners as is appropriate. Dr. Eptor would have to discuss the timing of Nick's sexual activity to determine which of his partners should be treated via EPT. Once filled, the prescription would be accompanied with literature on safety and how to contact a pharmacist if any of the women were to have questions.

Deciding Whether to Recommend EPT

There are several elements Dr. Eptor needs to consider in deciding whether to recommend EPT for Nick's partners.

Legal considerations. States where EPT is legal vary as to which diseases can be treated on this model of care. In some states, like California [11], both chlamydia and gonorrhea may be treated via EPT; in other states, like New York [12], EPT can only be used to treat chlamydia. Clinicians thus have a responsibility to understand the legal status of EPT in the states in which they practice, which can be easily found on the CDC website [9].

Is Nick reliable enough? Because EPT requires explicit conversations about taboo subjects, such as sex in general and STIs in particular, Dr. Eptor and Nick will have to have a frank

discussion about whether Nick is prepared to take on the responsibilities of EPT. EPT is an appropriate alternative to the standard process of referring sexual partners to seek clinical attention, but it is not demanded of Nick. In this case, both Nick and Dr. Eptor must be reasonably certain that Nick is willing to and capable of contacting partners and of passing along both the medication and attached information.

Whether Dr. Eptor is comfortable prescribing EPT for Nick's sexual partners depends on whether he considers Nick a reliable messenger of risk information to the unnamed women. Here, it is important to remember that Nick is requesting EPT as a means for self-care and as a means of expressing some regard for his sexual partners. Perhaps he's also trying to maintain or even repair those relationships, particularly if any of Nick's partners feel angry or betrayed that he may have infected them with gonorrhea. If Nick is concerned enough to seek out and distribute the antibiotics, then perhaps he can also be relied upon by Dr. Eptor to convey risks and encourage follow-up care. If Nick has no real relationship with these women (say, a one-night stand) and cannot find them, then Dr. Eptor cannot rely on Nick to communicate risk information or to distribute the prescription.

As we have noted above, Dr. Eptor has a responsibility here to have a frank conversation with Nick, one in which the patient is supported given his discomfort, and to inquire about facets of the case that include not just Nick, but also what Nick knows about his partners. This effort will ultimately benefit both Nick and the women who possibly may be infected.

EPT is an effective tool meant to facilitate and improve treatment rates for STIs, and compliance of partners is high [4]. EPT, though, is not a magic bullet. Should Nick feel uncomfortable as a messenger for whatever reason, standard public health reporting systems remain the default.

Does the threat of antibiotic resistance make EPT unsafe? One important consideration is that an antibiotic-resistant strain of gonorrhea is on the rise [13], although Dr. Eptor is not sure if this is the case where Nick lives. In part, the threat posed by antibiotic resistance has shaped public health law [13, 14]: in some states, such as New York, EPT is legal only for chlamydia [15]. A possible concern is that without proper follow-up testing, resistant strains of gonorrhea will likely spread, possibly even among people who have been treated for it before. Certain antibiotics are not eligible for EPT because they are not available in pill form and must be administered by a health care professional via IM injection [4]. Thus, Nick is eligible for the IM injection for his treatment of gonorrhea, but it is not possible to treat Nick's sexual partners via IM injection without a clinical visit; the CDC recommends EPT via prescription of antibiotics in pill form for those unlikely or unable to receive clinical evaluation and treatment [13].

In this case, Dr. Eptor could reasonably counsel Nick about risks of antibiotic-resistant strains of gonorrhea and plan for Nick to return for follow-up screening. If Nick tests negative, then Nick's treatment—and presumably Nick's partners' treatment via EPT—can probably be considered successful. If Nick tests positive for a resistant strain of gonorrhea, then Dr. Eptor will have to prescribe a different (IM) antibiotic to treat Nick and suggest the same for his partners, who would need to see doctors to receive it.

Obligations to Nick's partners. But what does Dr. Eptor know about or owe to Nick's female sexual partners? One ethical concern is that these women may believe that they have successfully treated their gonorrhea and thus see no need to seek follow-up treatment. If their STIs persist, however, one risk is that they could infect others. Another risk is that they might develop serious complications—such as PID, which can lead to infertility or ectopic pregnancy [16]—as a result of having what could turn out to be an untreated, subclinical STI [16]. Such outcomes could be personally devastating for these women, and treating infertility via assisted reproductive technologies, for example, is frequently not covered by insurance [17]. This makes it all the more important for Dr. Eptor to prescribe for Nick's partners only if he is confident that Nick can be relied upon to convey information about the need for follow-up care.

Recommendation. Although the use of EPT raises numerous ethical concerns from clinical and public health ethics points of view, we argue that Dr. Eptor would be acting responsibly from clinical and public health ethics points of view in prescribing EPT to Nick and his three partners, assuming it is legal in the state where they reside. EPT could benefit not only Nick but also his partners by providing them with treatments for their potential infections that are convenient (i.e., not requiring a visit with a health care provider) and possibly cost-free (i.e., covered by Nick or another third-party payer). Furthermore, it would enable Nick to take responsibility for his own health and the health of his sexual partners. Lastly, EPT helps Dr. Eptor contribute to the public health goal of reducing the transmission of STIs.

Additional decision: cost. If Dr. Eptor decides to prescribe EPT for Nick's partners, there remains the question about who should handle the cost of the medications. Given that these antibiotics are generally not expensive, Nick may choose to pay for his partners' medications out of pocket. Given the overall public health benefit and economic savings, one might argue that insurers ought to cover both Nick's and his partners' medications, but insurance policies vary in their coverage of EPT. Some state programs, such as California's Medi-Cal program, explicitly prohibit payment of a patient's partners' medications through EPT [8]. Here, we note there is further work to be done in advocating for policies that make EPT more accessible and thus increase its public health impact.

Social Justice Issues Surrounding EPT

It is important to note that Dr. Eptor might, because of gender norms regarding sexual activity, feel more comfortable prescribing EPT to Nick than if he had a female adolescent patient. Men who have multiple female partners can be lauded for upholding hegemonic masculinity by proving their sexual prowess. Dr. Eptor, while generally uncomfortable, does not seem to have a specific discomfort with the fact that Nick is [16 years old](#) and has had (at least) three sexual partners. While this could be because of an open mind about sexual activity, it also could be influenced by Nick's gender and the fact that Nick's behavior adheres to general social expectations about teenage boys (i.e., that they have "raging" hormones and want to have sex with as many women as possible). In contrast, had Dr. Eptor been treating a female patient, he might have consciously or unconsciously judged his patient in a way that undermined her credibility and perhaps treated her differently for violating the gender norm of feminine chastity.

Furthermore, it is problematic from clinical and public health ethics—in addition to social and cultural—points of view that the CDC recommends EPT for only heterosexual partners [13]. This limits who may benefit from EPT: if one or more of Nick's recent sexual partners had been male, Dr. Eptor would not be able to prescribe EPT. Homosexual sexual activity is generally considered a contraindication for EPT due to the lack of research on EPT in the LGBT community and because men who have sex with men are at an increased risk for HIV and therefore should be seen by a physician if they are concerned about having contracted any type of STI [13]. One could argue from both clinical and public health ethics perspectives that EPT should be extended to LGBT populations as a matter of justice, as well as to promote the public health goal of reducing STI rates.

Counseling Nick

In this case, Nick is uncomfortable discussing his own sexual health, and he's rather naive about relevant facts: out of embarrassment, Nick intentionally drove hours to seek care from a nonlocal physician. Nick's sexual activity (and presumably, his nonuse or incorrect use of condoms) has directly caused his current infection as well as the possible infection of his partners. These are certainly reasons for Dr. Eptor to initiate [compassionate but frank discussion](#) with Nick about his sexual practices. Beyond providing proper medications, Dr. Eptor is ethically obligated to be a source of trustworthy, clear, and thoughtful counseling to Nick about his sexual health, for the short and the long term.

Many physicians report feeling discomfort in discussing sex with patients [18, 19]; this discomfort may be greater for physicians discussing sexual health with LGBT patients [20]. Dr. Eptor's careful self-reflection is ethically relevant and required of him (and of physicians in similar circumstances) to provide thoughtful, patient-centered care. In his self-reflection, Dr. Eptor might consider: Why is he feeling uncertain about discussing

sexual health and sexuality with a teenager? Is his hesitation and worry about another misdiagnosis influencing his practice in Nick's case? If so, how? Although some physicians feel uncomfortable talking about sex with patients, given that sex and sexuality come into play commonly for adolescent patients, it is imperative that physicians develop self-awareness about their discomfort and that they overcome obstacles that interfere with their capacity to discuss sex and its clinical and public health risks with their patients.

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Barry DeCoster, PhD, is an assistant professor of philosophy and bioethics in the Humanities and Communication Department at the Albany College of Pharmacy and Health Science in Albany, New York. His research focuses on problems in health care ethics and the philosophy of science and medicine, including bioethical critiques of medicalization, LGBT health, and virtue ethics (with a focus on collaboration and political resistance).

Lisa Campo-Engelstein, PhD, is an associate professor at the Alden March Bioethics Institute of Albany Medical College in Albany, New York, and the co-editor of *Oncofertility: Ethical, Legal, Social, and Medical Perspectives* (Springer, 2010). A bioethicist specializing in reproductive and sexual ethics and gender theory, she has been published in the *Journal of Clinical Oncology*, *Science*, *The Hastings Center Report*, and *The American Journal of Bioethics*. She earned her PhD in philosophy from Michigan State University and completed a postdoctoral fellowship with the Oncofertility Consortium at Northwestern University.

Commentary 2

by Hilary E. Fairbrother, MD, MPH

In this case, Dr. Eptor is faced with the decision of how best to treat a probable sexually transmitted infection (STI) in his adolescent patient, Nick, and whether to prescribe for Nick's asymptomatic partners. This case thus pertains to expedited partner therapy (EPT) and partner-delivered patient therapy (PDPT). EPT involves a clinician treating an STI patient's sex partners without [actually seeing them in person](#) [1]; PDPT happens when a clinician writes additional prescriptions for the patient's sex partners that are delivered to those partners by the patient. In other words, EPT and PDPT constitute a kind of [proxy](#) health care delivery that work best when the clinician's actual in-person patient serves as a reliable messenger. Currently, the Centers for Disease Control and Prevention (CDC) advises that EPT only be used to treat suspected chlamydia and gonorrhea in patients with opposite-sex partners [2]. Multiple ethical and legal questions arise about EPT and PDPT, which are discussed here.

EPT and "Nontraditional" Clinician-Patient Relationships

Several considerations favor the use of EPT. One source of ethical complexity in this case, from the clinician's point of view, is the high probability that Nick has infected his sex partners. When one patient is treated and his sex partners are not, infection recurrence for the initially treated patient is possible. In response to this risk for this particular patient, Dr. Eptor could recommend to Nick that he abstain from all sexual relations with any partners until they are all treated and, if need be, cured. There is also a public health risk that the clinician must consider—that others in the community might be infected.

Another ethically relevant consideration has to do with whether the particular STI in question needs to be reported to a state or federal health official. (Clinicians are required, for example, to report confirmed cases of the following to the CDC: chlamydia, gonorrhea, chancroid, hepatitis B, hepatitis C, human immunodeficiency virus (HIV), and primary and secondary syphilis.) In this case, Nick's sex partners are identifiable third parties, so Nick could encourage them to see Dr. Eptor in person for examination, testing, and possible treatment. However, since this kind of "traditional" method of outreach only leads to about 20 percent of sex partners being treated [3], the physician should consider EPT as an ethical means of treating those his patient has put at risk.

Years ago, physicians began employing PDPT in an effort to reach more people potentially infected with STIs and thereby improve both individual patients' health and the health of the public [4]. Since the CDC's release of a white paper on the review and guidance for the use of EPT in 2006 [1], more research has been done. EPT has been shown to be efficacious for chlamydia and gonorrhea in heterosexual sex partners through multiple randomized clinical trials [5] and might also be safe to use in cases of *Trichomonas vaginalis* [6]. Repeat trials have shown EPT to increase the number of sex

partners treated and to lower recurrence and persistence of infections [7-10]. Because of this strong clinical evidence, EPT can be said to benefit both patients and the public. EPT requires that both the original patient's partners and clinicians be willing to interact with each other through an intermediary; this lack of intimacy and connection changes the physician-patient relationship.

EPT is widely practiced by physicians and endorsed by professional societies, with specific statements of support available from the American College of Obstetrics and Gynecology, the American Academy of Pediatrics, the Society for Adolescent Medicine, and the American Medical Association [11-14]. These endorsements suggest that the use of EPT and PDPT can be particularly helpful when patients' sex partners are unlikely or unable to seek evaluation, testing, and treatment.

Principlism and EPT

Nonmaleficence, beneficence, respect for patient autonomy, and justice [15] are values that can be used to consider Nick's case more from an ethics perspective.

Nonmaleficence is the "do no harm" principle of ethics, and beneficence means doing what is best for a patient. Although it is clear from the above discussion that EPT offers benefit to the patient, is there potential harm to the patients' partners? Some physicians might be concerned that a partner could be given a medication to which he or she has an allergy [16], causing discomfort or even a potentially deadly reaction. While an important consideration, it should be noted that an adverse outcome has never been reported in the seven randomized clinical trials performed on thousands of EPT patients [7]. Another possible objection relates to the limited scope of EPT. Although sex partners might be treated for chlamydia and gonorrhea, they would not be treated or tested for other STIs such as HIV, syphilis, or *Trichomonas vaginalis*. Yet it is known that patients with one STI are at increased risk for co-infection with other STIs [17]. Recent research performed since the publication of the CDC's white paper in 2006 has shown that it may be appropriate for *trichomonas vaginalis* to be included with chlamydia and gonorrhea as diseases that can be treated via EPT [6, 7]. Also, female patients infected with STIs are at risk for pelvic inflammatory disease (PID), infection extending beyond the cervix; of note, EPT is only prescribed to treat cervicitis. No research studies have been performed to determine the safety of EPT for PID. Due to the length of treatment required and the risks of infertility and systemic infection, a physician must still evaluate female patients with signs and symptoms of PID prior to initiating treatment.

EPT can also lead to a missed opportunity for patient care, and it could delay the identification and assessment of symptoms that might indicate diagnoses other than those for which the partner is being treated. Despite these concerns, the risk to patients who received EPT seems to be low [7]. Partners can be treated via EPT and then encouraged—presumably by the patient who is acting in the role of messenger—to

extend, for lack of a better term, a physician's invitation to be evaluated and assessed more fully. Physicians also cite concerns about the legality of EPT, specifically of prescribing a medication for a person they have never met or examined [18]. Currently, EPT is legal (explicitly allowed) or permissible (not explicitly illegal) in all but four states [19-23].

Respect for autonomy is a third principle to be considered, one expressing the importance of respect for a patient's right to self-determination. This right is protected by two additional concepts of ethical importance: informed consent and confidentiality. Given the remote nature of health care delivery in EPT, is meaningful informed consent possible? While educational materials are available, such as those offered online by New York City's PartnerCare [24] for a patient's sex partners, the remote nature of health care delivery provided via EPT means that clinicians' capacity to respond to patients' questions and concerns is limited. Despite this limitation, as I've argued, the benefits of EPT seem to outweigh the risk that patients might not be fully informed about taking their prescribed medications.

For EPT to work, physicians must convince patients to disclose protected health information, including a diagnosis, to their partners. This is one way physicians can express respect for the autonomy of patients they don't see directly. The Belmont Report states that patients, "to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them" [14]. Informed consent is abrogated by EPT, in that physicians never directly see or interact with the sex partners for whom they are writing prescriptions. It is impossible for full informed consent to be obtained without any sort of direct physician-patient interface, which is partially addressed by including prepared educational materials with the prescription for the sex partners of patients who will be receiving EPT [24]. The benefits of EPT seem to outweigh this very real negative ethical downfall of EPT.

Patient privacy is also violated in EPT, as it is typically necessary for patients to tell their sex partners about their diagnosis. Patient privacy is violated during most direct patient referral interactions as well, so this is not a particular weakness of EPT, but rather a factor of treating the partners of patients infected with sexually transmitted diseases.

Finally, we consider the principle of justice. Our current health care system, despite advances made in coverage by the Affordable Care Act, leaves many patients without access to care. As physicians operating in an imperfect system, it is important to remember that some patients will not be able to seek care due to financial constraints or lack of clinician availability. This might be particularly true for Dr. Eptor's patients, as he practices in a rural area. EPT promotes access and therefore increases justice. EPT, and other forms of remote health care delivery (e.g., telemedicine), despite their drawbacks, increase the chances that persons not willing or able to visit a physician in person—due,

perhaps, to a lack of insurance coverage, social or cultural factors, or immigration status, for example—can be treated.

When considered from a principlist perspective, EPT, despite the reservations noted above, is an ethical way to practice medicine. From a safety standpoint, research shows that EPT is safe for the limited STIs for which it is used. From a practical standpoint, treating patients remotely with an intramuscular injection of ceftriaxone is impossible, but a single 400-milligram dose of oral cefixime cures 96 percent of gonorrhea cases [25]. As long as the limitations of remote practice of health care are identified, considered, and responded to as fully as possible by clinicians practicing EPT, that can be called ethical medicine.

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Hilary E. Fairbrother, MD, MPH, is the associate director of undergraduate medical education and the co-clerkship director of the Emergency Medicine Selective for the Ronald O. Perelman Department of Emergency Medicine at New York University School of Medicine in New York City. She specializes in health care policy, ethics, and simulation education.

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The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental.

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ETHICS CASE

How Should Clinicians Treat Patients Who Might Be Undocumented?

Commentary by Jeff Sconyers, JD, and Tyler Tate, MD

Dr. Connelly, who recently finished her residency program, has now worked as a partner in a private primary care practice for a year. She shares the practice with an older physician who is considering retirement, taking on fewer responsibilities, and reducing his hours. The practice is part of a large hospital network and serves a diverse community in a large city. Dr. Connelly loves the prospect of owning the practice but is unsure whether she wants to assume sole responsibility for managing the business when her partner retires. She acknowledges that her training was medical and her business-oriented expertise is limited.

One day, the clerk at the front desk of the practice is welcoming one of the new patients, Ms. Nunez, and notices that the identification (ID) she presents lacks the holograms and graphics on IDs typically issued in the state. Unsure what to do, the clerk instructs Ms. Nunez to complete the usual forms and shows her ID to the fellow clinic staff members, some of whom suspect it to be false. One of the nurses, Kim, holds strong beliefs about illegal immigration and, based on Ms. Nunez's ethnicity and language preferences marked on her forms, assumes that she is an undocumented immigrant.

Kim approaches Dr. Connelly and demands that someone from their office report Ms. Nunez to the appropriate federal authorities. Taken by surprise and pressed for time, Dr. Connelly asks Kim to wait to discuss the matter as she enters another patient's room to try not to get further behind in her appointment schedule. By the time Dr. Connelly invites Kim to talk more about Ms. Nunez's ID, she learns that Kim has mobilized other members of the office and nursing staff, who agree upon their responsibility to report Ms. Nunez.

Dr. Connelly is reluctant to join them, as she is not convinced that a patient's immigration or political status should be a factor in determining who receives care. She considers seeking legal advice and wonders whether she does indeed have a legal obligation to report a patient suspected of not being a legal resident. But she also wonders whether Ms. Nunez, who may have presented a false ID, would give accurate clinically relevant information, given that she might not feel comfortable telling the whole truth.

Commentary

If Dr. Connelly had quick, easy access to a lawyer, she might ask several questions: “What am I required to do in this situation? What am I permitted to do? What am I prohibited from doing?” A lawyer could advise Dr. Connelly about any controlling legal authority, and, if asked, could express a personal view about the right thing to do, as well. Ultimately, however, it will be up to the client—Dr. Connelly—to decide what to do in the event.

Legal Considerations

Some of Dr. Connelly’s nurse colleagues and other staff believe they have [a responsibility to call the immigration authorities](#). There is a common misconception among nonlawyers that there is a general duty to report illegal activity. There isn’t. In the same way that the First Amendment to the US Constitution protects the right of free speech, it also protects the right not to speak. There is no general obligation to report a crime, even if one witnesses the crime directly. (Here, the office staff members assume Ms. Nunez is an undocumented individual; they have no actual knowledge that she has committed any illegal act.) While there are some exceptions to the rule that create a duty to report, none apply here [1].

Although Dr. Connelly has no obligation to report Ms. Nunez, she also has no obligation to see her or take her on as a patient. A [duty to treat arises](#) because a doctor has a pre-existing relationship with a patient or because in the circumstances the patient reasonably relies on the doctor’s help, such as when a doctor provides medical advice, even in a social situation, when asked directly for it [2].

Whatever moral obligations may attach when encountering someone who needs care, whether routine or emergent, the doctor is generally under no legal obligation to provide it [3]. Most doctors are familiar with the so-called “[Good Samaritan](#)” laws, which protect doctors who voluntarily, and without compensation, decide to provide care to an individual in need. These laws protect doctors who choose to act altruistically, so if a doctor chooses to volunteer, she should not bill for the services; Good Samaritan rules don’t apply when payment occurs. Doctors, like other citizens, are permitted to refuse service for any legal reason or for no reason at all.

Here, Dr. Connelly is concerned that Ms. Nunez might not tell the truth about her medical condition or other clinically relevant details. If Dr. Connelly reasonably concludes that she will be unable to treat Ms. Nunez safely because the patient is likely to withhold or misrepresent important information, she can decline to enter into the doctor-patient relationship from the start. What Dr. Connelly can’t do, however, is choose not to care for Ms. Nunez on the basis of her membership in a legally protected category—for example, race, religion, national origin, color, sex/gender/gender identity/sexual orientation, veteran status, or disability. State laws vary on what categories are considered

protected, and the intersection of state and federal laws in this area can be confusing. A good lawyer would tell Dr. Connelly not to discriminate, and which categories are protected in her state and under federal law.

Presumably, Ms. Nunez has come into the clinic and given her personal information to Dr. Connelly's staff for the purposes of obtaining health care. As a result, all the information she has provided—her name, her address, and any other data such as her health history and current complaint—is protected from disclosure under the [Health Insurance Portability and Accountability Act \(HIPAA\)](#) [4] and its implementing regulations [5]. To oversimplify an extremely complex set of rules, under HIPAA no one at the clinic with access to Ms. Nunez's personal information may disclose that information except (1) for purposes of providing her with health care services, obtaining payment, and conducting clinic operations (2) as and to the extent she authorizes disclosure in advance, or (3) in certain very limited circumstances without her prior authorization.

There is no general exception for reporting criminal activity, only an exception for "criminal conduct that occurred on the premises" of the clinic [6], which does not apply here. As already noted, no one has actual knowledge that Ms. Nunez is using a false ID; and even if she were, it is not generally a crime to use a name other than your own legal name [7]. Using a false name to obtain benefits to which that the person is not entitled (e.g., Medicaid coverage, a student loan, or preferential employment treatment) *is* almost always a crime, but no crime has yet occurred because Dr. Connelly's staff has acted before she has made any claim for benefits. As a result, neither Dr. Connelly nor the clinic may provide any information about Ms. Nunez to immigration or law enforcement authorities, and they must affirmatively protect her privacy—all the information collected from her for purposes of providing her with care—from disclosure.

What about Kim, the vigilante nurse? He is bound by the requirements of HIPAA just as much as are Dr. Connelly and the clinic. In the case, Kim has apparently not yet contacted the authorities; if he had contacted the authorities about Ms. Nunez, there would be several results. HIPAA breach notification rules require notice to the secretary of the Department of Health and Human Services in many circumstances [8]; a [breach](#) can lead to substantial fines and penalties. Dr. Connelly and her partner would need to consult a lawyer about the requirements of the breach notification rules, and if they concluded that notification is necessary, how to give it in keeping with the rules. At a minimum, the clinic owners would need to let Ms. Nunez know about any such disclosure by Kim or another member of the staff; they should recognize that Ms. Nunez might, in that case, have a claim for damages for violation of her privacy, and they might contact their insurer for advice on how to proceed.

In addition, under these circumstances, a difficult choice would confront Dr. Connelly and her partner: whether to discipline Kim for violating Ms. Nunez's privacy rights. Depending

on what Dr. Connelly and her partner concluded about Kim's knowledge of his confidentiality obligations, they would want to consider whether he would benefit from additional education because he was unaware of his confidentiality obligations, or whether his actions were deliberate in spite of adequate training and education and therefore suggest his possible suspension or even termination.

One final note on legal requirements: although Dr. Connelly has no obligation to report Ms. Nunez, or to take on her care, she does have an obligation to make sure any bills she submits for services are accurate. The clinic should have in place a process to verify that the information it provides to insurers for billing is correct. Private insurers like Aetna and Blue Cross can establish their own rules to drop or otherwise punish providers who bill them incorrectly, including requirements for verification of identity or coverage; providers need to check the rules of these payers and follow them. The state and federal governments, in the form of the Medicaid and Medicare programs, go further and impose severe penalties for bills submitted with inaccurate, false, or misleading information [9]. Medicare and Medicaid expect that clinics and other providers will have processes in place to verify all the information they submit, including reasonable steps in the circumstances to verify identity. With regard to Ms. Nunez, the clinic appears to be on notice that she may not be who she says she is: the ID she presents doesn't appear authentic. Before submitting a bill to any payer, but especially if the payer is Medicaid or Medicare, clinic staff should do more to determine whether her ID is genuine. Whether she receives services for her visit today, the clinic should not submit a bill until it is satisfied she is who she says she is.

Ethical Considerations

In terms of the ethical analysis of this case, there is no better place to start than the Hippocratic Oath. While the oath never explicitly states *primum non nocere* (first do no harm), a phrase it is often assumed to contain, it does give us the informative statement "Into whatever homes I go, I will enter them for the benefit of the sick...whether they are free men or slaves" [10]. The normative claim implicit here is that it is the duty of the physician to take care of anyone who comes to him or her for care, regardless of that person's societal status. This claim is intimately related to the principle of beneficence, which is a broad concept encompassing acts of mercy, kindness, charity, altruism, love, humanity, and a deep concern for the promotion of the good of others [11]. At times, the demands of beneficence can [conflict](#) with an agent's desire for a comfortable life; this conflict will influence Dr. Connelly's analysis of a relationship with Ms. Nunez.

We believe that if a patient has an acute life-threatening condition (for example, a stroke, respiratory distress, or ongoing blood loss), it is the physician's moral obligation to treat him or her, except under rare and extenuating circumstances—such as certain risk of dangerous exposure, injury, or death from attempting treatment. (This moral obligation is different from the legal rules outlined above.) If a patient is *in extremis*, a physician

must attempt to treat. However, these clear obligations need not apply in less acute scenarios like that of Dr. Connelly and Ms. Nunez.

Moreover, it is not Dr. Connelly's moral obligation as a physician to work for free. If Ms. Nunez does not have insurance, Dr. Connelly would likely not be reimbursed for her medical care (unless she paid in cash). This is where Dr. Connelly's interpretation of beneficence plays a critical role in her decision making. Although Dr. Connelly could decide, as a rule, to give free medical care to patients without insurance, or to work within a barter system (or within the framework of any legal and feasible system), most bioethicists would consider these acts to be supererogatory (above the normal call of duty). Whereas many would argue that being a physician does in fact require some degree of "self-effacement" [12], we believe that working for free has moved beyond duty, and while it may be morally praiseworthy, it is not required.

The physician does, however, have a professional obligation to leave prejudices at home when he or she enters the clinic or hospital. As Pellegrino and Thomasma argue in *For the Patient's Good*, "it is necessary to establish that persons within the [patient-doctor] relationship are bound by specific ethical obligations not necessarily binding for the rest of the population or for the same persons outside of that relationship" [12]. We believe that health care professionals cannot in good conscience narrow the category of patients who deserve their time, attention, and care based upon gender, race, ethnicity, sexual orientation, disease process, socioeconomic status, or any other factors, including [immigration status](#). This opinion is also codified by the American Medical Association [13]. The oath physicians take is real and binding; just as elected officials must act for the good of the public without discrimination, we believe physicians and other health care professionals must act for the good of all of their patients, irrespective of their category memberships. Of course, at times it can be difficult to know what the "good" actually is. However, we are confident that it is not limiting care to patients who fit within a certain class, framework, or demographic.

Would Dr. Connelly's obligations change if she *were* legally bound to report patients with suspicious immigration status? We would argue no—the demands of beneficence and the weight of the patient-doctor relationship can transcend the law, and Dr. Connelly would be morally justified if she chose not to report.

It is also important to consider this case within a historical framework—one of physicians acting as an arm of law enforcement. Jeremy Spevick does an excellent job of describing the sordid history of physicians acting unethically as "[agents of the state](#)" [14]. He highlights the human rights violations and macabre practices of experimentation, eugenics, and euthanasia performed by many German physicians in Nazi Germany at the government's request. He also identifies some more acceptable practices, however, such as mandatory reporting of patients with communicable

diseases or the administration of vaccines to school-aged children to fulfill legal mandates. These later practices are rooted in a utilitarian health-promoting ethic: some degrees of inconvenience, or loss of freedom, are ethically acceptable if the practices clearly benefit the community. Ultimately, though, we believe that physicians are morally justified in “conscientiously objecting” to any law that requires them to act in contradiction to their professional duties to patients.

Conclusion

It is Dr. Connelly’s prerogative to decide to what extent she wants to investigate Ms. Nunez’s immigration status. She has no legal obligation to call a lawyer, let alone law enforcement. However, she does have a moral obligation to (1) assess Ms. Nunez and treat her if she is acutely ill (in extremis), (2) accept her as a patient regardless of her background or status as a citizen of the United States, and (3) respect Ms. Nunez’s confidentiality as she would that of any other patient. This argument is rooted in beneficence, which we believe is an integral part of the vocation of health care.

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1. Some important exceptions to the rule include the duty of a conspirator who plans a crime but backs out of committing it to notify law enforcement about other conspirators and their plans; and the duty to answer truthfully (or assert Fifth Amendment rights against self-incrimination) when providing information to law enforcement.
2. The right answer in such cases is almost always “I would be glad to see you at the office—call for an appointment and I’ll make sure you get in quickly.”
3. If Dr. Connelly is staffing a hospital emergency room when Ms. Nunez presents for care, a different rule applies. The Emergency Medical Treatment and Active Labor Act (EMTALA) of 1986 requires hospitals that participate in the Medicare or Medicaid programs and, by extension, their employed physician staff, to provide a medically appropriate screening exam and any medically necessary stabilizing treatment for any patient who presents at the hospital’s emergency department. In this limited setting, there is in fact an obligation to provide care—but only until the patient’s emergency condition is stabilized or the patient is transferred to another facility. See 42 USC sec1395dd (2016).
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scope of the breach and how many other breaches may have occurred in deciding when and what she is required to report.

9. The False Claims Act, 31 USC sec 3729 (2016), imposes a penalty under federal law of up to \$10,000 plus 3 times actual damages for every false claim for services under the Medicare program. Similar laws apply at the state level. For example, Title 74, section 74.66.020 of the *Revised Code of Washington* imposes a penalty of up to \$11,000 plus 3 times actual damages for every false claim under the state's Medicaid program.
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Jeff Sconyers, JD, is a senior lecturer in the Department of Health Services in the School of Public Health and an adjunct member of the faculty of the School of Law at the University of Washington in Seattle. He serves on the ethics committees of Seattle Children's Hospital and Swedish Medical Center First Hill, served as the first General Counsel at Seattle Children's Hospital and is a past president of the Washington State Society of Health Care Attorneys and former member of the Board of Directors of the American Health Lawyers Association. A frequent speaker on legal ethics, and public health law and practice, he is also founding co-editor-in-chief of the *Washington Health Law Manual* and co-author of "Pediatric Risk Management" in *Risk Management Handbook for Health Care Organizations* (Jossey-Bass, 2009).

Tyler Tate, MD, is a fellow in pediatric bioethics at the Treuman Katz Center for Pediatric Bioethics at Seattle Children's Hospital and the Division of Bioethics in the Department of Pediatrics at the University of Washington School of Medicine in Seattle. He is also a practicing pediatrician in the University of Washington Division of General Pediatrics and Hospital Medicine. He is pursuing a master's degree in bioethics and is broadly interested in the intersection of theology and medicine, the ethics of suffering, value judgments in health care, the medical humanities, and global health.

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MEDICAL EDUCATION

One Model of Collaborative Learning for Medical and Law Students at the University of Baltimore and Johns Hopkins University

Gregory Dolin, MD, JD, and Natalie Ram, JD

Medicine, like law, is sometimes referred to as a “conservative” profession, as both can change slowly, stifling innovation [1]. While the art of medicine has produced important advances, there is at least one part of medicine that has not changed much in more than 100 years. Nearly all American medical schools have followed much the same educational model since Abraham Flexner published his famous report on the state of American medical education in 1910 [2]. The educational model promoted by that report emphasizes teaching students the science of medicine, but it is not well equipped for teaching students about the practicalities of medicine or for helping trainees adapt to circumstances that are radically different than those faced by physicians 100 years ago. This essay discusses one feature of modern medical practice that deserves more attention in medical educational curricula: the legal framework that situates and influences medical practice for all physicians and physicians-in-training.

The Current Place of the Law in Medical Education

Medical practice today is subject to a multitude of legal rules, both state and federal. Yet, medical students may have next to no knowledge about the existence of these rules, much less their scope or application. Indeed, when medical students hear the word “lawyer,” their train of thought might start and stop with medical malpractice. Rarely, in our experience, are issues such as compliance or insurance fraud and abuse presented to medical students. Nor are students exposed to legal problems that might be the underlying causes of the maladies that their patients suffer, such as when “a child’s chronic asthma is exacerbated by mold or other toxins in his apartment” [3].

Law students and medical students rarely interact, even within universities that have both law and medical schools [4]. Even when medical schools, such as Johns Hopkins University or Stony Brook University, offer [courses introducing students to selected legal concepts](#), these courses can be regarded by some students as superfluous. This is not to blame medical students or their educational institutions. Understandably, when securing a career in a chosen medical specialty does not depend on a student’s knowledge of the intersections between medicine and law, that knowledge will be given short(er) shrift by students. At the same time, judging by reactions we have observed while teaching legal issues to medical students, these students are very interested in learning more about the legal system and the effect it has on their personal and professional lives. Students

may fear the consequences of “being sued”—especially the risk of losing their hard-earned medical licenses—and yet have little opportunity in the traditional medical school curriculum to learn about the process of litigation and the pitfalls for the unwary that may be inherent in the process itself. Our efforts aim, among other things, to help students better orient themselves to the intersections between law and medical practice and about the differences and similarities between medical and legal approaches to [medical mistakes and negative medical outcomes](#).

Two Schools’ Efforts to Promote Medical and Legal Students’ Collaborative Learning

With these problems in mind, the University of Baltimore School of Law and the Johns Hopkins School of Medicine experimented with different ways to integrate legal content into medical education curricula. What we realized in teaching this content is that, in order to have any sort of lasting impact on students, the legal components of the curriculum must be no different than the medical components—that is, they must involve “hands-on” or “clinical” learning. We began by teaching medical malpractice because, again, this is the most familiar issue to medical students.

However, in addition to a lecture on the legal standards in medical malpractice litigation (which Johns Hopkins students continue to receive), we tried to put together a course that would simulate an actual malpractice case from beginning to end. To that end, we created a semester-long optional course offered to both medical and law students that combined classroom instruction with “hands-on” training. The goal of this course for medical students was to help them [integrate legal concepts into their applications](#) of medical knowledge and practice of clinical judgment. Similarly, the goal of the course for law students was to help students learn and appreciate how medical knowledge could inform their legal judgment and strategies as attorneys. Of course, litigation is just one of many legal concepts that medical students might benefit from learning more about. In addition, legal matters including contracts, risk management, scope of practice, and the like would make fertile ground for further medico-legal collaborations. But, as with any new project, this one started with a single proof-of-concept trial: the medical malpractice course.

At the University of Baltimore, the medical malpractice litigation course is taught by three people: a practicing attorney and adjunct professor, a full-time law professor, and a full-time physician. The course centers on a real-life case that one of the instructors litigated in the Maryland state courts. Early in the course, the medical file containing the real (albeit anonymized) patient’s chart, test results, physician notes, prescriptions, and other health records is distributed to all of the course participants—both medical and law students. As the course progresses, we encourage the law students to meet and communicate with their medical counterparts to figure out what to make of the patient’s file. The medical students, in turn, learn what will be expected of them in their assigned roles—serving as either expert witnesses or the defendant.

Curricular Focus on Litigation as One Important Legal Process in Medicine

Throughout the semester, medical and law students learn not only the governing law for medical malpractice litigation, but also the *process* of litigating a medical malpractice case. What we have consistently heard from medical students, residents, and even attending physicians is that they are bewildered by the very process of litigation and do not understand why a case takes certain twists and turns. By teaching the medical student participants in the course the typical main events in a litigation process, we hope to demystify the process and make the students more familiar, and thus, more comfortable with it. Accordingly, we have guest lecturers throughout the semester who discuss settlement negotiations, case evaluations from the perspective of both a plaintiff's attorney and a defense attorney, and testimony preparation. In order to maintain relevance to medicine, we also have lectures on how hospitals deal with medical mistakes, focusing on processes such as morbidity and mortality conferences, root cause analyses, and protocol creation. We intend that law students, in turn, will gain an appreciation for and understanding of how medical processes react to unexpected (or negative) outcomes within the hospital setting, how to gain knowledge from medical actors, and how to make use of that knowledge during settlement negotiations, trial preparation, and during trial itself.

Towards the end of the semester, the medical and law students participate in a mock deposition based on the medical file, applying skills they were taught in lecture. Among other things, students should have learned the mechanics of civil litigation depositions, as well as how to make use of a medical file to the advantage of a client (and the truth). Like a real deposition, the mock one is time limited (albeit significantly more so than is permitted under the relevant procedural rules) and recorded on video. Law students are expected to have gained an understanding of the medical facts of the case through reading the file and talking to their medical counterparts. Medical students are expected not only to know the medical facts of the case, but also to think about how their videotaped testimony would play to a jury.

Once the students have completed their depositions, the instructors role-play a sample deposition for all the students to see. Both the medical and law students get to experience in real time how a deposition can be used to aggressively pursue the interest of the client while maintaining a professional and courteous decorum. The video recordings of these depositions are available for further student reflection in preparation for later portions of the course.

The course culminates in a daylong mock trial presided over by a Maryland state judge. A jury of volunteers, composed mostly of undergraduate (i.e., college) and graduate (but neither medical nor law) students from the University of Baltimore is assembled or, in the legal vernacular, "empaneled." The law students put their expert witnesses on the

stand and conduct direct and cross-examination. The medical students play the roles of the expert witnesses and explain both the medical facts of the case and their opinions about the care the patient received to the lay jury. Based on these efforts, the jury ultimately renders a verdict. Unlike a real trial, the mock jury is then asked to explain its verdict to all of the participants and discuss how it was reached. This explanation helps elucidate for students what portions of their questioning (for the law students) and responses (for the medical students) had the greatest impact, and why. Such information can be invaluable for learning more about successful litigation practice and about what factors can help make medical professionals better or worse experts to a lay audience.

Course Outcomes, Challenges, and Next Steps

We have offered this course now for two years, and both times, judging by student evaluations and comments received from both the medical and law students, it has been a resounding success. Indeed, it has been so successful that we are developing another course to further facilitate the interaction between medical and law students.

We hope to create a course enabling law students to visit the local health clinics where the third- and fourth-year medical students do their rotations. The law students would shadow social workers while the medical students shadow their physician preceptors. Together, the students would seek to identify patients for whom legal difficulties are the underlying cause of medical problems (for instance, a landlord's failure to remedy mold, resulting in respiratory disease). The students would then learn what their possible roles could be in addressing those problems. For instance, a practicing attorney might represent a patient by preparing a letter to a landlord that seeks to remedy a mold situation in the home and identifying for the patient further legal actions that might be taken. A physician could facilitate this role both by connecting the patient and the attorney and by providing a medical opinion as to the etiology of the patient's respiratory disease.

Although successful, our attempts to integrate more legal education into the medical education curriculum have not been without challenges. Perhaps the most significant barrier to these joint courses is that medical students and law students work on radically different schedules. Whereas most law school classes conform to a traditional semester schedule, medical curricula operate on a schedule of much shorter modules. As a result, although interest in our medical malpractice litigation course has always been high (given that every year the class is at capacity), the actual number of medical students able to participate has been quite low. Instead, we have had to supplement our medical participants with residents and fellows. For the same reason, one of the problems we are encountering in creating the clinic-based course is that a rotation to which it could theoretically be attached lasts only four weeks—a period much shorter than a full law school semester.

What we've learned from our—admittedly anecdotal, yet consistent—experience is that medical students seem to want more exposure to legal aspects of medicine. Since legal issues will affect how this generation of students will practice their art [5], legal education opportunities in medical curricula should be expanded.

The current model of medical education has little, if any, room for opportunities to learn about the legal system. Students have neither the time nor the incentive (absent academic credit or personal and professional interest) to devote their energy to exploring these issues and collaborating with their nearby legal peers. But if medical and law schools were to work to create more options for crosslisted courses and to think outside the box about how to schedule and structure offerings that would allow students to do more than just sit through another lecture, students (both medical and law) would likely jump at the opportunity. What is more, the lessons learned from such experiences would likely remain with students for much longer than even the most riveting single lecture on “law and medicine.”

Medicine and law are indeed “conservative” fields, changing slowly and sometimes only with great difficulty. The scope of medical education is but one example. But today's medical students need and seem to want innovative approaches to teaching content beyond lectures on the basic sciences of medicine. With some creative thinking and role playing, medical students' legal knowledge can be developed and, more importantly, retained and later applied. Such an outcome would greatly benefit our health care system as a whole.

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5. For instance, modern modifications in the law of negligence and informed consent may bring physicians into closer and more frequent contact with long-standing doctrines in this area. See, e.g., *McQuitty v Spangler*, 976 A2d 1020 (Md Ct App 2009), which holds that informed consent doctrine extends to medical decisions, not just medical procedures.

Greg Dolin, MD, JD, is co-director of the University of Baltimore's Center for Medicine and Law, where he is also an associate professor of law. His scholarship centers on patent law and, in particular, on how the patent regime affects innovation in bio-pharmaceutical areas, and has led to a number of scholarly articles, presentations, amicus briefs, and Congressional testimony.

Natalie Ram, JD, is an assistant professor of law at the University of Baltimore School of Law and the associate director of the law school's Center for Medicine and Law. Professor Ram received her JD degree from the Yale Law School and her AB degree from Princeton University, and she previously clerked for Supreme Court Justice Stephen G. Breyer and for Judge Guido Calabresi of the US Court of Appeals for the Second Circuit. She writes about matters at the intersection of bioethics and the law and has been published in *Harvard Law Review*, *Columbia Law Review*, *Stanford Law Review*, and other law journals.

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STATE OF THE ART AND SCIENCE

Enabling Individualized Criminal Sentencing While Reducing Subjectivity: A Tablet-Based Assessment of Recidivism Risk

Pablo A. Ormachea, JD, Sasha Davenport, Gabe Haarsma, PhD, Anna Jarman, Howard Henderson, PhD, and David M. Eagleman, PhD

According to conservative estimates, the country spends a minimum of \$25,500-\$26,000 per year on each person incarcerated [1]. Incarceration also has long-term costs for both offenders and society. For example, a young person with a prison record may be precluded from becoming a citizen who votes, participates in community-building, and contributes to the community.

Someone's re-offending (i.e., in the case of recidivism, defined broadly as re-offending with any jailable offense) means social resources were squandered without rehabilitating the offender (i.e., without resulting in future behavior for which one could be arrested). Unfortunately, the United States has high rates of recidivism: two separate Bureau of Justice Statistics studies have found that more than 62 percent of offenders released from prison are rearrested within three years [2, 3]. Society thus achieves minimal rewards in return for its costly expenses, because nearly two-thirds of convicts re-offend and return to the criminal justice system.

Moreover, incarceration is potentially criminogenic: as a result of foregone employment opportunities and broken social circles, a person sent to prison might be more likely to return to crime after release [4, 5]. Specifically, research suggests that offenders who receive a suspended sentence instead of incarceration are less likely to re-offend [5]. Therefore, to make the most effective use of incarceration and limited social resources, researchers should strive to develop recidivism risk assessment and measurement tools.

Some progress has been made toward this goal with data-driven interview-based questionnaires, but we believe more can be done by harnessing advances from neuroscience and cognitive psychology. We briefly review the history of existing tools and describe our efforts to create a promising assessment battery through Baylor College of Medicine's Initiative on Neuroscience and the Law to measure cognitive and empathetic traits associated with recidivism. In addition to its practical contributions, this project touches on a fundamental ethical question: should individual profiles affect the treatment modalities used for offenders convicted of the same crime? This is a thorny problem, but, ultimately, we believe that, in a criminal justice system that already makes

person-by-person judgments, our tablet- and game-based approach will make the process more objective and results-oriented.

Quantifying Re-Offense Risk: Today

The risk principle, a widespread tenet in corrections, states that the intensity of supervision or treatment should be modulated based on [predictions](#) of an offender's [future risk](#) of recidivism. For decades, the United States criminal justice system lacked a formal, data-driven risk assessment system, initially relying on professional judgment. Starting in the early 1980s, in hopes of improving the objectivity of assessments, researchers around the country developed interview-based instruments to better understand the relationship between likelihood of future criminal offending and offenders' characteristics, traits, and behaviors (e.g., age at arrest, prior criminal history, and strength of social circles) [6].

This research formed the basis of structured risk-assessment surveys that were soon deployed in states across the country. These instruments' predictors of recidivism included static (e.g., criminal history), dynamic (e.g., treatment needs and responses), and community-level (e.g., family support and access to services) risk factors [7-14]. The more risk factors an offender has (typically, these can be represented in a "risk score"), the greater the likelihood of future criminal behavior [7]. Subsequent empirical analysis of these assessments has shown that those who score higher on the accumulation of predictors are indeed at an increased likelihood of engaging in future criminal behavior [7-14].

Interview-based risk assessments have improved county officials' (typically forensic psychologists') ability to identify re-offense risk, with risk factors for ORAS (a popular risk assessment system developed in Ohio) showing a correlation with recidivism ranging between 0.30 and 0.44 for women and 0.30 and 0.37 for men [15]. Higher risk scores are typically used to justify higher bonds, eligibility for parole, deferred or suspended sentences, or longer periods of incarceration. Despite the improvements risk-based assessments have brought about, they still suffer from two serious limitations. First, data collection requires a lengthy one-on-one interview, which means use of the instruments is restricted by the availability of expensive and highly trained forensic psychologists. Second, the instruments do not provide an objective measure of individual traits, such as impulsivity and risk taking, with the result that forensic psychologists must rely on *subjective* analysis of interviewee responses to a range of related questions to assess the risk of recidivism.

Quantifying Re-Offense Risk: Tomorrow

We are optimistic that our tablet-based approach will address those limitations of interview-based assessments. At Baylor College of Medicine's Initiative on Neuroscience and Law, we have developed a tablet-based and engaging battery of interactive

assessments to measure a range of cognitive traits of criminal offenders, including aggression, empathy, planning, executive function, impulse-control, and set shifting. First, our reliance on well-established psychometric assessments provides a direct, objective measure of individuals' decision-making traits associated with re-offense. Second, the use of self-scoring software allows data collection on a large scale—to date, we have assessed nearly 600 offender participants. Specifically, we are using the battery to quantify and compare traits in Houston-area probationers (550 participants) and age- and race-matched controls (150 participants). Ultimately, our hope is that an improved understanding of underlying traits that predispose to criminal behavior will enable not only alternative and more individualized sentencing strategies, but also optimal calibration of punishment severity for each offender in terms of sentence length and eligibility for certain programs.

Several traits are associated with increased criminal behavior, such as empathy deficits [16], reduced impulse control [17], and a propensity to react aggressively to perceived threats [18]. Previous studies have suggested that these traits can be a result of underdeveloped structures or underactive functionality in the brain, particularly in the dorsomedial prefrontal cortex, anterior insular cortex, caudate, and orbitofrontal cortex [19–22]. Although neuroimaging would provide a direct visualization of underdevelopment or hypofunction, the technology is currently too expensive to deploy on a mass scale within the criminal justice system.

Instead, we turned to popular, validated psychometric assessments that provide a score that measures the participant's performance. We then converted them into colorful, engaging iPad games. Our battery includes the Stop-Signal Task (self-control) [17], the Eriksen Flanker Task (attentiveness) [23], the Reading the Mind through the Eyes Task (cognitive empathy) [16], the Point-Subtraction Aggression Paradigm (reactive aggression) [18], the Tower of London Task (planning) [24], and the Balloon Analogue Risk Task (risk-taking) [25–27]. The battery is intended to improve risk assessment by providing a better understanding of the relationship between re-offense and cognitive decision-making traits. If successful in terms of improving risk predictions, this assessment tool could save money and human potential by supporting alternative rehabilitation strategies and allowing for optimization of sentence length (as well as other provided services) based on an offender's likelihood of recidivism.

Ethical Implications in Practice

Even if it is too soon to know whether our project will bear fruit, it is not too soon to grapple with the underlying ethical questions. Specifically, should people be treated differently by the criminal justice system because of their decision-making profiles?

We first note that there remains a disagreement about the purpose of punishment within the criminal justice system. The minority opinion is held by those who ascribe to

“an eye for an eye” and therefore argue that sentences should be retributive, even if they also increase criminogenesis [28]. They argue that the purpose of the criminal justice system is “to administer justice, not treatment” and that individualized treatment “muddles the message of punishment” [29]. The majority opinion appears to be relatively equally split between those who emphasize sentencing as a deterrent to other would-be criminals and those emphasizing individual rehabilitation [30].

We believe that individual rehabilitation and societal deterrence go hand-in-hand, because crime is committed in large part by *re-offenders* [3]. Reducing *each* offender’s risk of re-offense through individualized sentences for the same crime should reduce aggregate crime, thus benefiting society. If the purpose of the criminal justice system is to reduce aggregate crime, then we should therefore work to create a system that privileges individual rehabilitation over retributive justice.

Returning to the question of tailoring individual sentencing, we believe it is improper to evaluate reforms and new ideas in a vacuum and that a true analysis requires a comparison against the status quo. So should individualized sentences be based on offenders’ decision-making profiles? It is critical to understand that our criminal justice system already modulates sentencing and has since at least 1987, when a federal agency, the United States Sentencing Commission, developed the *Guidelines Manual*. This manual uses a series of tables to provide the judge with an appropriate sentencing range based on the present offense and the defendant’s criminal history [31]. Use of the manual was considered mandatory until a 2005 Supreme Court decision changed it into an advisory guide [32].

Whether mandatory or advisory, the *Sentencing Guidelines Manual* places authority in the hands of individual judges. For example, for first-time offenders who are convicted of assault (one of the most common crimes) there is a wide sentencing range of 0-14 months [31]. The judge selects an appropriate sentence within the range after weighing a large variety of subjective factors, including the “nature and circumstances of the offense” along with “the history and characteristics of the defendant” [33].

In the abstract, it might seem beneficial to vest this authority in the hands of judges, who presumably would deliver individual sentences reflecting their relevant experience as society’s gatekeeper for the prison system. In practice, however, judges deliver disparate and potentially discriminatory sentences for the same offenses [18, 34]. Moreover, the decisions appear to be heavily affected by nonlegal factors. For example, gender [35] and race [36] are correlated with disparate outcomes. The individual judge’s punishment philosophy also affects sentencing, with judges in a large urban county (who typically focus on rehabilitation) arriving at the least severe sentences and judges in a suburban county (who tend to focus instead on deterrence and retribution) providing the most severe sentences [37]. As an example, one study quantified the differences and found

that the incarceration rate for offenders arrested for burglary diverged greatly in nine counties in three states. The incarceration rate ranged from 26 percent in DuPage County, Illinois, to 52 percent in Erie County, Pennsylvania, to 75 percent in Kalamazoo County, Michigan—all for the same crime [34].

Drug possession arrests, arguably the most common jailable offense in our criminal justice system, provide another stark example of the disparity driven by the subjective factors in the US *Sentencing Guidelines Manual*. A study of 12 judges in Cook County, IL (Chicago) explored convictions of offenders with prior felony convictions. The rate of incarceration ranged from 37.5 percent to 90 percent. The average sentence also ranged from 14.5 months to 42 months [18].

Perhaps the most striking example of the impact of nonlegal factors on judicial decision making is a 2011 study of offenders' chances of receiving parole. The single most important factor was not the offender's prior criminal history or behavior during detention but whether the decision was made before or after the decision maker's lunchtime, with the percentage of "favorable rulings" dropping from approximately 65 percent to nearly 0 percent before a lunch break and then afterwards returning abruptly to approximately 65 percent [38]. The status quo, therefore, *already* modulates sentencing by vesting discretion in the judge. Moreover, the current system appears to be doing so poorly, given the tremendous amount of variation in punishment severity for the same offense. To be clear, offenders are assigned to judges at random, which means chance—and not a measured, objective analysis of defendant characteristics—is currently playing an outsized role in determining offender punishment.

An emphasis on psychometric assessments holds the promise of returning objectivity to this flawed process. Given that the criminal justice system already allows for a range of sentencing for the same crime, we believe it is both proper and more efficient to limit the role of chance by developing evidence-based, data-driven sentencing.

Some have expressed concerns that our tablet software will lead to "pre-crime" investigations or the detainment of innocent people only on the basis of their score instead of their behavior. We consider this scenario highly unlikely, because the Bill of Rights protects against such scenarios. The Fourth Amendment states that persons cannot lose their rights "to be secure in their persons, houses, papers, and effects" without probable cause, which in essence requires real evidence that a crime has already been committed (not that one may be committed in the future). The Fifth and Sixth Amendments, in turn, set forth specific procedural requirements, including the right to "a speedy and public trial," before being deprived of "life, liberty, or property" [39]. Overcoming these protections would require a groundswell in popular opinion leading to a new amendment to the Constitution.

We intend to release the tablet software for academic and educational use. For physicians, the software will enable a novel way to track patient recovery via previously unavailable continuous and objective measures. Specifically, it will provide physicians with the ability to administer established and validated neurocognitive tests—typically only available to clinical neuropsychologists—to quantify patients' response to treatments, therapies, and new medications.

Ultimately, we seek to foster scientifically based social policy, with the goal of diminishing rates of incarceration and providing novel, evidence-based options for assessing and managing criminal offenders. In practice, we hope our ongoing research project will allow policymakers to base sentencing decisions on direct, proven, open-source assessments of criminal propensity.

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Pablo A. Ormachea, JD, is a postdoctoral fellow at Baylor College of Medicine in Houston, Texas. He also serves as co-director of the Center for Science and Law, where he manages several data-driven projects sharing the goal of constructing a cost-effective legal system with higher utility and lower cost. He holds a JD from Harvard Law School.

Sasha Davenport is a senior research fellow at the Initiative for Neuroscience and Law at Baylor College of Medicine in Houston, Texas, where she researches neurocognitive risk assessment testing methods and predictive criminal recidivism models. A Ronald E. McNair Scholar with a BA in forensic psychology from the John Jay College of Criminal Justice, her work on neuropsychology and warfare has been presented at the U.S. Military Academy at West Point.

Gabe Haarsma, PhD, is a postdoctoral programmer at the Center for Science and Law in Houston, Texas, where spearheads big data analysis of millions of crime records to analyze and visualize patterns of crime and recidivism.

Anna Jarman is a research fellow at the Center for Science and Law and an analyst with Shell Technology Ventures in Houston, Texas. She studied psychology and cognitive science at Rice University and has worked in public policy and research for over five years.

Howard Henderson, PhD, is an associate professor in the Department of the Administration of Justice at Texas Southern University in Houston, Texas, where he also serves as the director of the graduate program. His research examines the psychometric properties of offender behavioral risk needs assessment.

David M. Eagleman, PhD, is a neuroscientist at the Baylor College of Medicine and the founder and director of the Center for Science and Law in Houston, Texas. He is also the creator and host of PBS's *The Brain* and the author of *Incognito: The Secret Lives of the Brain* (Pantheon, 2011). His areas of research include plasticity, time perception, vision, synesthesia, and the intersection of neuroscience with the legal system.

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HEALTH LAW

Needle Exchange Programs' Status in US Politics

Richard Weinmeyer, JD, MA, MPhil

In March of 2015, Governor Mike Pence of Indiana declared a public health emergency. This call was issued amidst the realization that, following months of rising case numbers, there was an outbreak of HIV in the southeastern part of the state [1]. The outbreak in this predominately rural community would culminate at a final count of 185 cases [2], largely the result of needle sharing by intravenous drug users abusing the prescription painkiller Opana [3]. What made this a noteworthy public health crisis was how the state government ultimately responded. In the hope of stopping the spread of HIV across this part of the state, Governor Pence called for the opening and funding of temporary [needle exchange programs \(NEPs\)](#) where injection drug users could dispose of used syringes and obtain sterile ones, despite his prior opposition to such programs [1].

For decades, NEPs have been a [controversial](#) public health strategy in the United States. Although the scientific literature on these programs has presented strong evidence of their efficacy in curtailing transmission of diseases such as HIV and hepatitis C among injection drug users [4-8], 33 states in this country have banned the practice (including Indiana) as of June 2014 [9], and federal law has long prohibited the US government from funding NEPs. In the wake of the Indiana HIV outbreak, states such as Kentucky, which once banned NEPs, have allowed NEPs to open following changes in state law [10]. The biggest change, however, has come from the federal government, which, as of 2016, has changed its legal position on NEPs, allocating federal funds to support these endeavors. This article discusses the political and legal history of the federal prohibition on funding NEPs and how these polarizing medical and public health strategies have finally gained greater acceptance.

Since their first appearance in Amsterdam in 1983 [11], NEPs have been a lightning rod of controversy when proposed as a means to limit disease transmission [12]. In the United States, opponents of NEPs have largely focused on three main arguments for blocking their use [13]. First, they argue, the federal funding of NEPs would contradict law enforcement efforts in the US's "war on drugs" by signaling tacit governmental approval of illegal drug use [14]. Second, they claim, federal funding of NEPs and availability of sterile syringes could cause a rise in drug abuse and diminish public health [14]. Third, they assert, federal approval of NEPs and removal of an obstacle to unsafe drug use could have a corrupting influence on children [15].

NEP proponents point to the myriad public health benefits these resources provide. There is a wealth of scientific evidence demonstrating that NEPs reduce blood-borne infectious diseases transmission among injection drug users [4-8], as has been acknowledged by, for example, many national governments [16], the World Health Organization [17], and the American Medical Association [18]. Supporters argue that NEPs provide resources on drug treatment, which can motivate users to pursue recovery, thereby potentially reducing illegal drug use rates and criminal behavior [13]. Finally, supporters aver that NEPs can protect nonusers, such as law enforcement officers and health care professionals, who could be pricked by a contaminated needle when interacting with or treating injection drug users outside the controlled, hygienic environments that NEPs provide [19].

Origins of the Federal Ban on NEPs

Opposition to NEPs in the United States has been purely ideological in nature [12], stemming from the political position that NEPs “undercut the credibility of society’s message that drug use is illegal and morally wrong” [20]. The federal ban on NEPs began in 1988, after North Carolina Senator Jesse Helms equated NEPS with a federal endorsement of drug abuse [17] and led Congress to enact a prohibition on the use of federal funds for such programs [21]. This ban became law through the Public Health and Welfare Act, section 300ee-5, which stated that “none of the funds provided under this Act or an amendment made by this Act shall be used to provide individuals with hypodermic needles or syringes so that such individuals may use illegal drugs” [22]. It was not an absolute ban, though [21], given that Congress included a provision in the ban stating that the funding prohibition could be lifted when “the Surgeon General of the Public Health Service determines that a demonstration needle exchange program would be effective in reducing drug abuse and the risk that the public will become infected with [HIV]” [22]. Despite evidence from the medical and public health communities that NEPs reduced infectious disease transmission, subsequent legislation in the years following this act focused exclusively on treatment, renewing the ban and including it in the much-lauded HIV/AIDS federal program, the Ryan White Comprehensive AIDS Resources Emergency Act [23].

Opportunity for Change During the Clinton Years

During the 1990s, a panel of the Institute of Medicine recommended that the US government lift the federal ban on NEPs, based on evidence that such programs reduced HIV rates without increasing drug usage [24]. Furthermore, the Centers for Disease Control and Prevention conducted its own review of NEPs and found equally beneficial results [25], adding even greater legitimacy to the call for lifting the ban.

In 1997, the opportunity for Congress to lift the NEP ban appeared to be at hand. That year Congress passed Public Law 105-78, which included amended language that would allow for the ban’s removal if “the Secretary of Health and Human Services determines

that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs" [26]. By April of 1998, Donna Shalala, then secretary of the Department of Health and Human Services, prepared to hold a press conference to announce that the Clinton administration had decided to lift the NEP ban [27]. Republican opposition intervened, however. On April 22, 1998, Republican Representative Denny Hastert of Illinois denounced this anticipated move on the floor of the House of Representatives, saying "I think we have a bad message, certainly a bad message to drug addicts to all of a sudden say it cannot be too bad. The Federal Government is giving me the paraphernalia to put these drugs in my veins" [28]. He echoed concerns that lifting the ban would send a mixed message to kids about drug use: "You cannot use drugs. That is bad. That is illegal. But if you want the free needles to use them, here they are" [28]. Amid discussions about political risks involved in lifting the ban, President Clinton ultimately decided to forgo pushing for changes to the federal law, and, instead of holding a press conference to announce an end to the NEP restrictions, Secretary Shalala stated that the ban would remain in effect [28].

A Reversal

During the George W. Bush Administration, the ban remained in place [29]. Although Barack Obama campaigned for the presidency promising to remove the funding restrictions on NEPs [30], his administration's first budget request to Congress included the following language: "no funds appropriated in this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug" [31]. Congressional Democrats opposed this language and worked with Congress and the president to remove it [27]. As a result, the NEP funding ban was lifted, and, by 2010, the Department of Health and Human Services issued guidelines for needle exchange programs wishing to receive federal funds [13].

The flow of federal funding for NEPs would be short-lived. After Republicans took control of the House of Representatives in 2011, they proposed reinstating the ban during budget negotiations with the president and Democratic leadership [32]. Although Democrats were able to remove a number of Republican-endorsed budget restrictions and policies, the Obama administration ultimately conceded to reestablish a funding ban on NEPs in order to avoid delaying or derailing the final 2012 budget for the entire federal government [32].

Effectively Removing the Ban

Following the outbreak of HIV in Indiana, along with rapidly rising rates of injection drug use across the country, Representative Hal Rogers and Senator Mitch McConnell of Kentucky and Senator Shelley Moore Capito of West Virginia spearheaded the inclusion of language into an omnibus spending measure to remove the ban [27]. Passed by Congress at the end of December 2015 [33], the modified law is technically only a partial repeal. The use of federal money to pay for sterile syringes is still prohibited, but funds

can now be used to pay for other aspects of NEPs, including personnel, vehicles, gas, rent, and other expenditures needed to keep NEPs operational [34]. Syringes, in comparison to the items just mentioned, are inexpensive, so the restriction on paying for syringes that remains in place via the omnibus spending bill is far less financially burdensome than the prior ban [34], finally allowing the medical and public health systems to have a greater source of funding for working with injection drug users and promoting broader American public health and disease prevention.

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Richard Weinmeyer, JD, MA, MPhil, is a senior research associate for the American Medical Association Council on Ethical and Judicial Affairs in Chicago. Mr. Weinmeyer received his master's degree in bioethics and his law degree with a concentration in health law and bioethics from the University of Minnesota, where he served as editor in chief for volume 31 of *Law and Inequality: A Journal of Theory and Practice*. He obtained his first master's degree in sociology from Cambridge University. Previously, Mr. Weinmeyer served as a project coordinator at the University of Minnesota Division of Epidemiology and Community Health. His research interests are in public health law, bioethics, and biomedical research regulation.

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POLICY FORUM

Graduate Medical Education Specialty Mix and Geographic Residency Program Maldistribution: Is There a Role for the ACGME?

Thomas J. Nasca, MD, and Douglas Carlson, JD

Over the past 25 years, considerable discussion and debate among legislators and the general public have centered on issues raised by the specialty mix and geographic distribution of graduate medical education (GME) programs and positions in the United States. Most recently, the Institute of Medicine examined strategic oversight, funding, governance, specialty mix, and geographic distribution of GME [1] and noted the following:

many studies have shown that the current GME program does not produce adequate numbers of physicians prepared to work in needed specialties or geographic areas. Nor does it train physicians to practice in the community-based settings where most Americans seek care [2].

Since a significant percentage of graduates of GME programs enter clinical practice in geographic proximity to their final GME program's location [3], the specialty mix and geographic distribution of GME programs are essential considerations in the [geographic distribution](#) of practicing physicians.

Frequently promulgated solutions to perceived or actual deficiencies—in numbers of generalists, residency positions, or internists (as compared to family physicians)—include participation by the Accreditation Council for Graduate Medical Education (ACGME) in shaping the specialty mix or geographic distribution of the physician workforce [1]. This might appear to be a logical approach, especially insofar as, internationally, the same government entities, such as ministries of health or education, are charged with both overseeing GME programs in their countries and implementing national workforce plans.

In the United States, however, private entities commonly perform some functions accomplished by government entities in other countries [4]. The [ACGME](#) is one such entity, recognized and relied upon [5] by resident physicians, prospective resident physicians, and patients, as well as a wide array of societal and professional entities, as the primary source of accreditation oversight of GME. Also reliant on the ACGME are the federal government, including the Department of Defense, the Department of Health and Human Services—for the purpose of disbursing billions of dollars of GME

reimbursement—and the Veterans Administration; state governments, through statutes and regulation; specialty physician certification boards; hospital credentialing entities; and other major membership organizations. Completion of years of GME training in an ACGME-accredited program is statutorily required of both domestic and international medical school graduates to obtain a state-issued license to practice medicine in the United States.

Thus, a reasonable assertion might be that the ACGME, as the entity entrusted with the establishment of GME accreditation standards and the evaluation of the effectiveness of GME programs in the United States, might also be the most qualified entity to be charged with implementing national physician workforce policy. Put another way, were there a national system of physician workforce needs determination and management, would not the ACGME be the entity most likely capable of (a) identifying GME quality parameters and (b) reconciling individual program and institutional aspirations with future regional and national physician workforce requirements?

Why, then, has the ACGME not assumed this responsibility? We suggest that there are three major factors that preclude the ACGME from assuming a role in implementing national physician workforce policy. The first two are unrelated to the ACGME, and the third is related to the ACGME.

First, while organizational and national reports—such as the Institute of Medicine (IOM) Report of 2014 [1] and the congressionally commissioned Government Accountability Office (GAO) report of 2015 [6], among others—address the need for both a national strategic vision for health care delivery and an organized plan for development and maintenance of the health professional workforce to support that delivery, there is currently no agreed-upon comprehensive national long-term plan for health care delivery [6]. Second, as there is currently no agreement on the structure of health care delivery, there is no basis for agreement on a national blueprint for health care workforce goals, including the number and specialty mix of physicians, and no linkage currently exists to tie the goals of such a plan to a financing plan for GME and other professional training [1, 6].

Third, if or when a national strategic vision for these elements emerges, the ACGME is not a governmental body with the authority of its functional counterparts in other countries; it is a private, not-for-profit body. Issues regarding the antitrust implications of a private, not-for-profit accreditation entity implementing national workforce policy remain, and this is this third element that we discuss here.

The ACGME was founded in 1981 to address many of the challenges faced by its predecessor organization, the Liaison Committee on Graduate Medical Education (LCGME), by consolidating accreditation of GME in the United States [7] and motivating

administrative efficiency and greater uniformity of accreditation processes among specialties. Structural aspects of the consolidation of the previously independent and occasionally duplicative residency review committees necessitated significant compromise. At its meeting on November 17-18, 1980, the LCGME voted to adopt a statement of policy, which the ACGME reaffirmed at its meeting of February 13-14, 1984, that in the accrediting process,

the ACGME is not intent upon establishing numbers of practicing physicians in the various specialties in the country, but rather...the purpose of accrediting by the ACGME is to accredit those programs which meet the minimum standards as outlined in the institutional and program requirements. The purpose of accreditation is to provide for training programs of good educational quality in each medical specialty [8].

This policy evinces an explicit intention to comply with US antitrust law. It remains the policy of the ACGME today.

The proposition that the ACGME would or should participate in implementing a national physician workforce policy would clearly require an expansion of its purpose. ACGME has asserted, in its written response to an inquiry from the IOM committee that issued a 2014 report on the financing and governance of GME [1], that it would be willing to participate and partner with others in deliberating upon and implementing a national physician workforce system (T.J. Nasca, written communication, 2012). However, two issues must be addressed before the ACGME could assume such a role, both of which were raised in its response to the IOM inquiry.

The first relates to the need for professional support for this new role for the ACGME. The ACGME is an independent, not-for-profit entity incorporated in Illinois that is exempt from federal income taxation under section 501(c)(3) of the Internal Revenue Code [9]. It has seven national member organizations [10], which have the right to nominate individuals for membership on the 34-person board of directors. (Members of the public, at-large members from the profession, and residents constitute the remaining members of the board; two federal government representatives participate in meetings of the board without vote.) Although the member organizations have only limited powers over amendment of certain of the ACGME bylaws, their support would be required for the ACGME to amend its purpose and assume a workforce responsibility on behalf of the public. As the member organizations just mentioned are either national individual membership organizations or national organizations, their approval would indicate general acceptance by the profession, as well as by the sponsors of GME programs, of the ACGME's authority to assume a prominent role in physician workforce goal-setting

and management for the benefit of the public. While it is possible that such approval could be obtained, it might not be without disagreement.

The second, and perhaps more significant, issue relating to an ACGME role in national future physician workforce policy is that this type of activity would risk exposure of the ACGME to allegations of anticompetitive behavior, i.e., antitrust. The IOM reminded us of this risk as recently as 2014:

GME accreditation is essential to ensuring that GME programs meet professional standards and produce physicians that are ready to enter practice with required knowledge, experience, and skills. However, antitrust and fair trade prohibitions preclude accreditors from addressing broader national objectives such as the makeup of the physician workforce, the geographic distribution of GME resources, or other priority concerns [11].

For the ACGME to play a role in the implementation of national physician workforce policy, it would have to secure protection from enforcement of state and federal antitrust laws. One way to do this would be to obtain federal statutory exemption from the relevant antitrust laws, similar to prior legislation declaring resident medical matching programs (and their participants and sponsors) lawful [12-14] under antitrust law, or an express exemption for entities designated by the Centers for Medicare and Medicaid Services (CMS) to participate in workforce policy development. Alternatively, the ACGME could contract with CMS or another government agency to provide physician workforce policy development and implementation. Even then, the ACGME would still have to secure protection from enforcement of state and federal antitrust laws.

Summary

As we've stated, GME is the final common pathway toward clinical medical practice in the US. It makes sense, then, that national physician workforce policy aimed at meeting future public health demands should be directed at this phase of medical education. It would also make sense that ACGME, as the single accreditor of all residency programs in the US [15], should be engaged in physician workforce policymaking on behalf of the public. We identified three issues that must be addressed in order for the ACGME to assume this role: First, there must be a national agreed-upon and long-term plan for the design and implementation of the health care delivery system. Second, there must be a nationally coordinated strategy for identifying long-term physician workforce needs and funding mechanisms to physician and other health care professional developments. Third, in order to execute these roles, the ACGME must receive support from the profession and national and state-level statutory protection from enforcement of state and federal antitrust law.

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Thomas J. Nasca, MD, is the chief executive officer of the Accreditation Council for Graduate Medical Education (ACGME), a professor of medicine at Sidney Kimmel Medical College of Thomas Jefferson University in Philadelphia, and a senior scholar in the Department of Education at the University of Illinois College of Medicine at Chicago. A career-long educator, investigator, and educational administrator who is board certified in internal medicine and nephrology, Dr. Nasca is interested in the ethical basis of the relationship between medicine and society, especially as it applies to medical education.

Douglas Carlson, JD, practices law in Illinois, with offices in Chicago, and is the long-standing ACGME Counsel. He is interested in accreditation law, including its interaction with antitrust law.

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POLICY FORUM

Shedding Privacy Along with our Genetic Material: What Constitutes Adequate Legal Protection against Surreptitious Genetic Testing?

Nicolle K. Strand, JD, MBioethics

We leave our genetic material everywhere we go. Our DNA—the building blocks of what makes us who we are, from our physical appearance, to our intelligence, to our susceptibility to stigmatized illnesses—is left behind in the hairs that fall off of our heads on the subway, the saliva we leave on the rim of a coffee cup, and the cigarette butt or chewing gum we discard on the street. Ten years ago, leaving behind DNA was of virtually no consequence—it would have been very difficult to isolate it, analyze it, and learn anything significant from it. Back then, the only people able to analyze DNA were scientists with access to laboratories and expensive equipment. Today, that has changed: direct-to-consumer (DTC) genetic testing companies make genetic analysis as easy as mailing a sample, paying \$199, and waiting a few weeks to access the results online [1].

Surreptitious genetic testing happens when a sample containing a person's genetic information is *accessed* without the knowledge or consent of that person and when that sample is *tested* without the knowledge or consent of that person. There have been some high-profile examples of concern about and perpetration of surreptitious genetic testing. An article posted online by a CNN affiliate reported that Madonna is afraid of fans stealing her DNA and thus demands her dressing rooms be wiped clean upon her departure [2]. In 2013, CNN reported that cousins of the late Princess Diana had submitted their DNA to a British ancestry DNA testing service without the family's consent to determine the ancestral origins of the future royal children [3]. Celebrities, politicians, and other public figures are obvious targets of surreptitious genetic testing, with potential for compromise of their public positions and fame as a result of genetic revelations.

Surreptitious genetic testing could also easily be a problem for ordinary people. For example, there are Internet services offering to isolate DNA from personal items (such as sheets and clothing) in order to expose infidelity [4] and others offering to analyze the paternity of a child from swabs of the child and his or her presumed biological father [5]. Other examples of surreptitious genetic testing might include sending the genetic material of a work associate or an acquaintance to a DTC genetic testing company to glean information about the person that could be used in any number of ways. Potential employers could offer interviewees a glass of water, send DNA to be analyzed, and use

information about disease risk to make employment decisions. Political candidates could steal DNA and blackmail opponents into leaving a race. Someone wondering whether to propose marriage to a romantic partner could steal DNA to secretly determine whether the potential spouse has a genetic profile that he or she considers unfavorable or that poses risk of passing an allegedly problematic trait on to future children.

No matter the intended or actual use, surreptitious genetic testing is ethically and legally problematic. In each of the examples described above, the potential for harm—whether in the form of unjust discrimination or another consequence—is generated by the genetic material having been stolen. So, surreptitious genetic testing is ethically and legally problematic not only because of potential harmful consequences of testing, but also because both sample acquisition and the acquisition of information generated by testing the sample threaten privacy. In 2013, an article published in *Science* showed that, even in the absence of other identifiers, such as a person's name, an individual's whole genome sequence alone can result in identification, by matching of the data set to publicly available data from genetic databases and other information about the person whose sample was tested [6]. As science advances, the amount and variety of personal information that can be gleaned from a single tested sample will also likely continue to expand; our wariness about privacy violations, thus, should also grow.

In its 2012 report, *Privacy and Progress in Whole Genome Sequencing*, the Presidential Commission for the Study of Bioethical Issues recognized these kinds of potential for harm, both instrumental and otherwise, in surreptitious genetic testing and recommended that states develop consistent minimum standards of genetic [privacy protections](#) to deter and punish the practice [7]. The Presidential Commission found a great deal of variation in state laws' privacy protections and also found that it is difficult in some cases, due to ambiguous statutory language, to determine whether a given state adequately deters and punishes surreptitious genetic testing. As a result, the degree of protection from surreptitious genetic testing a given state confers on people depends on where they reside, where the sample is analyzed, how state law is interpreted, and other factors [7].

State Regulation of Surreptitious Genetic Testing

States have taken a variety of approaches to protecting against surreptitious genetic testing. As of March 2012, 12 states had developed comprehensive protections aimed at deterring and punishing surreptitious genetic testing, 13 others prohibited laboratories from testing samples without the consent of the person from whom the sample was taken, 9 others required consent for different reasons, and 16 states' laws and regulations were silent on the practice [7].

For states to adequately protect individuals from surreptitious genetic testing, laws must define the following things as comprehensively as possible: who counts as a perpetrator,

the type of testing prohibited, the set of contexts and settings covered, appropriate exceptions, and penalties. These are described and elaborated below. More stringent laws would also be ethically acceptable; what follows is the minimum level of protection that would adequately protect privacy.

Perpetrators. First, to achieve an adequate standard of protection, the law should protect against surreptitious genetic testing regardless of where, how, or by whom the sample was obtained. For example, instead of only prohibiting health care workers from conducting unauthorized analyses on samples obtained with informed consent, as some states do, the law should protect against unauthorized genetic analysis or testing regardless of how or by whom the sample was obtained [7].

As described above, surreptitious genetic testing can occur in a variety of contexts and can be perpetrated by almost anyone. We expect that health care professionals typically have ready access to genetic information about patients or to their biological samples from which that information can be derived, but we don't typically expect that anyone with access to a toothbrush or used drinking glass can also conduct surreptitious genetic testing. An adequate law would deter or punish as many members of society as possible who might engage in surreptitious testing—from clinicians and laboratory employees to vindictive ex-spouses and potential employers.

In addition, adequate protections would emphasize that informed consent should be obtained not only for an initial sample collection, but also for any subsequent uses [7]. A person might consent to donate a sample for de-identified research but might object to certain analyses or tests of that sample or disclosures of information learned from that sample. Prohibiting the collection, analysis, and retention of samples containing genetic material and the disclosure of information about that sample by any person or entity without the knowledge and informed consent of the person whose sample is accessed, tested, and learned about seems to adequately cover many potential scenarios of surreptitious genetic testing, and it underscores the importance of detailed informed consent procedures.

For example, biological samples are often collected from patients in clinical settings, creating the potential for genetic analysis and a variety of subsequent uses of the data and information obtained from those samples. In the 1950s, a woman named Henrietta Lacks was diagnosed with cervical cancer. Doctors removed cells from her tumor for clinical testing, but those cells were also passed on without her knowledge or consent to a researcher and became an immortal cell line that has been used by scientific researchers around the world ever since [8]. Recently, the cell line was genetically typed, and genetic information about Henrietta Lacks and her family was published on the Internet [9]. Informed consent has vastly improved since the 1950s, but the case remains a prominent example of the importance of detailed informed consent, especially

when biological material (and, thus, genetic material) is involved. This case also illuminates potential harms of nonconsensual use and sharing of information learned from samples, including threats to the privacy of not just the person whose sample is gathered and tested but that person's family members.

Two Washington state laws prohibiting surreptitious genetic testing provide an example of inadequate privacy protections. One statute pertains to specimens of genetic material obtained solely for the purpose of a court-ordered paternity test, prohibiting people who come into contact with such specimens (such as employees of the court or of a laboratory that analyzes data for the court) from releasing genetic samples or data from those samples without the consent of the donor [10], but not prohibiting release of information obtained from other types of analyses. Another statute prohibits health care professionals with access to results of genetic analyses from releasing or disclosing them without the donor's consent [11]. These two laws discourage release of any genetic information or of samples obtained for paternity tests by groups of people who most commonly and readily have access to genetic information. However, they do not protect against disclosure of information derived from samples obtained by unauthorized persons, much less improper collection or analysis of samples, and, therefore, do not adequately cover the most likely potential opportunities for surreptitious genetic testing.

New Hampshire state law avoids the shortcomings of the Washington state law. Its surreptitious testing law takes care to prohibit unauthorized genetic testing in the state, on any resident of the state, and on any materials obtained in the state [12]. The law is comprehensive in the scope of its definition of who counts as a violator—anyone who surreptitiously collects or analyzes another person's genetic material or discloses another person's genetic information falls under the purview of the law, opening them up to civil suits and damages of \$1,000 or more.

Testing. Second, to achieve an adequate level of protection, the law should provide a clear definition of the type of testing or analysis it addresses. The definition provided or referenced in the statute must be neither too vague (or absent) nor too narrow. Instead, it should specifically prohibit surreptitious genetic analyses that claim to pertain to paternity, asymptomatic disease propensity, symptomatic disease, and ancestry and other analyses that potentially yield information that could be learned now or in the future by someone without the knowledge and consent of the person whose sample has been tested.

Georgia state law provides an example of a vague, and therefore a poor, definition of genetic testing. The law defines genetic testing as analysis of DNA for mutations "which are associated with a disease or illness that is asymptomatic at the time of testing" [13]. A definition limited to prohibiting testing for asymptomatic disease propensity only is too

narrow and does not provide adequate privacy protection because it does not restrict surreptitious paternity testing, ancestry testing, or testing for symptomatic genetic diseases.

In New York (a state that prohibits unauthorized genetic testing but defines the term *genetic test* narrowly to encompass only health-related testing) [14], an odd case of surreptitious testing occurred. An artist picked up discarded cigarette butts and chewing gum on the street, sent them in for analysis, and used the information about face structure, hair and eye color, and other features to construct portraits of the people who had discarded the material [15]. This activity was not prohibited in the state because of the narrow definition of the restriction [14]. The artist did not technically engage in genetic testing under the law, which restricts the definition to testing that reveals health information but does not prohibit testing that reveals physical traits. What the law permitted—displaying artistic renditions of people’s faces in a gallery in New York City based on biological samples obtained from discarded items—could, for some, represent a serious privacy violation. This case demonstrates why a law that adequately protects people’s privacy would broadly define the scope of what constitutes a genetic test.

Encompassing various testing contexts. It is also important that states not limit their surreptitious testing protections to contexts in which people are likely to be harmed by unauthorized use of their genetic material or information. *All* unauthorized uses and analyses of samples and disclosures of information from those samples should be restricted. Throughout this article, examples of surreptitious testing have been cited and described in a variety of contexts, from New York City artists to medical researchers to celebrity stalkers to battling parents. Although each case and context is different and raises a different set of privacy concerns and potential consequential harms, the victims in each case deserve protection of their privacy. Wisconsin, for example, only prohibits *employers* from conducting genetic tests without consent [16]. It takes care to prohibit any use of a genetic test result by an employer, whether the employer ordered the analysis or gathered data from an intermediary [16]. This state attempted to protect its citizens from unauthorized use of samples and genetic information gained from those samples in the context of employment, in which a particular harm such as discrimination might result, but did not circumscribe genetic testing in other contexts.

Exceptions. It is important to acknowledge exceptions in order to avoid prohibitions on genetic testing for legitimate, legally sanctioned, and beneficial purposes. States might disagree about which exceptions are legitimate and should be state-sanctioned because a given state’s statutes or regulations hope to confer a privacy protection benefit that outweighs the potential privacy violation. But each state, in crafting laws prohibiting surreptitious testing, must be sure to consider which exceptions are important to their citizenry and avoid accidentally sweeping in scenarios that the legislature means to continue to allow. In crafting exception provisions, states can enumerate legitimate kinds

of genetic testing and exempt them from coverage [7]. For example, Alaska statutes exempt genetic testing for the purposes of law enforcement, storage in the state criminal offender database, court-ordered determination of paternity, legally required newborn screening, and emergency medical treatment [17]. These are all examples of genetic testing that is legal in that state without obtaining the consent of the individual from whom the sample is derived and for which there are stated reasons, i.e., those pertaining to individual and public welfare, not to require consent.

Penalty. A perfectly crafted statute with comprehensive coverage and appropriate exemptions is nonetheless toothless without associated penalties for violation. Thus, it is important that a prohibition against surreptitious testing also provides for a remedy or a penalty, either in the form of fines or prison time (criminal law) or in the potential for private suit (civil law) in order for the law to achieve adequate protection of citizens' privacy. If a state has a law prohibiting certain kinds of surreptitious genetic testing but does not stipulate a remedy or a penalty, then the existence of the statute might make it easier for an individual to sue a violator under tort law. Without any cases on the issue it is unclear whether such a statute would have any impact.

Alaska state law, for example, specifically defines violation of the surreptitious testing prohibition as a Class A misdemeanor [18]. In addition, it explicitly provides that a person may bring a civil action to recover monetary damages related to surreptitious testing [19]. Laws that provide for civil damages and criminal penalties ensure both remedy for the violated and deterrence for future violators.

There is still room for flexibility in state lawmaking, despite these necessary components of an adequately comprehensive law. For example, in Massachusetts, the prohibition on surreptitious testing places the burden on the laboratories and health care professionals, as opposed to individual persons doing the sequencing [20]. In crafting this law, Massachusetts's legislature expressed its desire to protect citizens against surreptitious testing but also to place most of the responsibility for good genetic testing practices on companies, laboratories, hospitals, and clinicians.

Conclusion

We shed our DNA everywhere, but should we also shed our right to the privacy of the information that can be gleaned from that DNA? The Presidential Commission asserted in 2012 that the answer is clearly no [7]. But technology and industry have moved quickly, and law needs to catch up. A variety of laws regulate genetic privacy and genetic discrimination at the federal level, including the Genetic Information Nondiscrimination Act [21], the Health Insurance Portability and Accountability Act [22], and the Common Rule regulating federally funded human subjects research [23]. But DTC advertising is still inadequately regulated. Loopholes that allow surreptitious genetic testing to occur must be closed to ensure that privacy is adequately protected. States considering

drafting prohibitions against surreptitious testing should ascertain that all of the elements of protection discussed in this article are included. Sealing up the current patchwork of protections will allow genome science and technology to continue to advance, with less threat of privacy breaches and other harms resulting from unauthorized collections and analyses of genetic material or unauthorized disclosures of genetic information.

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Nicolle K. Strand, JD, MBioethics, is a senior policy and research analyst at the Presidential Commission for the Study of Bioethical Issues in Washington, DC. She is a graduate of Wellesley College and the University of Pennsylvania School of Law and received her masters of bioethics degree from the University of Pennsylvania. She has conducted work, both independently and for the Bioethics Commission, on genetic privacy, incidental findings, and neuroscience ethics and policy.

Disclosure

The findings and conclusions reported here are those of the author and do not necessarily represent the official position of the Presidential Commission for the Study of Bioethical Issues or the US Department of Health and Human Services.

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POLICY FORUM

State Oversight of Hospital Consolidation: Inadequate to Protect Patients' Rights and Community Access to Care

Christine Khaikin, JD, and Lois Uttley, MPP

In 2010, Sierra Vista Regional Health Center, the sole health care provider in rural Sierra Vista, Arizona, began a trial affiliation with a large Catholic health system. As a condition of the affiliation, Sierra Vista Regional Health Center was required to adhere to the Ethical and Religious Directives for Catholic Health Care Services. This meant it would [no longer offer](#) key reproductive health services. Women in a three-county area were left without the ability to have a tubal ligation following delivery of a child, and a pregnant woman suffering a miscarriage was turned away by the hospital and sent 90 miles away to a hospital in Tucson for termination of the doomed pregnancy. Obstetrician-gynecologists voiced dismay at being unable to practice medicine according to the standards of care they had long followed. (The affiliation was halted after months of community protest [1].) The hospital affiliation had taken place without any public hearing or consideration of the views of clinicians or consumers because, in Arizona, there is no state certificate of need program.

The situation that Sierra Vista residents faced is not unusual. The hospital landscape in America has been shifting dramatically in recent years. The country is experiencing a wave of hospital [mergers and consolidations](#), with large-scale regional and national health care systems acquiring and operating dozens of hospitals nationwide. Services at many independent and community hospitals have been discontinued or moved to other facilities following those hospitals' mergers with health systems; other local hospitals are closing in the face of financial pressures. This can drastically and rapidly alter access to care.

All of these hospital industry transactions are happening with inadequate state oversight and limited patient and clinician input, which would help ensure that hospital services meet the needs of the communities they are licensed to serve. A new national study conducted by the MergerWatch Project [2] identifies gaps in state government oversight of hospital transactions across the country, discussed here. The study also suggests model policies that would improve oversight, ensure consideration of consumer and clinician views, and protect access to care.

Recent Trends: More Consolidation, Less Oversight

Increased mergers and consolidations. The rate of hospital mergers and consolidations began increasing in the late 1990s, propelled by financial concerns and hospitals' desire to capture greater market share, thereby increasing their bargaining power with insurers [1, 3]. The enactment of the Patient Protection and Affordable Care Act (ACA) has added another impetus for consolidation by encouraging, through reimbursement incentives, the creation of integrated care systems (e.g., accountable care organizations, integrated delivery networks) and care coordination [4]. There is also an incentive for smaller hospitals to partner with larger health systems in order to gain access to the medical information technology demanded in today's health care market [5, 6].

As a result of these factors, hospital mergers, acquisitions, and affiliations are increasing. In 2010, the year the ACA was enacted, there were 66 hospital mergers. In 2013, there were 98 mergers, and in 2014, there were 95. The number of hospital mergers sharply increased in 2015, with 112 announced [7]. Industry analysts predict that merger activity will likely continue to increase in 2016 [8].

Erosion of community member voice and government oversight. Even as the pace of hospital and health system consolidations increases, there has been an erosion of the level of state government oversight that would ensure that these transactions promote, rather than threaten, patient access to care. Because of this inadequate government oversight, transactions are taking place without real assessments of their potential impact on community access to care and without consideration of the perspectives of affected health consumers and clinicians. In our experience, too often transactions are completed without appropriate notice to the public or any governmental attempt to seek feedback from patients and their doctors.

State government oversight of hospital transactions, in the form of "certificate of need" (CON) programs, was designed during the 1960s and 1970s, when concerns arose about hospital expansion and the potential duplication of services that could lead to increases in health care costs [9, 10]. CON programs were implemented to ensure that health care business decisions were congruent with needs assessments and regional health planning [10]. Enacted in 1974, the federal Health Planning and Resources Development Act mandated that each state implement CON review programs.

These programs required hospitals to demonstrate need for their expansion proposals, as well as alignment with statewide health planning goals, in applications for state approval [11]. CON programs also required public notices and hearings regarding proposed hospital transactions, so that people who would be affected by the proposed changes in their hospitals could have their voices heard. The act also created state/local agencies called Health Systems Agencies (HSAs) meant to evaluate community health needs [10].

After the repeal of the Health Planning Resources and Development Act in 1987, many states terminated their certificate of need laws or greatly diminished their scope, since there was no longer a federal mandate [10]. Today, 36 states and the District of Columbia maintain CON programs [11], but, as we will discuss in the next section, many of them are woefully inadequate to deal with the current health care climate of increased mergers and consolidations, which is vastly different from the climate that existed when they were created. This lack of state oversight to ensure that state health policy goals are furthered by proposed transactions can be very dangerous to consumers, who can see their access to health care services in their own communities change quickly and without notice.

Study Results: Problems in States' Oversight of Hospital Transactions

CON programs can be a valuable means for state governments to ensure that proposed hospital consolidations will line up with the health planning goals of a state, including consumers' access to all of the health care services they might need in the future. CON review can only fulfill this intended role, however, if it is updated to apply to the current market conditions and if it provides for robust community member and clinician engagement in the oversight process.

The MergerWatch Project analyzed CON programs and other state mechanisms for overseeing hospital transactions in all 50 states to assess their usefulness in our current era of increased mergers and consolidations [2]. This study identified many gaps in the programs that need to be filled in order for them to be useful in ensuring access to care. The research has also identified model oversight policies that could be adopted more widely to strengthen state hospital oversight and allow for greater community member participation.

Many proposed transactions are not subject to government review. Each state has a different set of circumstances under which a proposed hospital transaction must undergo government review. There are 33 states that require CON review for the creation of a new hospital [11], but only 4 states require review for the proposed closure of a hospital, which can have a major impact on a community.

Further, most CON programs have not been updated to reflect that many hospital consolidations are now taking place in the form of affiliations, strategic partnerships, or joint ventures rather than full-asset mergers or acquisitions [12]. The MergerWatch study found that 19 states require CON review for a sale or purchase of a hospital, but only 8 require such review when hospitals create less formal partnership arrangements like a stock transfer. Stock transfers and other similar changes in board control are quite common in the current health care climate and can have a great impact on the community's access to care [13]. In Washington State, a wave of affiliations has occurred

in recent years. Washington's CON program, however, only required review for a transaction structured as a "sale, purchase, or lease" [14]. In 2013, the governor of Washington directed the Department of Health to require CON review for looser hospital affiliations, but that rule was overturned by the Washington Supreme Court because the change required a vote by the legislature [15].

Without government review of a hospital transaction, community members who depend on the local hospital may not even be notified of changes. For them to be protected against a potential loss or change in services, all proposed transactions must be subject to review.

Community members and clinicians are not represented or given a voice in CON review.

Community member participation in CON review is a key way to protect access to needed care when hospitals consolidate. Consumers are directly affected by reconfiguration of their local hospitals, particularly those who are vulnerable, such as the frail elderly or low-income patients with chronic diseases and limited ability to travel to other health providers.

Our study determined that only eight states and the District of Columbia require consumer representation on the board that performs the review of hospitals' CON applications. Without consumer representation, a CON review board may fail to fully consider the potential impact of a transaction on vulnerable patients and their clinicians.

Public notice of CON review is crucial to ensuring adequate community knowledge about hospital transactions and meaningful participation in the review process. Almost every state does have a website listing current CON applications under review, but these websites generally are not designed to be user-friendly for laypeople. How would members of the public find out, then, if their local hospital is planning to merge, downsize, or close? In 16 states, there is no requirement for public notice at all when an application for CON review is submitted. In 17 states, there must be a public notice published in a newspaper's legal notices section—not something read by the general public—and two other states require only notification through their state's administrative register.

To ensure that community members can be meaningfully engaged in the CON process, the public must be notified in a more robust manner. The information should be available on a website in multiple languages and written for lay audiences to understand, with the potential impact of the transaction clearly outlined. Notices should also be placed in multiple newspapers and distributed by other means, such as postings in public libraries.

Also crucial to ensuring public engagement is a public hearing on the proposed hospital transaction, in which affected members of the community can interact with the decision

makers and provide testimony on how their access to care might change. The MergerWatch study found that only 11 states and the District of Columbia require a public hearing during which community members can provide testimony to the review board. Another 20 states allow affected individuals to request a public hearing, but the review board has discretion as to whether to hold it. The lack of public hearings or the ability to participate meaningfully in hearings means that the community member voice is not being taken into account in many of these processes.

Conclusion

As hospital consolidation increases across the country, the current state of government oversight of proposed hospital transactions is woefully inadequate to meaningfully protect community access to vital health services. Strong certificate of need programs can be an important means of addressing this need, and the MergerWatch study details model policies that could promote such an outcome. Existing CON programs need to be strengthened and updated to protect consumers facing potentially negative changes to health services in their communities. In states without a certificate of need program or other government oversight mechanism, new policies are needed to provide adequate oversight and community member engagement to protect health services access.

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Christine Khaikin, JD, is the advocacy coordinator at the MergerWatch Project in New York City.

Lois Uttley, MPP, is the founder and director of the MergerWatch Project and is on the faculty in the health advocacy master's program at Sarah Lawrence College in New York City. Formerly the director of public affairs for the New York State Department of Health, she has also served as president of the Public Health Association of New York City.

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POLICY FORUM

Privacy Protection in Billing and Health Insurance Communications

Abigail English, JD, and Julie Lewis, MPH

Protecting patients' privacy and the confidentiality of their health information is a fundamental ethical requirement for health care professionals. Because our health insurance landscape currently requires disclosure of a great deal of confidential health information for processing of claims and other administrative purposes, meeting this ethical obligation presents a major challenge, requiring policy solutions that are emerging but not yet fully defined. Finding effective policy solutions has become more pressing as an increasing number of people have acquired health insurance and because it has become clear that solutions implemented at the health care provider level cannot effectively address this challenge. To address this, states are beginning to adopt a variety of statutory and regulatory approaches to protect patients' privacy, even as a wide array of communications continue to occur among health care providers, insurers, policyholders, and patients in billing and health insurance claims processes. Some of these approaches build on [protections](#) that already exist in the Health Insurance Portability and Accountability Act (HIPAA) privacy rule but have not been fully implemented. However, we need policy-level solutions that are consistent with long-standing confidentiality requirements. Examples of such solutions are found in statutes and regulations of a growing number of states.

Confidentiality Obligation

Ethical obligation. The obligation of health care professionals to protect the privacy of their patients has a long history dating back to the Hippocratic Oath. More recently, the confidentiality obligation has been enshrined in the codes of ethics and policy pronouncements of the medical profession, including those of the American Medical Association, the American Academy of Pediatrics, the Society for Adolescent Medicine, and numerous other organizations [1].

Legal requirements to protect confidentiality. The confidentiality obligation of health care professionals has found expression in an extensive array of state and federal laws [2], many of which have implications for third-party billing and health insurance claims processes [2]. Federal and state laws are replete with requirements to protect the confidentiality of patients' health information. The federal HIPAA privacy rule, which defines patient-specific health information as "protected health information" (PHI), contains detailed regulations that require health care providers and health plans to guard against privacy breaches [2]. Other important federal protections are contained in the

statutes and regulations governing the Title X Family Planning Program, the Ryan White HIV/AIDS Program, the Federally Qualified Health Centers (FQHCs) Program, and Medicaid [2]. At the state level, a wide array of statutory and regulatory provisions protects the confidentiality of medical information [2]. Examples in state law include general medical confidentiality laws, those implementing the HIPAA privacy rule, and minor consent laws, along with many others [2].

The HIPAA privacy rule, the Title X confidentiality regulations, and the confidentiality protections that flow from state minor consent laws are particularly noteworthy. Of special relevance in health insurance billing and claims, the HIPAA privacy rule allows patients, including minors who have consented to their own care, to request two different kinds of protections. First, they may request restrictions on the disclosure of their PHI [3]. Health care providers and health plans are *not required* to agree to these requests, but if they do agree they must comply and they must honor requests when the health care has been fully paid for by the patient or anyone other than the health plan [3]. Second, patients *must* be allowed to request that they receive communications regarding their PHI “by alternative means or at alternative locations” [4]. Health care providers must accommodate reasonable requests and may not insist that patients claim they would be endangered by disclosure; health plans must accommodate reasonable requests but may require a statement of endangerment [5]. These two protections are not well understood or frequently used by patients but have provided the foundation for some of the policy approaches emerging at the state level.

The federal Title X Family Planning Program [6] stands out as a leading example of legal support for the ethical obligation of health care professionals to protect confidentiality. The Title X confidentiality regulations [7] have been on the books for more than four decades and are among the strongest in federal or state law. These regulations are broader in their scope than the HIPAA privacy rule; they protect the information of patients of all ages who seek family planning services and prohibit disclosure without the patient’s permission unless otherwise required by law or to provide services to the patient [7]. Thus Title X has been a significant source of confidentiality protection in family planning services for low-income vulnerable patients, including adolescents.

Key protections for adolescents can be found at the state level in minor consent laws, which exist in every state. These laws vary among states but allow minors to consent to their own care in a variety of circumstances based on their age, their status (e.g., homeless or a parent), or the services they seek (e.g., contraceptive services or mental health care) [8]. Some of these minor consent laws also contain or are associated with confidentiality protections for minors’ information when they are authorized to give consent [8].

A Threat to Confidentiality: Legal Requirements to Disclose Information

The conflict. In tandem, and sometimes in conflict, with the myriad confidentiality requirements, federal and state laws contain many provisions that require disclosure of confidential health information, sometimes allowing it even without the permission of the patients to whom the information pertains. The juxtaposition of confidentiality obligations and disclosure requirements causes a conflict for providers and concern for patients. All persons have privacy interests, and when they seek care they expect health care professionals to protect their health information from confidentiality breaches. As documented in decades of research findings [9, 10], fear of such breaches can deter people from seeking health care, with potentially severe consequences for their health and public health.

Patients who may have the greatest fear of breaches of confidentiality include those seeking sensitive services such as sexual and reproductive health care, mental health services, or substance abuse treatment [11]; adolescents; those affected by domestic or intimate partner violence [9, 12]; and those covered as dependents on a family member's health insurance policy. When a patient is covered on a policy of someone else—a parent or a spouse—communications about claims often go to the policyholder, thereby disclosing the patient's confidential health information.

Leading examples of these disclosure requirements can be found in the HIPAA privacy rule and federal and state laws governing health insurance communications. For example, although health care providers generally seek patients' permission to disclose their information for the purpose of submitting health insurance claims, the HIPAA privacy rule allows disclosure of PHI without authorization for "treatment, payment, or health care operations" [13]. This provision creates significant risk of confidentiality breaches.

Most significant are the laws that require insurers' sending to policyholders explanations of benefits (EOBs) (which detail the services rendered and the amounts paid by and owing to the insurance company) and notices when health insurance claims are denied in whole or in part [2, 11, 14-16]. The Employee Retirement Income Security Act (ERISA) and the Patient Protection and Affordable Care Act (ACA) both require insurers to communicate to policyholders about the benefits received and denied. These communications are commonly referred to collectively as EOBs.

Although intended to promote consumer protection and greater transparency in the health insurance claims process, these requirements have an unintended effect when the patient and the policyholder are two different people: they often result in the disclosure of patients' sensitive information to the holders of the policies through which they are insured as [dependents](#), which can expose the patients to danger or deter them from seeking health care [11].

These communications from health insurers to policyholders are ubiquitous. The requirements in both federal and state law for the sending of notices when claims are denied in whole or in part, and the way in which the partial denial of a claim is defined, mean that virtually all claims result in the sending of a notice, which usually goes to the policyholder [2, 11, 14-16]. The potential for loss of privacy exists in both public and commercial insurance, but it is most acute in the private sector and is especially associated with the sending of EOBs to policyholders. While this risk is lessened within the Medicaid program because EOBs are not sent to beneficiaries in many states and because people enrolled in Medicaid are their own policyholders, the challenge of protecting information can still surface under Medicaid managed care plans [2, 11].

The HIPAA privacy rule does not protect against the sending of EOBs and other claim-related notices. In fact, HIPAA allows for such disclosures for the purposes of payment without authorization, and it also allows broadly for disclosures with authorization, which patients are usually required to grant to their insurers as a condition of coverage and to their providers to facilitate submission of claims.

With the passage of the ACA, many more people have Medicaid or commercial health insurance and millions of young adults ages 18-25 are now able to remain on their parents' plans [17]. These young adults have no way to ensure their privacy while using their parents' health insurance even though, as adults, they may rightfully assume they are entitled to the same confidentiality protections as other adults; the limitation on their privacy results from their coverage on a plan for which their parent, who is the policyholder, is likely to receive most communications [18]. As a result, patients insured as dependents sometimes still choose to act as though they were uninsured, thus undermining the personal and social benefit of insurance and burdening safety-net providers.

Example: Title X-funded family planning health centers. The ethical dilemma posed by the juxtaposition of the confidentiality obligation and the disclosure requirements for billing and health insurance claims processing is starkly illustrated by the quandary confronting Title X-funded family planning health centers. On the one hand, Title X confidentiality regulations, as described above, are very strong, and the ethical commitment to protecting patient privacy is firmly embedded in the policies and practices of providers of Title X-funded family planning services [7]. On the other hand, Title X providers' generation of needed revenue, by billing health insurers for services covered by their patients' commercial health plans or Medicaid, risks confidentiality breaches.

Although Title X providers may receive reimbursement for care through grant funding or other limited sources even when the patient has access to insurance, the financial pressures on Title X providers are profound, with funding levels flat and patients' needs increasing. Title X regulations also require grantees to bill financially liable third parties

when it is possible to do so while still protecting confidentiality [19]. Thus arises the quandary: providers are reluctant to bill insurers unless they can assure their patients that confidentiality breaches can be avoided, and patients who are unable to pay out of pocket continue to express a desire to receive confidential services without their insurance being billed.

This scenario results in Title X providers forgoing revenues from their patients' health insurance coverage in order to honor their ethical—and legal—obligation to protect the confidentiality of patients' information. In a recent survey, 62 percent of Title X-funded family planning providers said that they do not send bills at all for patients who request confidentiality, and 74 percent stated they use grant funds and charge based on income by using a sliding fee scale for patients in need of confidentiality [20].

This quandary exists not only for Title X providers and other health care professionals and health care delivery sites, but also for patients themselves. Patients may refuse to get needed services if they can only afford them through their health insurance and are thus forced to choose among necessary services because they cannot afford to pay out of pocket for all the services they need. Or patients are put in a bind because they are uncertain whether use of coverage will result in a confidentiality breach in spite of the providers' promises.

Evolving Protections in State Laws

Recognizing the extent of this dilemma, states have begun to address the problem with a variety of approaches, particularly in the commercial health insurance sector. These approaches include the management of EOBs, denials of claims, and other communications; enabling patients to request restrictions on disclosure of their health information; explicit confidentiality protections for minor and/or adult dependents; and varied strategies for implementing these protections [2, 11]. So far several states—including California, Colorado, Maryland, Massachusetts, Oregon, New York, Texas, and Washington—have adopted or proposed one or more statutes, regulations, or policies related to payment and billing or the health insurance claims process—either in Medicaid or in commercial health insurance—that are designed to increase confidentiality protections in some way [2, 11].

Several states have employed the communications management strategy. California's Confidentiality of Health Information Act (CHIA) of 2013 contains detailed clarifications of and requirements for implementing HIPAA standards [21]. CHIA allows minors and adults to request "confidential communications" when they are seeking any of a group of "sensitive services" or believe they would be endangered—which, under the California law, also means harassed or abused [22]—if their request were not honored. Insurers must honor both requests related to sensitive services even without a claim of endangerment and requests based on an endangerment claim without requiring an

explanation. Another significant example is a 2015 Oregon law that defines insurance communications broadly; it explicitly allows “enrollees” (i.e., patients) to request that communications be redirected and sent to them and not to the policyholder, and it requires insurance carriers to honor such requests [23]. Other strategies include excluding information about sensitive services from EOBs, as in a proposed Massachusetts law [24], and not sending EOBs when there is no “balance due” or residual financial liability on the part of the policyholder, as New York State law allows [25].

An example of the strategy that allows restrictions on disclosure is a Washington State regulation, promulgated at about the same time as the HIPAA privacy rule, that requires insurers to restrict disclosure of health information about patients if they state in writing that disclosure could jeopardize their safety [26]. Washington, like California, also requires insurers to restrict disclosures about sensitive services regardless of whether the patient claims endangerment. However, while the California statute specifically addresses the handling of communications, the Washington regulation speaks more generally about restrictions on disclosure for particular groups of patients.

Adopting a more general approach, Colorado issued a regulation in 2013 that requires insurers to “take reasonable steps” to protect the information of any adult dependent covered by a family member’s policy and to ensure that communications between the insurance company and the adult dependent remain “confidential and private” [27]. Unlike the California and Washington laws, Colorado’s is limited to adults and does not include minors, even though Colorado law does allow minors to consent to a range of health care services and receive them confidentially.

Conclusion

As states take preliminary steps to enable patients to use their health insurance coverage and health care providers to bill insurers without breaches of confidentiality, the ethical dilemmas and the policy challenges loom equally large. Continued refinement of policy is essential, as is implementation to test its effectiveness. With each new approach, two outstanding challenges must be addressed. First, when communications are redirected or restricted to protect patients’ privacy, policyholders might not learn whether and how claims are affecting their deductibles and other financial liabilities. Second, the burden of electing to redirect or restrict communications lies entirely with the patient. This may be burdensome for patients who are unfamiliar with navigating health insurance choices, younger patients, or those in dangerous situations. Creative solutions to these and other questions are needed in order to allow health care providers to both protect patient privacy and receive payments from health insurers and to allow patients to access services they need using the health insurance coverage to which they are entitled.

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Abigail English, JD, is the director and founder of the Center for Adolescent Health and the Law in Chapel Hill, North Carolina. A lawyer, researcher, and advocate for the rights of vulnerable young people, her research and advocacy focus on health insurance and public financing of care for adolescents and young adults, consent and confidentiality protections, and sexual and reproductive health care.

Julie Lewis, MPH, is a public health and policy expert at the National Family Planning and Reproductive Health Association in Washington, DC, where she directs the Confidential and Covered, a multi-year research project investigating how Title X-funded family

planning providers can maintain patient confidentiality while mitigating revenue loss.

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POLICY FORUM

Federal Privacy Protections: Ethical Foundations, Sources of Confusion in Clinical Medicine, and Controversies in Biomedical Research

Mary Anderlik Majumder, JD, PhD, and Christi J. Guerrini, JD

The privacy of patient information is protected by the US Department of Health and Human Services (HHS) under the Health Insurance Portability and Accountability Act (HIPAA) [1] and other laws, including the Basic HHS Policy for Protection of Human Research Subjects (often referred to as the “Common Rule”) [2]. Although the term “privacy” does not appear in HIPAA’s title, attention to privacy is critical to achieving its goals, which include facilitating coordination of care as people change insurance plans and providers and promoting electronic exchange of information within the health care system. Further, HIPAA and the Common Rule exist within a broader biomedical context in which data sharing is increasingly recognized as critical to both clinical care and research. A National Research Council report on sharing biomedical information identifies “careful handling of policies to ensure privacy as *the central issue* in its entire vision” of accelerating innovation [3].

The aim of this essay is threefold. We first describe the ethical foundations for HIPAA and other privacy laws. We then suggest that, contrary to claims that HIPAA is ethically questionable because it obstructs coordinated clinical care, *confusion* about HIPAA is sometimes, perhaps even frequently, the barrier to high-quality care. Finally, we raise some questions about the ethical status of proposed changes to the Common Rule that concern privacy in the context of medical research.

Ethical Foundations of Privacy Law

Privacy is defined broadly, encompassing the right to be free of unwarranted surveillance and interference and the right to control sharing of personal information [4]. Under the umbrella of privacy, *confidentiality* concerns the protection against unauthorized disclosure of patient or client information obtained within the context of a professional relationship [4].

The importance of privacy and confidentiality to the practice of medicine has been recognized [from ancient times to the present](#). For example, the Hippocratic Oath commits the oath taker to keep all information obtained about patients’ lives secret [5]. Opinion 5.05 of the current AMA *Code of Ethics* states that the patient should be able to “make a full disclosure of information” secure in the knowledge that “the physician will respect the confidential nature of the communication” [6]. Revealing confidential

information without express patient consent is only permitted when “ethically justified because of overriding considerations” [6].

What are the ethical considerations supporting these strong endorsements of privacy and confidentiality?

Trust. Opinion 5.05 of the AMA *Code of Ethics* implies that trust—the bedrock of the patient-physician relationship—requires privacy protections. A person’s level of trust in health care professionals is likely to affect his or her willingness to seek professional help, reveal relevant information, adhere to a treatment plan, return for further care, and participate in research. Trust is built and preserved by consistent, reliable privacy protection practices within and across professions and institutions engaged in the provision of health care and the conduct of research.

Beneficence and fiduciary responsibility. Beneficence and the health care professional’s fiduciary responsibility to patients entail not only commitments to protect and promote patients’ health-related and other interests, but also commitments to avoid causing loss or harm to one’s patients. Disclosure of patients’ private information can cause harms including: (1) economic harm, such as employment discrimination (if diagnostic or health risk data are not properly protected) or identity theft; (2) social harm, such as stigmatization or damage to family relationships (e.g., from disclosure of an HIV diagnosis or misattributed parentage revealed by genetic testing); and (3) legal harm, such as prosecution for drug-related offenses of a patient seeking treatment for a substance use disorder.

Respect for autonomy and for patients. Respect for autonomy includes respect for a patient’s right to decide with whom to share his or her personal information. AMA *Code of Ethics* Opinion 5.05 appeals to this consideration by treating disclosures to which the patient has expressly consented differently than disclosures without patient endorsement [6]. Related to respect for autonomy is the more encompassing principle of respect for persons, which entails recognition of and sensitivity to patient vulnerability, efforts to preserve and restore patient dignity, and protection of patients from exploitation. This ethical consideration translates into efforts to screen patients’ bodies from view and restrictions on the ability of health care professionals to use patient information for purposes unrelated to the care of the patient (e.g., fundraising and selling that information to third parties).

Fidelity. There are generally recognized exceptions to the duty to maintain confidentiality (discussed below) and the existence of legal obligations to disclose information in some circumstances (for example, reporting cases of communicable disease to public health authorities and cases of suspected child abuse to child protection agencies). Even given these, however, a health care professional’s implicit or explicit promises to a patient of

confidentiality regarding a particular encounter or disclosure must be factored in when evaluating whether the ethical considerations supporting an exception to confidentiality are “overriding.”

Clearing Up Confusion about HIPAA

HIPAA’s strong commitment to privacy is in keeping with the ethical considerations reviewed above [7]. It restricts uses and disclosures of individually identifiable protected health information (PHI) by covered entities (i.e., most health care providers, health plans, and health care clearinghouses) without patient authorization, but allows exceptions to facilitate the delivery of care. Three major categories of exceptions are disclosure for treatment, payment, and health care operations purposes [8].

Assigning to the patient the role of gatekeeper to his or her personal information is consistent with the principle of respect for autonomy. So is enshrining patients’ rights to receive a notice of their privacy rights, to access and amend their PHI held by health care professionals and institutions, and to receive an accounting of disclosures. The exceptions for payment and health care operations (but not for treatment purposes) are subject to a “minimum necessary” standard that reflects awareness that, even when disclosure is justified, it exposes patients to risks and so should be tailored to need [9].

Despite the existence of these exceptions, HIPAA is often invoked as a frustrating barrier to coordinated delivery of care and appropriate sharing of information (i.e., to promote patient well-being). A 2015 report to Congress from the Health Information Technology Policy Committee found, however, that it is not the provisions of HIPAA but *misunderstandings* of privacy laws by health care providers (both institutions and individual clinicians) that impede the legitimate flow of useful information. The report refers to “many examples where misinterpretations” have inhibited information exchanges permitted under HIPAA [10].

Such provider misunderstandings include the following:

- The belief that HIPAA requires patients to provide authorization before information can be shared for treatment purposes between physicians and other health professionals, hospitals, ambulance companies, health information exchange organizations, and others involved in providing or coordinating care (potentially generating inefficiencies such as delays and unnecessary paperwork burden and inhibiting coordination of care);
- The belief that HIPAA forbids appropriate communication with patients’ families, friends, and the clergy (potentially isolating patients and depriving them of support); and
- The belief that HIPAA restricts appropriate use of electronic technologies for communication (potentially depriving providers, patients, and the larger health

care system of the capacities of these technologies to facilitate communication and make the transfer of information more efficient).

All of these misunderstandings were labeled as such in a 2004 HHS Office for Civil Rights (OCR) letter to health care providers [11], among other sources [12-14]. Yet the myths persist [10, 15]. What follows is accurate information about HIPAA's provisions.

Information sharing among treating entities. As noted above, HIPAA permits sharing of information among those treating the patient without separate authorizations. The OCR letter states: "Providers can freely share information with other providers where treatment is concerned, without getting a signed patient authorization or jumping through other hoops" [16]. Further, as noted above, such sharing is not subject to the "minimum necessary" standard, which requires reasonable steps to limit uses and disclosures to the minimum necessary for accomplishing the intended purpose [9].

Disclosure of information to patients' family, friends, and clergy. Disclosure of information is permitted when others are in the room with the patient, and a patient's location and general condition information can generally be shared with loved ones. The OCR letter states: "Doctors and other providers covered by HIPAA can share needed information with family, friends—or even with anyone else a patient identifies as involved in his or her care—as long as the patient does not object" [16]. In addition, when a patient is incapacitated, it is permissible to share information so long as the health care professional believes that doing so is in the patient's best interests [11-14, 17].

Use of electronic technologies. In the words of former OCR director Richard Campanelli, "HIPAA is not anti-electronic" [16]. The HIPAA regulations neither privilege paper communication nor restrict particular modes of electronic communication. Further, facilitating health information exchange using electronic technologies remains a top national policy priority, with policymakers embracing these methods' potential to promote patient access to information and make sharing among providers more efficient [18]. It would be incorrect to state, for example, that HIPAA requires written authorizations from patients before information can be transmitted via a health information exchange for treatment purposes, or that it prohibits participation in such an exchange. Such statements reflect confusion about HIPAA and perhaps also the desire to avoid the technological, financial, and policy challenges associated with using electronic technologies to share information in an ethically responsible, secure manner.

The HIPAA regulations do require systematic attention to privacy and security concerns across all modes of [documentation and communication](#), and they also permit providers to impose some requirements for tracking and identity verification purposes [11, 17]. When physicians or other clinicians encounter an institutional policy related to information access or sharing that they believe is creating inefficiencies, impeding coordination of care, or causing other problems affecting quality of care, the ideal next

step is an inquiry to determine whether the policy is truly mandated by HIPAA or another law. If not, a critical assessment of its justification is warranted.

We have argued that the provisions of HIPAA governing protection of patients' information are, in general, consistent with ethical norms, although we would certainly not endorse every detail. Further, we believe that clearing away confusion about what HIPAA requires is important from an ethics perspective and should serve to improve health care quality and promote patient well-being.

Privacy Law and Research

Although the HIPAA framework is consistent with ethical norms governing patient care, its application to modern medical research raises several ethical concerns. In recent years, the landscape of medical research has undergone a dramatic transformation as a result of the explosion in number and scale of clinical trials, the development of increasingly sophisticated techniques for analyzing biospecimens, and the escalation of efforts to store and combine large datasets for analysis. Together, these changes have brought into sharp focus questions about identity, consent, and commercialization that have important privacy implications.

The relationship between HIPAA and the Common Rule. In the context of medical research, there are two main sources of federal privacy protections. The first is HIPAA, which applies to medical research in which (1) the researcher is providing medical care in the course of research and transmits any health information in electronic form, or (2) the researcher is employed by a covered entity, such as a hospital, or a hybrid entity, such as an academic medical center providing medical care in addition to noncovered functions [19]. As described below, the 21st Century Cures legislation, which was approved by the House of Representatives in July 2015 and is currently pending in the Senate, would make several important changes relevant to HIPAA's application to medical research [20].

The second major source of federal privacy protections in medical research is the Common Rule, which applies when a researcher obtains either identifiable private information or data about an individual through an intervention or interaction with that individual [2]. In September of 2015, HHS proposed sweeping changes to the Common Rule that, if adopted, would have important privacy-related implications for researchers [21].

In their current forms, HIPAA and the Common Rule are aligned on several key issues, such as allowing research subjects' broad consent to secondary research use of data and biospecimens. However, the laws differ in important ways, such as the mechanisms they provide for removing identifiers from research data and the specific activities that they exclude and exempt.

The conflicting requirements of these two laws have been perceived by some to add unnecessary complexity to the conduct of medical research [22]. A proposed [amendment to the Common Rule](#) is intended to reduce some of this complexity by excluding certain data also protected by HIPAA from protection under the Common Rule [21]. Another amendment to the Common Rule would require researchers to adopt safeguards to protect the security of data and biospecimens used in research, but this requirement could be satisfied by complying with HIPAA's security provisions [21]. Although these proposals, if enacted, would alleviate some administrative burdens associated with satisfying two sets of legal requirements, they also generate new ethical questions.

Do biospecimens have different ethical claims in research than data? Both HIPAA and the Common Rule exclude from protection data and biospecimens that are not identifiable—i.e., they cannot be traced back to individual sources [1, 2]. If one of the major amendments to the Common Rule is adopted, however, any secondary research involving biospecimens would be subject to the protections required by the Common Rule regardless of whether the biospecimens or the information they generate are identifiable [21]. (If the secondary research involves only data, the usual rules would apply, with coverage under the Common Rule turning on the identifiability of the data.)

The change is justified on two ethical grounds. First, it is asserted that the principle of beneficence supports the change because sophisticated analytical techniques, including whole-genome sequencing, have made it possible to re-identify nonidentified biospecimens using publicly available information and free web-based tools [23], although the likelihood of re-identification is widely recognized to be remote. The new rule is intended to minimize the risks of and harms resulting from inappropriate disclosure of information generated from biospecimens. Second, in light of new participatory models of research in which subjects want and expect to be consulted regarding the disposition and use of their biospecimens, respect for persons is claimed to support the change [21].

The question remains, however, whether [biospecimens should be treated differently](#) from data in the legal arena. The controversy surrounding the HeLa cell line, which was derived from tumor cells taken from Henrietta Lacks and used in research without her consent, is a poignant reminder of the harms to dignity that can result from unknowing research use of biospecimens [24]. But in that case, researchers made little attempt to hide Ms. Lacks as the source of the cell line, whereas today both HIPAA and the Common Rule provide standards for de-identifying both biospecimens and data [1, 2]. Although reidentification has been shown to be possible in an academic proof-of-concept study [23], even the commentary to the proposed Common Rule amendments acknowledges that the risk of reidentification is not unique to biospecimens but also exists for

information, like whole-genome sequencing data, that is extracted from them [21]. Yet the amendments take the position that such data is not inherently identifiable, while the biospecimens from which the data is generated *are*. The ethical basis for treating these two forms of research (that in which genetic sequencing data is generated and that only involving analysis of the data) differently is unclear and has led to claims of unjustified “biospecimen exceptionalism” [25]. The practical result of this exceptionalism will be to encourage medical researchers to avoid using biospecimens in their studies, even when biospecimen analysis is most suited to their particular research questions.

Is “broad consent” ethically defensible? Another lingering ethical question concerns broad consent to storage and secondary research use of biospecimens and data obtained during research. There is a range of available options for obtaining consent for secondary research use [26], and both HIPAA and the Common Rule have been interpreted to permit broad consent when the secondary research is adequately described. Specifically, HIPAA allows subjects to give informed consent to secondary research use of data [27], and the Common Rule allows subjects to consent to secondary research use of data and biospecimens when they are given a reasonable idea of the types of research that might be conducted in the future and associated risks [28]. But can broad consent ever be truly informed—and therefore ethically acceptable—given that the contexts in which research subjects’ biospecimens and private information will be analyzed are not yet known?

If the ethical aim is to respect persons as autonomous agents by consulting them about the future use of their biological samples and private information, it is debatable whether that aim can be achieved when persons are not and cannot be told when, why, or how that future use will occur or what the results will mean for them, their families, or society. Moreover, there is a real possibility that, over time, changed life circumstances and values could cause some persons to weigh their participation in future research studies differently than they did initially [29]. On the other hand, it might demonstrate lack of respect for autonomy to deny people the opportunity to provide broad consent when they comprehend and are comfortable with the attendant uncertainties [30].

Moreover, research on complex diseases involving multiple factors cannot reach statistically significant conclusions without the participation of large numbers of people. To improve health, biospecimens and data must therefore be accessible to as many researchers as possible for use in as many future studies as possible, not all of which can be specified or even predicted at the time of initial consent [31]. In the end, societal interest in promoting public health may trump any ethical claim that private persons should be allowed to participate in only those existing research studies that are known and well defined.

Is it ethical to permit the sale of subjects' health data? Finally, unresolved ethical concerns surround the commercialization of research subjects' biospecimens and private information. The Common Rule does not forbid the sale of these raw research materials [2], although proposed amendments would require consent to research involving biospecimens to include, where applicable, a statement that the biospecimens may be used for commercial profit [21]. HIPAA does prohibit the sale of private health information for most purposes without prior authorization [7], but amendments proposed by the 21st Century Cures legislation would permit it for research purposes [20].

The principle of respect for persons provides reason to question the propriety of allowing such profiteering when research subjects are not notified of the possibility of its occurrence, particularly in light of consistent evidence that patients and the public are distrustful of a major category of potential purchasers and resellers—*for-profit entities*—in genomic research contexts [30, 32]. The amendments to the Common Rule begin to address this issue by requiring researchers to inform subjects of their intentions to profit from subjects' biospecimens [21]. The reason for declining to extend this requirement to researchers who intend to profit from subjects' private information, however, is unclear. The principle of respect for persons suggests that research subjects should at least be notified of the possibility that their biospecimens *or* personal data could be sold by researchers for profit.

Conclusion

Federal privacy laws describe overlapping but not identical requirements that impact medical practice and research. Although the ethical bases of these laws are sound, their application to particular circumstances sometimes breeds confusion. Moreover, pending amendments to these laws generate difficult ethical questions. A goal of this essay has been to illuminate some of the intersections between privacy law, ethics, and current policy debates.

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Mary Anderlik Majumder, JD, PhD, is an associate professor of medicine at the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, Texas. Her research focuses on the ethical and social implications of new genomic technologies and ethical and policy questions related to problems of cost, quality, and access in health care.

Christi J. Guerrini, JD, is a research instructor at the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, Texas, and a graduate student at University of Texas School of Public Health. Her research focuses on health privacy, human research subject protections, and the intersection of intellectual property law and genomics.

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POLICY FORUM

Medical Malpractice Reform—Historical Approaches, Alternative Models, and Communication and Resolution Programs

Joseph S. Kass, MD, JD, and Rachel V. Rose, JD, MBA

Legal responsibility for medical malpractice is not a new concept, with a history that can be traced back to the Code of Hammurabi in 2030 BCE [1]. Roman law recognized medical malpractice as a legal wrong, and this concept was expanded and introduced to continental Europe around 1200 CE [1]. English common law, from its medieval origins, “provide[s] an unbroken line of medical malpractice decisions, all the way to modern times” [2]. Derived from English common law, United States medical malpractice law—grounded in the legal concept of tort law—has evolved through decades of state and federal court decisions and been modified by legislative intervention [1]. As *Black’s Law Dictionary* defines it, “A tort is a legal wrong committed upon the person or property independent of contract” [3]. It is an umbrella concept encompassing myriad categories such as negligence, gross negligence, professional negligence, recklessness, and acts of intentional harm (referred to as intentional torts). Medical malpractice is a form of professional negligence, since professionals discharging their professional duties are expected to act with a higher standard of care than nonprofessionals.

To prevail in a medical malpractice claim against a physician, the injured party (the patient or patient’s family) must demonstrate that it was more likely than not (this requirement is known as the “preponderance of the evidence” standard) that the following four elements were present: (1) the physician had a duty to the patient; (2) the physician was negligent in his or her execution of the duty, (i.e., by breaching the standard of care); (3) the physician’s negligent action was the proximate cause of the patient’s injuries; and (4) the patient’s injury resulted in damages, whether economic or other [4]. A breach of a physician’s duty to patients can take many forms. For example, injuries may result from misdiagnosis, errors in the choice or technical execution of procedures, improper administration of medications, failure to follow up appropriately with a patient, and failure to obtain adequate [informed consent](#) [5]. The standard of care requirement means that the finder of fact, typically the jury, must hear testimony from both sides of the litigation about what the standard of care is and then evaluate that information to decide if the physician breached it, i.e., whether a reasonably prudent physician confronting similar circumstances would not have acted as the defendant physician did.

Studdert, Mello, and Brennan state that “[t]here are three social goals of malpractice litigation: to deter unsafe practices, to compensate persons injured through negligence, and to exact corrective justice” [6]. Thus, patients might reasonably expect medical malpractice law to serve as a deterrent to the improper practice of medicine and to compensate—through a negotiated settlement or a trial—patients who are victims of physician negligence. However, only a small number of harmed patients receive compensation, and a large number of compensated patients appear not to be victims of actual negligence [7, 8]. As Kessler [9] asserts, “[w]hile it is more difficult to assess the extent to which the malpractice system has provided incentives for appropriate care, a variety of evidence suggests that it has not” [10].

A significant literature suggests that physicians believe that pressure to avoid malpractice litigation [leads to](#) “defensive medicine” [9, 11]. Defensive medicine is medical practice performed primarily to limit future risk of a successful lawsuit against the physician and only secondarily to adhere to the medical standard of care. Defensive medicine can lead to a broad set of consequences: providing care that is “unproductive, not cost effective, or even harmful” or “declining to supply care that could be beneficial” [10]. Additionally, defensive medicine can also inflict moral harm on the physician and damage the patient-physician relationship. Defensive medicine is problematic ethically because it moves the focus of medical care away from the best interests of the patient toward the best interests of the physician. The ethical consequences of this change in focus are considerable. As Rentmeester and George write,

when a practitioner orients herself to a patient defensively, for example, the scope of her moral perception narrows and she draws her concern away from her patient toward herself. This kind of physician-centered practice suggests a physician’s narrowed moral outlook toward her patients: what constitutes a reason to respond with care to a patient is defined narrowly (instead of broadly), exclusively (instead of inclusively), and meagerly (instead of generously) [12].

Studies measuring the effect of malpractice pressure on malpractice premiums, claims frequency, or claims severity tend to find evidence of defensive, unproductive care [7, 13, 14]. The costs of defensive medicine to the health care system, which a Cleveland Clinic study estimated to be \$6 billion—in addition to the economic and noneconomic costs of malpractice litigation itself—have driven advocacy for malpractice reform [15]. Furthermore, it appears that medical malpractice tort reform does have a positive impact on the health care bottom line. For example, the Congressional Budget Office concluded in 2009 that “the weight of the empirical evidence now demonstrates a link between tort reform and the use of healthcare services” [16].

This article examines this country's historical approach to medical malpractice, traditional reform models, proposals based on alternative models, and the role of mediation and ethics consultation in medical malpractice cases.

Background: Malpractice Reform Attempts

In the United States, medical malpractice claims began to appear in the 1800s [17], but it was not until the 1960s that a surge of medical malpractice claims appeared in the courts [18]. This surge was likely driven by a number of factors: new and more complex treatments with higher risks of iatrogenic harm, a changing legal landscape that removed barriers to lawsuits and changed liability rules that had previously shielded charitable institutions from suit, and changes in satisfaction with the health care system, among others [19]. The rising incidence and costs of malpractice litigation led organized medicine to lobby for state and federal interventions to curb the burdens of the current malpractice liability system [9].

Medical malpractice reform is the product of political processes, whereby groups with different interests attempt to push their agendas. Physicians and physician organizations have tended to view most medical malpractice claims as spurious and injurious to the medical system, whereas patient advocates view the malpractice system as both a deterrent against the practice of dangerous medicine and an avenue for much-deserved compensation for injured patients [9].

In 2011, the National Conference of State Legislatures (NCSL) compiled an analysis of medical malpractice reform goals and initiatives [20]. The NCSL sought to address the challenges of cost containment while acknowledging that medical malpractice reform (i.e., tort reform) needs to address three major areas: limiting the costs associated with medical malpractice, deterring medical errors, and ensuring fair compensation for patients who are harmed [20].

Traditionally, reforms have attempted to change the medical malpractice climate in one of three ways: (1) allowing fewer lawsuits by creating barriers to filing, such as a prefiling certification or review of the medical merits of the case [20]; (2) limiting plaintiffs' compensation by imposing damage caps for noneconomic damages such as pain and suffering [21]; or (3) changing how awards are paid out to plaintiffs (payments over time versus large lump-sum settlements) [22]. Caps on noneconomic damages are the most common types of reforms and have been implemented in over half the states in various forms [23].

Hyman and colleagues used claim-level data to estimate the effect of Texas's 2003 cap on noneconomic damages on jury verdicts, post-verdict payouts, and settlements in medical malpractice cases closed during 1988-2004. The investigators found that the cap affected 47 percent of verdicts favoring plaintiffs and reduced mean allowed

noneconomic damages by 73 percent and mean total payout by 27 percent. The noneconomic damages cap affected 18 percent of cases settled without trial and reduced predicted mean total payout by 18 percent [24]. In addition to affecting indemnity payments, it appears that damage caps also modestly reduce the rise in malpractice insurance premiums [25].

Although malpractice reform in the form of caps on noneconomic damages may reduce the actual payouts to plaintiffs, the broader impact of these reforms on reducing defensive medicine is less clear. Waxman and colleagues attempted to gauge the impact of these reforms on emergency department care in three states with malpractice reform—Texas, South Carolina, and Georgia—as compared to neighboring states without reforms [26]. Using a 5 percent random sample of Medicare fee-for-service beneficiaries, the investigators identified all emergency department visits to hospitals in the three reform states and in neighboring (control) states from 1997 through 2011. They examined pre- and post-reform changes in the use of computed tomography or magnetic resonance imaging, per-visit emergency department charges, and the rate of hospital admissions and they did not find any policy-attributable reduction in care intensity: no significant reduction in the rates of CT or MRI utilization or hospital admission in any of the three reform states and no significant reduction in charges in Texas or South Carolina was found. Georgia, however, did see a modest 3.6 percent reduction in per-visit emergency department charges [26].

Alternative Dispute Resolution Methods

While traditional malpractice reform efforts could reduce the number and success of malpractice lawsuits in some states, they do little to help patients injured by physician negligence obtain what research suggests they truly desire: (1) an account of why the harm occurred; (2) an apology from the health care professionals involved; (3) information about how similar harms can be avoided in the future; and (4) appropriate restitution for an avoidable harm [27].

Society as a whole has an interest in cultivating a medical system in which medical practitioners do not practice defensive medicine but rather engage in process improvement at both the individual level and the system level. Therefore, to be effective, medical malpractice reform must balance the needs of all parties. The health care system must promote a culture of open communication between clinicians and patients that persists even after a patient has experienced a negative outcome (regardless of who or what is to blame), allows for robust process improvement, and offers compensation to injured parties. A possible beneficial effect of such a culture may be that patients trust their physicians when physicians truthfully explain that a poor outcome was due to the natural history of disease rather than the negligent practice of medicine. Such a system would be adversarial only as a last resort, and even under those circumstances it should

build on mediation-based models such as communication and resolution programs, discussed in more detail below.

A 2013 study estimated that between 210,000 to 400,000 people die annually in the US due to medical error [28]. Ethically, a reformed medical malpractice system must address the fact that medical errors do injure patients and are at play in a significant number of malpractice cases. For example, Studdert and colleagues analyzed 1,452 closed malpractice claims from five liability insurers and concluded that 63 percent of the claims did, in fact, involve injuries due to medical error [29].

Alternative dispute resolution (ADR) models, which allow physicians and the health systems in which they operate to acknowledge openly when errors have occurred and offer reasonable compensation to the injured parties, balance the needs of clinicians—to act ethically by being truthful and engaging in vigorous quality improvement—and of patients—to receive compensation for negligence-induced iatrogenic harm. Alternative dispute resolution allows litigants to move out of a “battle” mentality and into a facilitated conversation to achieve resolution of the conflict.

Alternative dispute resolution typically includes either mediation or arbitration. These two approaches are quite different, but both can be quite effective in resolving disputes in a less adversarial and less costly manner than traditional litigation [30]. A number of health care institutions have experimented with a unique twist on ADR by developing communication and resolution programs (CRPs), novel approaches to addressing medical error that have paid off in terms of the costs associated with malpractice litigation [31–34]. These programs encourage open communication and transparency with patients and their families and facilitate restitution for injured parties when appropriate. They also support physicians in disclosure conversations with patients.

The Lexington, Kentucky, Veterans Affairs (VA) Medical Center was a pioneer in this area. In 1987, the Lexington VA implemented its CRP, which provided a full disclosure of the occurrence that led to harm as well as an expression of regret on behalf of the institution and its personnel [33]. Under this system, patients and their families are invited to bring attorneys to discuss offers of compensation early in the process. Although ADR in a health care situation likely provides a number of benefits to both the health care provider (by promoting honesty and ethical behavior) and to the patient and patient’s family (by providing an honest accounting of what happened, including a statement of regret and possibly an offer of compensation), the empirical literature discussing ADR typically emphasizes quantitative, economic measures in the form of payouts as a measure of success. With the implementation of this program, the Lexington VA became the VA hospital with the lowest payouts. Between 1990 and 1996, the average settlement per claim in Lexington was approximately \$15,622 [33], whereas in other VA institutions it

was \$98,000. Additionally, the average duration of cases decreased from 2-4 years to 2-4 months [35].

CRPs also exist outside the VA system and come in two varieties: early settlement and limited reimbursement [36]. The University of Michigan Health System (UMHS) was the first non-VA health system to adopt a CRP, implementing an early settlement model in 2001. UMHS self-insures [37]; all its physicians are employed and insured by the university rather than by commercial malpractice carriers, thereby simplifying buy-in to the CRP. This model has four components: (1) acknowledging when patients are injured due to medical error; (2) compensating fairly (commensurate with degree of harm) and quickly when there is a deviation from the standard of care; (3) aggressively defending against meritless cases; and (4) studying all adverse events to determine how health care delivery can be improved. Because the payments are made on behalf of the institution only, they are not reported to the National Practitioner Data Bank (NPDB) [36]. This operational detail is significant because the NPDB, which was created by Congress, "contains information on medical malpractice payments and certain adverse actions related to health care practitioners, entities, providers, and suppliers" [38]. It is publically available information that may affect a physician's reputation and follows a physician throughout his or her career. By not reporting this information to the NPDB, UMHS reduces an important barrier to physician participation in this CRP.

In a retrospective chart review of UMHS claims reported in the eight years before and the five years after full implementation of the CRP in 2003, investigators compared the number of new claims for compensation, the number of claims compensated, the time to claim resolution, and claims-related costs from 1995-2007 [31]. After full implementation of the CRP, the average monthly rate of new claims decreased from 7.03 to 4.52 per 100,000 patient encounters, the average monthly rate of lawsuits decreased from 2.13 to 0.75 per 100,000 patient encounters, and the median time from claim reporting to resolution decreased from 1.36 to 0.95 years. Moreover, the average monthly cost rates decreased by at least 50 percent for total liability, patient compensation, and noncompensation-related legal cost [31].

The model employed by COPIC Insurance Company, a large medical liability insurer in Colorado, is an example of a limited-reimbursement model, the second type of CRP. In 2000 COPIC developed its 3Rs program—Recognize, Respond, and Resolve—to address situations in which their enrollees' patients were unsatisfied with their health outcomes [32, 39]. When patients suffer adverse outcomes they receive a disclosure of what occurred and compensation for out-of-pocket expenses not covered by insurance (up to \$25,000) and for lost time (up to \$5,000). Disclosure and compensation occur [without a determination of physician fault](#). Patients retain the right to sue, and payments are not reportable to the NPDB. Physician participation is voluntary, and participating physicians undergo disclosure training. Exclusion criteria include death, clear negligence, attorney

involvement, a complaint to the state board, and a written demand for payment. From October 2000 to October 2007, there were 4,800 qualified events, with 1,026 patients receiving payments averaging \$5,286. Seven paid cases were litigated, and only two resulted in tort compensation. Sixteen unpaid cases were litigated, and six resulted in tort compensation. Anecdotal evidence and survey data suggest to the COPIC leadership that the system is successful. The majority of physicians and patients find the system effective and only a small fraction of cases that go through the 3R system evolve into litigated and compensated claims. Because of the open disclosure and compensation, the animosity between the injured patient and the physician appears to be reduced, and many patients maintain their therapeutic relationship with their physician [32].

Facilitating CRPs: Apology Laws

CRPs are one innovative approach to medical malpractice reform that address both patient and institutional needs. CRPs require, however, a culture shift in the medical community and a management of expectations on the part of injured patients who may be anticipating larger payouts than they are offered in this type of system. CRPs also require a favorable legal environment; they work best if “apology laws” explicitly protect clinicians and health institutions from penalty for discussing adverse events openly and honestly with patients and their families. Currently, apology and disclosure laws in the majority of states do not go far enough in fostering open communication after a medical error has occurred.

A 2010 study of state apology laws found that the laws of 34 states and the District of Columbia were not written in ways that foster open and honest communication between the physician and the injured party [40]. Of these jurisdictions, 25 states and the District of Columbia had “sympathy only” laws. This type of law prevents an expression of sympathy (e.g., “I’m sorry”) from being entered into evidence as proof of malpractice. However, an [explanation](#) of the cause of the error and admission by the person at fault *could* be used at trial as evidence of malpractice. Only six states have laws protecting expressions both of sympathy and of fault; only three protect expressions of sympathy and an explanation of why the error occurred [40]. Furthermore, only nine states even require physicians to disclose an error to the patient, although hospital accrediting bodies such as the Joint Commission do in general terms require disclosure to patients. The Joint Commission Standard RI.2.90 states: “Patients and, when appropriate, their families are informed about the outcomes of care, treatment, and services that have been provided, including unanticipated outcomes” [41].

The interplay between CRPs and a given state’s legal landscape surrounding malpractice reform (e.g., damage caps) and evidentiary standards (e.g., apology laws and protection of peer review), is complex and a full discussion of the many ways in which individual state laws affect CRP implementation is beyond the scope of this article. However, in general terms, certain state laws are believed to threaten CRP implementation. Sage and

colleagues aver, "Consequently, changes to malpractice law and procedure might play a useful role in convincing providers and insurers to adopt CRPs.... Lack of motivation is a greater risk in states such as Texas and Washington that have less malpractice litigation; risk aversion is a bigger problem in states with more and more costly litigation, such as New York, Alabama, and Illinois" [42]. CRPs provide a system for physicians to discharge their ethical obligation to communicate honestly with patients. Even outside the context of a CRP, physicians should understand that patients are less likely to sue when they believe they have been dealt with honestly. Furthermore, attorneys, as a practical matter, rarely introduce apology-related information as evidence during trial because doing so contradicts the narrative of the physician as uncaring. However, these trends are not absolutes, and limited evidentiary protection of physician disclosure likely stymies open and honest conversation (thereby necessitating the development of CRPs) [42].

While CRPs require buy-in from an entire health system, a grass roots effort to encourage open communication after an adverse event began in 2005, inspired by the Lexington, Ky, VA approach. This advocacy organization, called Sorry Works!, aims

to encourage physicians, hospitals, and insurers to think differently about the medical malpractice crisis... [and] want[s] healthcare, insurance, and legal professionals to realize the solution was in their hands (as opposed to a legislature) by simply developing disclosure and apology programs that pro-actively heal everyone injured by an adverse event [43].

Sorry Works! has developed commercially available toolkits to train health professionals about disclosure. However, buy-in from the medical community is still a challenge outside an organized CRP. For example, in 2015 Medscape polled 4,000 physicians, including oncologists, about their experience with medical malpractice lawsuits, asking them if apologizing "would have helped avoid or mitigate a malpractice claim" [44]. Only 2 percent of male physicians and no female physicians reported feeling that an apology would have helped. However, the survey did not ask about experiences with disclosure and apology training [44].

Although most medical malpractice litigation takes place in the context of state law, the federal government's desire to expand alternative approaches to traditional litigation in medical malpractice cases is expressly delineated in the Affordable Care Act (ACA), section 280g-15(a): "The Secretary is authorized to award demonstration grants to States for the development, implementation, and evaluation of alternatives to current tort litigation for resolving disputes over injuries allegedly caused by health care providers or health care organizations" [45]. The Agency for Healthcare Research and Quality (AHRQ) awarded a number of demonstration grants to institutions [46], which implemented novel ways of dealing with physician malpractice [29]. To date, the effects

of these novel approaches is unknown, and little has changed in the realm of medical malpractice under the ACA. However, the focus of many AHRQ demonstration grants is the development of CRPs.

Conclusion

Transparency and open communication with patients and families about medical errors allow medical practitioners to fulfill their ethical obligations to their patients even when outcomes are poor. These ethical obligations are grounded in the principles of autonomy, beneficence, and nonmaleficence and the virtues of compassion, courage, and honesty. Alternative dispute resolution models mitigate stress on clinicians, de-emphasize tendencies of health systems to try to hide fault, and help avoid dragging clinicians, patients, and others through time-consuming, costly, and reputation-damaging litigation. They can also mitigate the stress on patients and allow injured parties to receive reasonable compensation in a reasonable timeframe without the emotional and financial toll of the arduous litigation process. Creating a cultural, legal, and economic environment where communication and resolution programs can thrive may be an effective approach to creating a win-win situation for patients, physicians, and therefore society as a whole.

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Joseph S. Kass, MD, JD, is an associate professor of neurology, psychiatry, and medical ethics at Baylor College of Medicine in Houston, Texas, where he also serves as the assistant dean of students and the vice chair for education in the Department of Neurology. He is the chief of neurology at Ben Taub General Hospital.

Rachel V. Rose, JD, MBA, is a principal with Rachel V. Rose—Attorney at Law, PLLC and teaches bioethics in Baylor College of Medicine’s Center for Medical Ethics and Health Policy in Houston, Texas. She is co-editor (with Roberta L. Carroll and Peggy Nakamura) of the second edition of *Enterprise Risk Management Handbook for Healthcare Entities* (American Health Lawyers Association, 2013) and co-author (with Raymund C. King) of *The ABCs of ACOs: A Practical Handbook on Accountable Care Organizations* (American Bar Association, 2015) and (with Jonathan P. Tomes) *What Are...International HIPAA Considerations?* (American Bar Association, 2015).

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SECOND THOUGHTS

Undocumented Immigrants Face a Unique Set of Risks from Tuberculosis

Treatment: Is This Just?

Kelly A. Kyanko, MD, MHS, Jun-Chieh James Tsay, MD, MSc, Katherine Yun, MD, MHS, and Brendan Parent, JD

Consider a hypothetical scenario: Rosa, a 35-year-old healthy woman, visits a primary care physician at a community clinic for a routine checkup. She immigrated to the United States one year ago from Mexico, a country with a higher prevalence of tuberculosis (27 cases per 100,000 people) [1] than the US [2]. The primary care physician recommends screening for latent tuberculosis infection (LTBI) based on established guidelines. Rosa's purified protein derivative (PPD) skin test is positive, and she is started on isoniazid (isonicotinylhydrazide or INH). While taking it, she develops jaundice and lower extremity edema and is admitted to the hospital. She becomes critically ill and is found to have fulminant hepatic failure—acute liver failure—an iatrogenic consequence of INH treatment. A liver transplant would save her life, but Rosa is deemed not to be a good candidate for transplant because she is [poor, uninsured, and undocumented](#). She dies of liver failure and sepsis. Here we consider the unique risks that undocumented immigrants incur when accepting LTBI therapy and the physician's duty to disclose these risks, and we present policy and clinical solutions that would protect public health without placing undue burden on undocumented immigrants.

LTBI screening and treatment serve a dual purpose of preventing reactivation of tuberculosis (reactivation TB) in the individual and protecting public health by preventing the spread of TB in the community. Although 9,421 new TB cases were reported in the US in 2014, an estimated 11 million people in the US are living with LTBI [2, 3]. The lifetime risk of reactivation TB in those with LTBI is 10 percent, but identification and treatment of LTBI can reduce the risk of active disease by 60-90 percent [4-6].

LTBI screening and treatment are particularly important for immigrants from regions where TB is common. Over half (66 percent) of US LTBI cases occur in people born outside the US, and the case rate of reactivation TB among that group is about 13 times higher than among persons born in the US [2]. The Centers for Disease Control and Prevention (CDC) recommend LTBI screening for all immigrants from high-prevalence countries who have lived in the US for less than five years [7]. There were approximately 7 million new immigrants in the US in 2010, including approximately 2.7 million from three high-prevalence countries: Mexico, China, and India [8]. This population also includes 1.8-2.3 million undocumented immigrants [9, 10]; these are immigrants who

either entered the US without legal documentation or who entered legally but have since violated the terms of those documents. Over half of this cohort originated in countries with a high prevalence of TB [9, 10].

The antibiotic INH, the current preferred treatment for LTBI [7], carries a small but measurable risk of hepatotoxicity and hepatic failure. Up to 20 percent of patients receiving INH will have mild subclinical liver injury or elevated liver transaminases, and 0.2-0.5 percent will have serious and potentially fatal hepatotoxicity [5, 11]. The fatality rate for INH-induced hepatitis (5-10 percent) increases with age and alcohol use [12, 13]. Alternative regimens for LTBI include rifampin, which has less (but not zero) risk of hepatotoxicity as well as a shorter treatment duration (four to six months rather than nine months with INH) and improved adherence [14, 15]. However, it is not widely used due to cost, interaction with other medications, lack of large prospective randomized studies, and concerns over development of rifampin-resistant TB [16].

Treatment for INH-related liver failure might require liver transplantation, which is rarely available to undocumented immigrants [17, 18]. They are not explicitly ineligible for transplant [17], but ability to pay for posttransplant care, often understood in terms of whether one has health insurance, may be considered when determining transplant eligibility (i.e., listing decision) [19], and an estimated 63 percent of undocumented immigrants are uninsured [9]. Undocumented immigrants are not eligible for most federal, means-tested public benefits such as [Medicaid](#) or marketplace exchange insurance plans established by the Patient Protection and Affordable Care Act [20]. The only federal, means-tested public insurance program available to undocumented immigrants is [Emergency Medicaid](#), which does not cover organ transplantation [20, 21]. Accordingly, while all uninsured people face barriers to transplant listing, undocumented immigrants—by virtue of being ineligible for Medicaid and marketplace plans—are at a greater disadvantage.

Legal and Ethical Analysis

Physicians have the [responsibility](#) to act in the best interests of their patients. This responsibility requires that physicians help patients make decisions that align with their own values. Physicians who inform undocumented immigrant patients with LTBI about risks of INH-related liver failure but neglect to describe the likely unavailability of the only treatment for that failure (liver transplantation) are not informing members of this patient population to make decisions based on relevant risks. Since not all patients with LTBI have equal access to transplants, physicians who recommend INH treatment are asking undocumented uninsured patients to incur greater risk than persons eligible for transplantation. There is no ethical basis for this disparate treatment.

Physicians must also consider public health and safety in their practices, at least as mandated by state and federal law. Protecting public health is why patient

confidentiality, otherwise sacred, may be breached when the patient poses clear and substantial danger to himself or an identifiable third party [22, 23]. It is also why patients may be quarantined during a declared public health emergency [24, 25]. However, unless defined by statute (and most medical cases are not circumscribed by public health law), it is less clear when patient privacy, liberty, and autonomy may be superseded by public welfare. At present, treatment of LTBI is *not* required by public health departments but is instead strongly encouraged, both for the benefit of the person at risk of reactivation TB (which can, in and of itself, be fatal) and for public health [7].

These benefits—both to the patient and to society—must be considered in the context of the personal risks incurred when the patient undergoes treatment. Because liver failure is a risk of INH treatment and uninsured undocumented patients, due to their lack of health insurance, are generally ineligible for transplant, they are asked to put themselves at greater risk when accepting INH treatment than those eligible for transplant. Whereas other uninsured people, including US citizens, may be denied listing for transplant due to insurance status, they have the opportunity to change that status by participating in marketplace plans or spending down assets to qualify for Medicaid. Undocumented immigrants are unique in that, unless they find employer-sponsored insurance or live within a limited number of regions with nonfederal public insurance programs that are open to all low-income residents [18], they are, under the current framework, *uninsurable*.

With any public health effort that requires risk to the individual, we must weigh that risk against the risk to the public. The risk to undocumented immigrants with LTBI in undergoing INH treatment, while not high in probability, is high in severity (likelihood of significant harm and/or death) and far more severe than the risk to US-born persons, who are eligible for the treatment that would prevent INH-related liver failure from being lethal. This disparity in risk is unjust.

Recommendations

To [resolve this injustice](#), at a minimum, counseling of undocumented immigrants about INH treatment should include detailed discussion of the risks and benefits that they, in particular, are facing, so that they can make an informed choice about INH treatment. Their physicians should explain whether waitlisting for liver transplantation is available to them when presenting potential adverse effects of INH. There is a risk that some undocumented immigrant patients, after engaging in such an informed consent process, would refuse LTBI treatment, placing themselves, their families, and the public health at increased risk of TB. Policy-based solutions and use of a less hepatotoxic alternative agent, such as rifampin, may be required.

If we as a society want an efficacious system of preventing TB reactivation, we could continue to use INH for the majority of LTBI patients despite its risks. If we also want a

just system, we should protect all patients, regardless of immigration status, from possible adverse effects of INH. This would mean allowing undocumented immigrants with INH-related liver failure to be candidates for liver transplantation, regardless of ability to pay, and insuring them against liver transplant-related costs. In light of the overall efficacy of INH treatment for LTBI and the low probability of INH-related liver failure, such coverage should be feasible and not too costly. One option is to include liver transplant and subsequent posttransplant care for INH-related liver failure as services covered under each state's Emergency Medicaid program, for which undocumented immigrants are eligible. There is a precedent for this: although Emergency Medicaid is usually reserved for inpatient care and follow-up, some outpatient services for nonemergent but life-threatening conditions, such as cancer chemotherapy and radiation or dialysis for end-stage renal disease (ESRD), are covered by some state Emergency Medicaid programs [26].

Another alternative could be to create a TB treatment injury compensation program similar to the National Vaccine Injury Compensation Program (VCIP) [27, 28]. The VCIP, operated by the Health Resources and Services Administration (HRSA), was created not only to protect vaccine manufacturers from litigation and to ensure adequate access to vaccines and cost stability, but also to ensure that patients injured by vaccines have access to compensation [27]. The VCIP covers damages, wrongful death, lost wages, and medical expenses for a specific set of injuries related to vaccines and is funded by a \$0.75 tax on all vaccines [27]. The proposed TB treatment injury compensation program would only cover INH-related liver failure, and claims would need to be adjudicated rapidly if they were to influence decisions to transplant. A funding mechanism would need to be created; HRSA has set up a similar fund for compensation for injuries related to "countermeasures" (i.e., vaccines, medications, devices, or other items that are used to prevent, diagnose, or treat a condition, such as pandemic flu or Ebola, that constitutes a public health emergency or security threat) [29, 30]. Tuberculosis is not currently considered a public health emergency, but eliminating it is a national public health priority [31], and the precedent of ensuring compensation for those experiencing individual harm for the public good is now well established. Whether offering coverage through Emergency Medicaid or establishing a compensation fund, these policy-based solutions will require strong physician leadership and partnership with nonmedical organizations to be realized.

A clinical approach for clinicians and health systems to consider is the use of rifampin in LTBI treatment for undocumented patients. As mentioned earlier, rifampin has a lower risk of hepatotoxicity than INH [14, 15], and it is considered an acceptable alternative to the preferred INH regimen [7]. Lacking additional large prospective studies, it is too soon to state conclusively that rifampin is a safer choice than INH and similarly efficacious, but the data are promising [14] and a multicenter randomized control trial is ongoing [32].

The most significant barrier to rifampin for this population may be its cost; in the US, a 30-day supply of rifampin is about ten times as costly as INH [33].

Conclusion

There is no valid reason to ask undocumented immigrants to bear greater risk than US-born persons in the pursuit of eliminating tuberculosis in the US. Physicians should consider using rifampin over INH in LTBI treatment for undocumented immigrants, although even rifampin has a risk of acute liver failure. Whether treating with INH or rifampin, physicians have an obligation to disclose risks of the treatment until society is able to establish a mechanism to ensure equitable access to liver transplant for those with LTBI treatment-related liver failure.

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Kelly A. Kyanko, MD, MHS, is an assistant professor of population health and medicine at New York University School of Medicine and a primary care physician at Bellevue Hospital Center in New York City. Her research focuses on primary care transformation and use of out-of-network care in private insurance plans.

Jun-Chieh James Tsay, MD, MSc, is an instructor of medicine in the Department of Medicine within the Division of Pulmonary, Critical Care, and Sleep Medicine at New York University School of Medicine in New York City. Dr. Tsay’s current research interest is pulmonary diseases, specifically early stage lung cancer biomarkers.

Katherine Yun, MD, MHS, is an assistant professor of pediatrics at the PolicyLab at the Children's Hospital of Philadelphia and the Perelman School of Medicine at the University of Pennsylvania in Philadelphia. Dr. Yun's research focuses on health system navigation by Bhutanese and Latino immigrant families in Philadelphia.

Brendan Parent, JD, is the director of applied bioethics at New York University School of Professional Studies and a faculty affiliate of the Division of Medical Ethics at New York University Langone Medical Center in New York City. Previously, he was special legal advisor to the New York Task Force on Life and the Law. His research focuses on ethical issues in vascularized composite allograft transplants and in genetics technologies.

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Suggested Readings and Resources

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About The Contributors

Theme Issue Editor

Arina Evgenievna Chesnokova, MPH, is a third-year medical student at Baylor College of Medicine in Houston, Texas. Arina completed her masters of public health degree at Columbia University Mailman School of Public Health in 2011, where she developed a special interest in health law and public health ethics. Subsequently, she worked as a researcher at the Children's Hospital of Philadelphia PolicyLab. Her scholarly interests include reproductive health law and policy and geospatial components of health disparities.

Contributors

Lisa Campo-Engelstein, PhD, is an associate professor at the Alden March Bioethics Institute of Albany Medical College in Albany, New York, and the co-editor of *Oncofertility: Ethical, Legal, Social, and Medical Perspectives* (Springer, 2010). A bioethicist specializing in reproductive and sexual ethics and gender theory, she has been published in the *Journal of Clinical Oncology*, *Science*, *The Hastings Center Report*, and *The American Journal of Bioethics*. She earned her PhD in philosophy from Michigan State University and completed a postdoctoral fellowship with the Oncofertility Consortium at Northwestern University.

Douglas Carlson, JD, practices law in Illinois, with offices in Chicago, and is the long-standing counsel of the Accreditation Council for Graduate Medical Education (ACGME). He is interested in accreditation law, including its interaction with antitrust law.

Frank A. Chervenak, MD, is the Given Foundation Professor and chair of the Department of Obstetrics and Gynecology at Weill Cornell Medical College in New York City. He is writing (with Laurence B. McCullough and John H. Coverdale) a book titled *Professional Ethics in Obstetrics and Gynecology*.

John H. Coverdale, MD, MEd, is a professor of psychiatry and behavior sciences in the Menninger Department of Psychiatry and Behavioral Sciences at Baylor College of Medicine in Houston, Texas. He is writing (with Frank A. Chervenak and Laurence B. McCullough) a book titled *Professional Ethics in Obstetrics and Gynecology*.

Sasha Davenport is a senior research fellow at the Initiative for Neuroscience and Law at Baylor College of Medicine in Houston, Texas, where she researches neurocognitive risk assessment testing methods and predictive criminal recidivism models. A Ronald E.

McNair Scholar with a BA in forensic psychology from the John Jay College of Criminal Justice, her work on neuropsychology and warfare has been presented at the U.S. Military Academy at West Point.

Barry DeCoster, PhD, is an assistant professor of philosophy and bioethics in the Humanities and Communication Department at the Albany College of Pharmacy and Health Science in Albany, New York. His research focuses on problems in health care ethics and the philosophy of science and medicine, including bioethical critiques of medicalization, LGBT health, and virtue ethics (with a focus on collaboration and political resistance).

Greg Dolin, MD, JD, is co-director of the University of Baltimore's Center for Medicine and Law, where he is also an associate professor of law. His scholarship centers on patent law and, in particular, on how the patent regime affects innovation in bio-pharmaceutical areas, and has led to a number of scholarly articles, presentations, amicus briefs, and Congressional testimony.

David Eagleman, PhD, is a neuroscientist at the Baylor College of Medicine and the founder and director of the Center for Science and Law in Houston, Texas. He is also the creator and host of PBS's *The Brain* and the author of *Incognito: The Secret Lives of the Brain* (Pantheon, 2011). His areas of research include plasticity, time perception, vision, synesthesia, and the intersection of neuroscience with the legal system.

Abigail English, JD, is the director and founder of the Center for Adolescent Health and the Law in Chapel Hill, North Carolina. A lawyer, researcher, and advocate for the rights of vulnerable young people, her research and advocacy focus on health insurance and public financing of care for adolescents and young adults, consent and confidentiality protections, and sexual and reproductive health care.

Hilary E. Fairbrother, MD, MPH, is the associate director of undergraduate medical education and the co-clerkship director of the Emergency Medicine Selective for the Ronald O. Perelman Department of Emergency Medicine at New York University School of Medicine in New York City. She specializes in health care policy, ethics, and simulation education.

Christi J. Guerrini, JD, is a research instructor at the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, Texas, and a graduate student at University of Texas School of Public Health. Her research focuses on health privacy, human research subject protections, and the intersection of intellectual property law and genomics.

Gabe Haarsma, PhD, is a postdoctoral programmer at the Center for Science and Law in Houston, Texas, where he spearheads big data analysis of millions of crime records to analyze and visualize patterns of crime and recidivism.

Howard Henderson, PhD, is an associate professor in the Department of the Administration of Justice at Texas Southern University in Houston, Texas, where he also serves as the director of the graduate program. His research examines the psychometric properties of offender behavioral risk needs assessment.

Anna Jarman is a research fellow at the Center for Science and Law and an analyst with Shell Technology Ventures in Houston, Texas. She studied psychology and cognitive science at Rice University and has worked in public policy and research for over five years.

Joseph S. Kass, MD, JD, is an associate professor of neurology, psychiatry, and medical ethics at Baylor College of Medicine in Houston, Texas, where he also serves as the assistant dean of students and the vice chair for education in the Department of Neurology. He is the chief of neurology at Ben Taub General Hospital.

Christine Khaikin, JD, is the advocacy coordinator at the MergerWatch Project in New York City.

Kelly A. Kyanko, MD, MHS, is an assistant professor of population health and medicine at New York University School of Medicine and a primary care physician at Bellevue Hospital Center in New York City. Her research focuses on primary care transformation and use of out-of-network care in private insurance plans.

Julie Lewis, MPH, is a public health and policy expert at the National Family Planning and Reproductive Health Association in Washington, DC, where she directs the Confidential and Covered, a multi-year research project investigating how Title X-funded family planning providers can maintain patient confidentiality while mitigating revenue loss.

Mary Anderlik Majumder, JD, PhD, is an associate professor of medicine at the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, Texas. Her research focuses on the ethical and social implications of new genomic technologies and ethical and policy questions related to problems of cost, quality, and access in health care.

Laurence B. McCullough, PhD, holds the Dalton Tomlin Chair in Medical Ethics and Health Policy in the Center for Medical Ethics and Health Policy at Baylor College of Medicine in Houston, Texas. He is writing (with Frank A. Chervenak and John H. Coverdale) a book titled *Professional Ethics in Obstetrics and Gynecology*.

Thomas J. Nasca, MD, is the chief executive officer of the Accreditation Council for Graduate Medical Education (ACGME), a professor of medicine at Sidney Kimmel Medical College of Thomas Jefferson University in Philadelphia, and a senior scholar in the Department of Education at the University of Illinois College of Medicine at Chicago. A career-long educator, investigator, and educational administrator who is board certified in internal medicine and nephrology, Dr. Nasca is interested in the ethical basis of the relationship between medicine and society, especially as it applies to medical education.

Pablo A. Ormachea, JD, is a postdoctoral fellow at Baylor College of Medicine in Houston, Texas. He also serves as co-director of the Center for Science and Law, where he manages several data-driven projects sharing the goal of constructing a cost-effective legal system with higher utility and lower cost. He holds a JD from Harvard Law School.

Brendan Parent, JD, is the director of applied bioethics at New York University School of Professional Studies and a faculty affiliate of the Division of Medical Ethics at New York University Langone Medical Center in New York City. Previously, he was special legal advisor to the New York Task Force on Life and the Law. His research focuses on ethical issues in vascularized composite allograft transplants and in genetics technologies.

Natalie Ram, JD, is an assistant professor of law at the University of Baltimore School of Law and the associate director of the law school's Center for Medicine and Law. Professor Ram received her JD degree from the Yale Law School and her AB degree from Princeton University, and she previously clerked for Supreme Court Justice Stephen G. Breyer and for Judge Guido Calabresi of the US Court of Appeals for the Second Circuit. She writes about matters at the intersection of bioethics and the law and has been published in *Harvard Law Review*, *Columbia Law Review*, *Stanford Law Review*, and other law journals.

Rachel V. Rose, JD, MBA, is a principal with Rachel V. Rose—Attorney at Law, PLLC, and teaches bioethics in Baylor College of Medicine's Center for Medical Ethics and Health Policy in Houston, Texas. She is co-editor (with Roberta L. Carroll and Peggy Nakamura) of the second edition of *Enterprise Risk Management Handbook for Healthcare Entities* (American Health Lawyers Association, 2013) and co-author (with Raymund C. King) of *The ABCs of ACOs: A Practical Handbook on Accountable Care Organizations* (American Bar Association, 2015) and (with Jonathan P. Tomes) *What Are...International HIPAA Considerations?* (American Bar Association, 2015).

Jeff Sconyers, JD, is a senior lecturer in the Department of Health Services in the School of Public Health and an adjunct member of the faculty of the School of Law at the University of Washington in Seattle. He serves on the ethics committees of Seattle Children's Hospital and Swedish Medical Center First Hill, served as the first General

Counsel at Seattle Children's Hospital, and is a past president of the Washington State Society of Health Care Attorneys and former member of the Board of Directors of the American Health Lawyers Association. A frequent speaker on legal ethics, and public health law and practice, he is also founding co-editor-in-chief of the *Washington Health Law Manual* and co-author of "Pediatric Risk Management" in *Risk Management Handbook for Health Care Organizations* (Jossey-Bass, 2009).

Nicolle K. Strand, JD, MBioethics, is a senior policy and research analyst at the Presidential Commission for the Study of Bioethical Issues in Washington, DC. She is a graduate of Wellesley College and the University of Pennsylvania School of Law and received her masters of bioethics degree from the University of Pennsylvania. She has conducted work, both independently and for the Bioethics Commission, on genetic privacy, incidental findings, and neuroscience ethics and policy.

Tyler Tate, MD, is a fellow in pediatric bioethics at the Treuman Katz Center for Pediatric Bioethics at Seattle Children's Hospital and the Division of Bioethics in the Department of Pediatrics at the University of Washington School of Medicine in Seattle. He is also a practicing pediatrician in the University of Washington Division of General Pediatrics and Hospital Medicine. He is pursuing a master's degree in bioethics and is broadly interested in the intersection of theology and medicine, the ethics of suffering, value judgments in health care, the medical humanities, and global health.

Jun-Chieh James Tsay, MD, MSc, is an instructor of medicine in the Department of Medicine within the Division of Pulmonary, Critical Care, and Sleep Medicine at New York University School of Medicine in New York City. Dr. Tsay's current research interest is pulmonary diseases, specifically early stage lung cancer biomarkers.

Lois Uttley, MPP, is the founder and director of the MergerWatch Project and is on the faculty in the health advocacy master's program at Sarah Lawrence College in New York City. Formerly the director of public affairs for the New York State Department of Health, she has also served as president of the Public Health Association of New York City.

Richard Weinmeyer, JD, MA, MPhil, is a senior research associate for the American Medical Association Council on Ethical and Judicial Affairs in Chicago. Mr. Weinmeyer received his master's degree in bioethics and his law degree with a concentration in health law and bioethics from the University of Minnesota, where he served as editor in chief for volume 31 of *Law and Inequality: A Journal of Theory and Practice*. He obtained his first master's degree in sociology from Cambridge University. Previously, Mr. Weinmeyer served as a project coordinator at the University of Minnesota Division of Epidemiology and Community Health. His research interests are in public health law, bioethics, and biomedical research regulation.

Katherine Yun, MD, MHS, is an assistant professor of pediatrics at the PolicyLab at the Children's Hospital of Philadelphia and the Perelman School of Medicine at the University of Pennsylvania in Philadelphia. Dr. Yun's research focuses on health system navigation by Bhutanese and Latino immigrant families in Philadelphia.