Stemming the Standard-of-Care SPRAWL

Clinician Self-Interest and the Case of Electronic Fetal Monitoring

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Care that serves the patient's best interests and care that is recognized as good medical practice do not always coincide. The best-interests standard is based on evidence about outcomes, but the legal standard of care is often based on evidence about typical physician practice and can be influenced by other factors. Aligning the standards requires identifying the many sources of the legal standard.

The "best interests of the patient" standard—a complex balance between the principles of beneficence and autonomy—is the driving force of ethical clinical care. Clinicians' fear of litigation is a challenge to that ethical paradigm. But is it ever ethically appropriate for clinicians to undertake a procedure with the primary goal of protecting themselves from potential legal action?

Complicating that question is the fact that tort liability is adjudicated based on what most clinicians are doing, not the scientific basis of whether they should be doing it in the first place. In a court of law, clinicians are generally judged based on the "reasonably prudent" standard: what a reasonably prudent practitioner in a similar situation would do. But this legal standard can have the effect of shifting the medical standard of care—enabling a *standard-of-care sprawl* where actions undertaken for the primary purpose of avoiding liability reset the standard of care against which clinicians will be adjudicated. While this problem has been recognized in the legal literature,[1] neither current ethical models of care nor legal theory offer workable solutions.

One of the best examples of the conflict between evidence-based medicine and common clinical practice is the use of electronic fetal monitoring. EFM is used in obstetrics and midwifery to protect an unborn baby by monitoring fetal heart rate during labor for evidence of oxygen deprivation. But empirical research consistently confirms that routine, continuous EFM use for healthy women with healthy pregnancies offers no long-term clinical benefit for babies when compared to intermittent methods

Kayte Spector-Bagdady, Raymond De Vries, Lisa Hope Harris, and Lisa Kane Low, "Stemming the Standard-of-Care Sprawl: Clinician Self-Interest and the Case of Electronic Fetal Monitoring," *Hastings Center Report* 47, no. 6 (2017): 16-24. DOI: 10.1002/hast.781

of monitoring.[2] In fact, continuous EFM *adds* clinical risks for women and babies by increasing the chances of a cesarean or an instrumental vaginal delivery (that is, one using instruments, such as forceps or a vacuum).[3] Yet, despite strong evidence and professional guidelines that argue against the use of EFM for healthy pregnancies, the practice persists.

It is often assumed that one of the main reasons that clinicians still use continuous EFM in healthy pregnancies is concern for their own liability.[4] We know that physicians generally overestimate their risk of being sued,[5] but the risk of being sued as a gynecologist is, in fact, much higher than average. A recent survey, done by the American Congress of Obstetricians and Gynecologists, found that 74 percent of obstetricians and gynecologists have a professional liability claim filed against them during their career, with an average of almost three claims per clinician in their lifetime. Almost half reported making a change to their practice in response to liability concerns, with 17 percent increasing their performance of cesarean deliveries specifically.[6] More than half of insurance payouts in high-risk areas of practice involve an allegation that a clinician could have, but did not, prevent fetal neurological damage—most often allegedly caused by a delay in treatment for fetal distress.[7] Malpractice lawsuits not only negatively affect medical practice but also have been found to cause "significant mental effects" in defendant clinicians.[8]

But is there a way to adequately balance the right of laboring women to avoid unnecessary, perhaps harmful, interventions with legitimate concerns of clinicians to protect themselves from liability? The dominant ethics model in maternity care focuses on autonomy and beneficence-based obligations to the patient and (possible) beneficence-based obligations to the baby—leaving no room for the interests of providers.[9] Alternative models of perinatal ethics, including care-based models, stress the importance of identifying a patient's relevant social contexts during ethical deliberations,[10] but they do not suggest that the social contexts of the *clinician* have a role in determining appropriate patient care.

Some scholars have promoted an explicit informed-consent process that painstakingly details all risks and benefits—down to the "results and limitations of the trials"[11]—as a potential solution to the lack of evidence-based recommendations in labor and delivery generally[12] and EFM specifically.[13] But the informed-consent process is crafted so as to try to disclose risks and benefits in a way that is balanced and tailored to the individual patient. Ideally, there should be enough information to enable a patient to make a knowledge-based decision, but not so much that the patient is confused or overwhelmed.[14] Use of the informed-consent process to rationalize interventions that are not evidence-based inappropriately shifts the burden of deciding whether to use a medical intervention of dubious clinical value from the clinician to the patient—and does nothing to counteract unjustified risks to the patient. The informed-consent process is not absolution from a clinician's fiduciary duty to make recommendations that are in the patient's best interest.

The complex interests at play in this tension between evidence-based medicine and practice—and the inadequacy of the current legal, ethical, and professional structures in responding to the tension—demand further exploration, and the routine use of continuous EFM is a useful case study. It shows the need to resolve clinicians' liability concerns without putting patients in the position of being asked to consent to a medical intervention that the clinician has recommended, at least in part, out of his or her own self-interest.

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Electronic Fetal Monitoring

EFM was introduced to obstetric care in the 1960s as an alternative to intermittent auscultation (listening to fetal heart tones with a stethoscope or fetoscope in prescribed intervals). The underlying assumption behind EFM was that continuous data generation would improve accuracy in assessing fetal well-being and improve neonatal outcomes by, for instance, reducing the risk of cerebral palsy. Indeed, in certain high-risk pregnancies, it does just that. EFM allows for continuous assessment of the fetal heart rate as displayed electronically on monitors in a patient's room as well as in a central monitoring station. These data can also be printed out for concurrent or later review as a "monitor strip." By contrast, intermittent auscultation is written down as a single number at regular intervals.

EFM quickly became the standard of care even though there was no clinical evidence regarding its efficacy in the prevention of neonatal neurological damage in an average, healthy delivery. By 1976, more than 75 percent of physicians believed that it should be used in all labors.[15] By 2011, 89 percent of women who gave birth in the United States experienced EFM, and 80 percent of that use was continuous.[16]

The medical community initially predicted substantial benefits to women and children from the use of EFM. In 1969, it was estimated that EFM could save as many as 20,000

babies a year and reduce injuries for babies by 50 percent.[17] Investigators did not subject EFM to clinical trials for several years—partially out of concern for depriving women in the control arm of an intervention that was assumed to be valuable.[18]

However, post-hoc research on EFM has found that its routine use for healthy pregnancies offers almost no clinical benefit. When compared to intermittent auscultation, EFM provides no reduction in the overall risk of perinatal death. It is associated with a reduction in neonatal seizures, but this reduction has not been associated with improved long-term outcomes.[19] Only two studies, by the same first author, have demonstrated evidence of benefit,[20] but this research has been criticized for its poor methodology (including lack of statistical power and flaws in randomization).[21]

EFM also has notoriously high inter- and intraobserver variability in the interpretation of monitor strips.[22] As a 2006 editorial in the *New England Journal of Medicine* put it, "Although electronic fetal heart-rate monitoring is technically easy to implement, interpretation of the data is subjective, difficult to standardize, and poorly reproducible."[23] Even computerized interpretation has not been able to reduce or improve reliability: a recent trial comparing computerized to clinician interpretation of EFM data found no difference in neonatal outcomes.[24]

EFM use can also increase risks to a pregnant woman and her baby. The most significant risk is a higher likelihood of an instrumental delivery or surgical delivery (via cesarean section).[25] A nonreassuring fetal heart rate—as demonstrated via EFM with its attendant high false positives—is the leading indication for a cesarean section.[26] Cesarean deliveries are in turn associated with greater iatrogenic harms to women (including infection, hemorrhage, injury to organs, extended hospital stays and recovery time, and increased maternal mortality) and babies (including premature birth, respiratory distress, and a low Apgar score summarizing health).[27] Once a woman has undergone a cesarean section, she is more likely to undergo another in any subsequent pregnancy, which puts her at an increased risk for abnormal invasion of the placenta into the uterus with potential for catastrophic hemorrhage.[28] A woman who undergoes or attempts a vaginal birth after a cesarean is also at a higher risk for uterine rupture and related sequela for herself and the baby.[29]

Policy statements from U.S. maternity care providers' professional organizations now widely agree that EFM is overused. Acknowledging that continuous fetal monitoring offers no clinical benefit for healthy laboring women over intermittent fetal monitoring, three major professional associations—the American Congress of Obstetricians and Gynecologists, the American College of Nurse-Midwives, and the Association of Women's Health and Neonatal and Obstetric Nurses—caution their members against the routine use of continuous EFM for low-risk women. ACNM recommends intermittent auscultation for healthy women with low-risk pregnancies,[30] AWHNON recommends that "a woman's preferences and clinical presentation" should guide the choice "with consideration given to . . . least invasive methods,"[31] and ACOG states that either EFM or intermittent auscultation is acceptable for patients without complications. All three professional organizations have also endorsed guidance regarding EFM data interpretation categories in an attempt to improve consistency.[32]

Many assume that EFM remains the standard of care, in spite of the evidence and professional guidelines, because clinicians are worried about liability if they do not use it. As scholars have noted, EFM "remains the norm, even in the face of clinical trials showing no better results . . . because in the current obstetrical climate, every patient is approached as a potential litigant"[33] and every birth is approached as a potential disaster.[34]

Interestingly, some have suggested that the use of EFM has had the counterintuitive effect of *increasing* the rates of medical malpractice litigation.[35] Before the advent of EFM, there was a low rate of obstetric malpractice. In the era of intermittent auscultation, clinicians called before the court could testify that they did not hear anything indicating fetal intolerance of labor—there was no objective measurement or record to challenge that assertion. EFM provides that record—which can then be interpreted, after the birth, by appointed experts on both sides of the trial.[36] An EFM monitor strip can be introduced as exculpatory evidence, showing that a reasonable practitioner had no cause to be concerned about fetal distress or ordered a cesarean section at the appropriate time. But it can also be used as evidence of malpractice. Outcome bias inevitably affects expert testimony, and the judge—without specialized training—is the final arbitrator of the admissibility of an expert's argument.[37]

Most healthy women are unaware that continuous EFM offers no clear, documented benefit to themselves or to their baby or that ambiguities in the interpretation of its data might lead to idiosyncratic decisions about the management of their labor that could increase the risk of harm—even from well-meaning and trusted clinicians. The continued use of EFM thus illustrates two emblematic problems in clinical care: (1) its routine use is hypothesized to be for the benefit of the clinician—in other words, the result of liability concerns rather than medical ones—which (2) violates the clinician's obligation of beneficence to the patient, by increasing risk without equivalent medical benefit.

The Law in Context

Concern for litigation in obstetric and midwifery care, as discussed above, is indeed justified, as it is a highly litigated area of practice.[38] Maternity care providers can be held

liable for injuries during labor and delivery in many ways. In addition to suits on behalf of the child,[39] damages can be established on behalf of the mother of a stillborn baby.[40] If a child dies after birth, the clinician can be held liable for a negligently performed delivery on behalf of the child and the mother—even if the baby was born at such an early age it had no chance of surviving.[41]

Clinicians reasonably want to protect themselves against claims of liability, but whether there is an ethical way to do so is unclear. Indeed, 93 percent of practitioners who are paying the highest rates of liability insurance (including obstetricians and gynecologists) reported practicing "defensive medicine,"[42] defined as diagnostic testing or care provision "motivated in whole or in part by the desire to protect oneself from a malpractice suit or to serve as a reliable defense if such a suit occurs."[43] Additionally, very few market pressures discourage expensive, and possibly unnecessary, medical interventions. In the case of maternity care, for example, providers receive a global payment for the bundle of services associated with a vaginal or cesarean birth: the decision to specifically use EFM (or not) does not affect reimbursement rates.

But clinicians have a duty of care toward their patients to act in their best interests. If by not fulfilling that duty they cause injury to their patient, they can be held liable for medical malpractice.

Two specific sources of clinician liability are particularly relevant to EFM. The first is liability for an injury that results from an intervention for which proper informed consent was not obtained. The second is liability for failing to meet the clinical standard of care. Informed consent cannot fully protect a clinician from not meeting the standard of care; likewise, acting fully within the standard of care cannot shield a clinician from not participating in the process of informed consent. Both types of liability are relevant to our analysis of the complex interests at play in clinician self-interest and evidence-based medicine.

Obtaining informed consent for obstetric care. The ethical goals of beneficence and autonomy are notoriously difficult to reconcile, and this tension is clearly visible in the medical informed-consent process. In soliciting the informed consent of a patient, a clinician is tasked with enabling both the patient's health and autonomy. Often, these duties conflict—as in the case of a patient refusing an intervention a clinician believes to be the best thing for the patient's health.

Informed consent in obstetric care is particularly complex because of the unique intersection of the interests of the patient, the baby, and the clinician. It is also unique, however, in that there is often ample opportunity during prenatal care to fully discuss the risks and benefits of potential interventions.

The legal standard of informed consent not only requires that the patient have the capacity to consent but also compels the clinician to disclose enough information to enable that consent to be informed.[44] Thus, the clinician's duty to disclose during informed consent is broader than simply answering patients' questions—clinicians are obligated to prospectively volunteer the information that patients need to make their decisions.[45]

But the theory behind informed consent also acknowledges that the clinician and the patient come to the table with unequal information. Patients cannot match a clinician's years of education and experience in a single informed-consent conversation. This lack of information is among the reasons they are seeing the medical expert in the first place.[46] If there is a medical consensus about a recommendation or patients cannot understand the complex data underlying the recommendation, then patients defer to their health care provider. Cesarean by maternal request represents only a small percentage of deliveries, and notable variation in delivery mode exists across hospitals and low-risk pregnancies—strongly suggesting that individual clinician practice is the driving force behind the high cesarean rate.[47] Similarly, a recent study into perspectives of midwives found that "merely improving a woman's knowledge about fetal monitoring options is not the only or the most important feature when attempting to offer an informed choice. . . . [M]idwives may consciously or unconsciously exert control over women's choices because their knowledge is often viewed as legitimate by women."[48] This is why the principle of beneficence is fundamental to clinical care—the assumption must be that the clinician is acting in the best interests of the patient. It protects the patient from "mandatory autonomy"[49] and allows patients to weigh information given to them by their clinician—with the assumption that it was selected to support their best interests.

A clinician's disclosure obligations are therefore also *limited* by beneficence obligations, such as considering "the patient's mental and emotional condition" when deciding the appropriate information to disclose.[50] About half of U.S. states require

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clinicians to disclose what the "reasonable practitioner" would generally reveal during the informed-consent process, while the other half require the clinician to reveal what the "reasonable patient" would want to know. The *physician-based standard* is based on the customary practice of a reasonably prudent practitioner in the same medical specialty and geographic area. The *patient-based standard* is based on an objective and hypothetical patient and what he or she—or at any rate what the jury thinks he or she—would want disclosed.[51] Neither standard is tailored to the information that a specific patient sitting in front of the clinician would want to know. Such a *subjective patient-based standard* was proposed by the Oklahoma Supreme Court in 1979[52] but has since been largely abandoned as impractical.[53]

Consider these legal standards in the obstetric context: women are more likely to report a positive birth experience when they feel as though they engaged in shared decision-making.[54] Women also report wanting to know the risks and benefits of other potential interventions such as induction, epidural, or cesarean.[55] In comparison to the beneficence-balanced informed-consent standard, some scholars argue, informed consent to obstetric care should mean a thorough and individualized weighing of every risk and benefit of each intervention, including

> the name and nature of a particular procedure or drug and why she should allow the procedure or drug to be administered to her and her unborn child; the dangers or disadvantages to her and her unborn child of not receiving the procedure or drug; the existence of other methods of treatment available to her and her unborn child; the risks and benefits of these other methods to her and her unborn child; the benefits or advantages of this procedure or drug as it applies to both her and the unborn child; an understanding of her physician's experience in providing these procedures or drugs to people similarly situated; her prognosis, and the likely outcome to her and her unborn child following the administration of the procedure or drug; and all areas of uncertainty (gaps in medical knowledge) associated with the administration of the drug or procedure that are known by the physician.[56]

Scholars have argued that women having a healthy birth should also give consent specifically for the fetal assessment method employed, in other words, continuous EFM or intermittent auscultation.[57]

Another challenge to respecting the laboring woman's autonomy is that clinicians often describe the competing interests of a second "patient" during labor: the baby. Giving birth is a socially and culturally laden balance of the rights of the woman and the interests of the child. In fact, many doctors agree with the statements "For the safety of the baby, the maternity care team sometimes need [*sic.*] to override the needs of the woman" and "Encouraging women to have more control over their childbearing compromises safety."[58] Doctors' believing that they may justifiably overrule a woman's preferences during childbirth is a "startling exception" to the modern conceptions of consent and autonomy in clinical care.[59]

Just as applying the legal informed-consent standards in practice is complex, establishing in court that a practitioner failed to meet them is hard as well. While a tort generally requires an injury that was caused by a breach of a duty of care, courts rarely recognize the lack of informed consent as an injury in and of itself.[60] As a result, patients who believe that their informed-consent process was faulty must establish not only that they were injured but also that, had they been informed that that specific injury was a risk, they would not have consented to the intervention to begin with.

For example, a patient would have to demonstrate that she suffered a bladder injury during her cesarean section and that, had she been informed during the consent process that a cesarean could result in a bladder injury, she would not have agreed to the surgery (in other words, that she had not accepted the risk). The jury would then deliberate about whether the potential for a bladder injury would be something that the reasonable patient would want disclosed (in a state using the patient-based standard) or that a reasonable practitioner would have disclosed (in a state using the physician-based standard). If the risk of bladder injury should have been disclosed and was not, then the patient has a case. Thus, because of the complexity of establishing both the appropriate standard for informed consent in the clinic and a lack of informed consent in a court, much obstetric litigation surrounds the second type of liability: failure to meet the standard of care.

Standard of care for obstetric litigation. In addition to enabling fully informed consent, clinicians are generally required to provide patients with the "standard of care." The law does not generally prospectively require a specific standard of care; it is based on evidence of customary practice or what a reasonable practitioner would do in a similar situation. Some recognized exceptions exist for interventions followed by a "respectable minority" or "general practice of reasonable physicians utilizing the same treatment."[61] A tort law assessment of whether there has been a breach of the duty of care will usually be measured against the standard of care.

The problem is that standard of care is not synonymous with best or evidence-based medicine. This is true not just for the case of EFM in obstetrics and midwifery but for a wide range of clinical specialties. For example, a review of ten years of multidisciplinary articles in the *New England Journal of Medicine* concluded that 146 (40.2 percent of) studies found that the standard of care was

no better or worse than the practice it replaced.[62]

The current tort liability system does not adequately grapple with these fluctuations in evidence-based medicine. In a 2003 example from the specialty of internal medicine, a medical resident in Virginia was brought to trial for failure to perform a prostate-specific antigen test in a fifty-three-year-old man. This patient was later found to have incurable advanced prostate cancer. The resident had discussed the risks and benefits of PSA testing with the patient, and the patient had declined it. While many, if not most, clinicians order a PSA test for all men over fifty without asking their patients for specific consent, the practice is considered controversial because of risks such as false positives, which can cause intervention-related sequelae (much like EFM). Nearly all national guidelines recommend a shared decision-making model for PSA testing, just as the resident in this case had followed. But the patient's attorney argued that, despite guidelines based on evidence-based medicine, the standard of care among the majority of physicians in Virginia was PSA testing without consent—and therefore that was the standard to which the resident should be held. The jury held the residency program liable for one million dollars.[63]

The law provides some protections for the level of scientific evidence that may be introduced in court. Under the *Daubert* standard, information must be relevant to the case and scientifically reliable.[64] Legal scholars have argued that the reason that *Daubert* has failed to exclude EFM evidence from the courtroom is that professional organizations that agree that continuous EFM is not an improvement for a healthy pregnancy do not do enough to actively discourage its use; rather, they call for improved methods of interpretation of its data.[65] ACOG, for example, has yet to issue a clear statement that EFM monitoring strip data are unreliable in the courtroom.[66] Given the inadequacy of the tort system to respond to these tensions, several states have tried to carve out a safe harbor from liability for guideline-based practices, but such tort reform efforts have thus far proven ineffective.[67]

Tort liability's requirement of an injury poses a special challenge to establishing a claim for failure to follow the standard of care in delivery. A baby who has been allegedly unnecessarily harmed or dies is an emotionally compelling case for the jury. At the same time, cesarean section—such as one ordered in response to EFM data that the doctor believed indicated nonreassuring fetal status—is considered the standard of care. It is hard for a woman to argue successfully that a cesarean that her clinician claims was indicated was, in and of itself, an injury requiring redress. Put more bluntly by one obstetrician, "You don't get sued for doing a C-section. You get sued for not doing a C-Section."[68] In obstetric malpractice claims, "underperformance" of a cesarean section is the basis of a lawsuit ten times more often than failure to proceed vaginally.[69]

Gibson points out that when an intervention is recommended, not because of its evidence base, but because it is perceived to be the standard of care, it creates a "doctrinal feedback loop" where it then *becomes* the standard of care—a concept we describe as a "standard-of-care sprawl." Gibson explains, "Suppose a potential tortfeasor [a person who commits a tort] wants to steer clear of conduct that would fall short of the reasonable care metric. Because it is difficult to know ex ante what conduct will qualify, he or she may overcomply (i.e., exercise more caution than the standard actually demands). If others behave the same way, however, that degree of caution will become the new measure of negligence; if everyone is exhibiting the same overcautious level of care, the 'ordinary person" has become overcautious as well. What was once overcompliance therefore becomes mere compliance.'"[70]

In the case of EFM, clinicians are caught in something of a catch-22: continuous EFM data are ambiguous proof of nonreassuring fetal status, but failure to produce such data after the technology has diffused into practice can be construed as failure to meet the standard of care. In fact, the lack of an EFM monitor strip for the court to consider significantly increases the likelihood of settlement or a verdict in favor of the plaintiff.[71] As one obstetrician argued, "It is one thing to avoid introducing a new technique because trials show it to be ineffective. It is another to abandon a widely used method that is not only perceived to be useful, but records of which are carefully scrutinized and sometimes pivotal in expensive legal actions."[72]

Gibson agrees that this is the key tension at play in the use of EFM for healthy pregnancies, saying that its "use can no longer be considered overcompliant behavior; it is instead merely compliant, such that its absence would expose the practitioner to liability."[73] In other words, even though EFM has limited medical indication for its use and then only for high-risk pregnancies, because the medical malpractice standard is based not on evidence of *effectiveness* but evidence of *practice*, clinicians can be

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found liable for violating a standard not supported by data. Standard-of-care sprawl occurs when the standard of care in practice diverges from the standard of care as defined by best evidence. And, as we have seen in several case studies,[74] this is a process that can then serve to redefine the standard of care courts will use to judge clinical decisions.[75]

The Inadequacy of Beneficence and Autonomy

Current ethical paradigms are not adequate for grappling with the tensions we have described. Certainly, considerations of clinician interests are not entirely foreign to the clinical ethics enterprise. The American Medical Association's "Principles of Medical Ethics" recognizes a physician's responsibility to "patients first and foremost, as well as to society, to other health professionals, *and to self*" (emphasis added).[76] However, as the *Principles* also points out, clinicians' primary commitment is to their patients, and examples abound in which physicians are explicitly expected to put the best interests of the patient above their own, such as when clinicians take care of patients with infectious diseases.[77] Recommending or ordering an intervention because of liability concerns, particularly insofar as that intervention involves additional risk or actualized harm for a patient, is a violation of these norms.

This issue is particularly difficult in cases that involve the diffusion of new technology and situations where clinicians are particularly concerned about legal liability. There is need for more research on and attention to the sociological motivations behind the persistence of medical interventions when the evidence against their use is strong and consistent. Recently, the American Board of Internal Medicine launched a "Choosing Wisely" initiative in which national medical organizations are challenged to ask their providers to "choose wisely" before ordering a test or procedure that is overused in their field.[78] In 2014, the American Academy of Nursing selected the automatic initiation of continuous EFM during labor for women without risk factors as one of its areas for improvement.[79]

As discussed, some scholars who have grappled with this ethical morass generally, and with EFM specifically, have proposed that patients be given highly detailed information as part of the consent process.[80] However, this solution does nothing to protect patients from the underlying harm of a procedure and undermines the ethical and legal protections of informed consent that require information tempered by physician discretion.

Laboriously disclosing the details of an intervention, particularly with the specific intent of discouraging its use in cases where the clinician believes the standard of care is inappropriate, is not an ethical solution. The duty to beneficence cannot be replaced by the duty to warn or caveat emptor (buyer beware), with patients simply put on "notice" for all risks during the informed-consent process and left to decide best care themselves.[81]

Autonomy was neither envisioned nor exists as a solution to a conflict with clinicians' obligations of beneficence. You cannot cure diminished beneficence with *more* autonomy—the very point of beneficence is that patients are inherently dependent and vulnerable and do not have the capacity to hear, learn, and comprehend all of the medical information potentially relevant to their care. This is why patients entrust clinicians with their health in the first place. Clinicians must not abdicate their professional knowledge obligation to the patient and insist that patients instead guide practice. Furthermore, it is wholly inappropriate for clinicians to ask patients to consent to interventions that are not evidence based but are instead inspired by the clinicians' conscious or subconscious liability concerns; doing so confounds the very autonomy interests that the informed-consent process is supposed to protect. That burden is not the patient's to bear—to place it on her during the informed-consent process is not resolution but transference.

Courts also have found that clinicians have a fiduciary obligation to patients—one that requires them to disclose information regarding personal interests that could affect their judgment.[82] Fiduciary obligations, while most often cited in financial cases, can be recognized in other situations where one party (the fiduciary) possesses "superior knowledge and related skills,"[83] and the other party is in a position of trust or vulnerability. For example, in *Moore v. Regents of the University of California* (in which a patient sued his physician for the collection and use of his clinical biospecimens in lucrative research without his permission), the court found that there had been a breach of the physician's fiduciary duty. It argued that the physician had an obligation to disclose to Moore his interest in using Moore's biospecimens for his future research at the time he recommended Moore submit to clinical testing.[84]

Moore v. Regents argued that informed consent must include not only the risks of the procedure but also the "personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment" in recommending that procedure.[85] Under this understanding, the concept of fiduciary obligations may well even *require* that clinicians disclose when they are recommending a procedure undertaken primarily as a defense to a possible medical malpractice suit. An interest in avoiding legal liability can be argued to be a conflicting interest influencing the clinician's recommendations, perhaps implicating a physician's fiduciary responsibility to disclose it.

Standard-of-care sprawl is a predictable consequence of an excess of caution and concern with legal liability in medicine. Examination of the way EFM has altered the standard of care in labor and delivery highlights the difficulty of finding satisfactory ethical and legal responses to this

and similar phenomena. Providing a surfeit of information to patients may seem to be a solution, but it is contrary to the legal and ethical principles embodied in the informed-consent process. Legal solutions, such as calling for EFM to be considered "junk science" under the *Daubert* standard or protecting physicians who practice evidence-based medicine contrary to standard practice, have generally proven ineffective.[86] Finding a workable way to rein in standard-of-care sprawl will require collaboration between ethicists, clinicians, social scientists, lawyers, and patient advocates. The combined expertise of intradisciplinary teams is necessary to identify the organizational, cultural, medical, and legal sources of the problem and will allow us to understand what drives the diffusion of technological innovations in medicine and what contributes to the persistence of clinical practices when the evidence against their use is strong and consistent. Ethnographic research, including observations and interviews with clinicians, patients, and administrators, can uncover the clinical and nonclinical factors that set the standard-of-care sprawl in motion. This evidence can then be used to rethink the role of fiduciary obligations and the management of conflicts of interest in the informed-consent process.

In this article, we present a theoretical analysis, but we must not forget that the harms of this trend are real and profound for patients and practitioners alike.[87] We who aspire to provide the best standard of care for our patients have a professional obligation to ensure that such care reflects both their autonomy and welfare interests.

Acknowledgments

We would like to thank Elizabeth Bogdan-Lovis, Edward B. Goldman, Nicholson Price, Patti Zettler, and the Regulation and Innovation in the Biosciences 2017 workshop for their comments on earlier versions of the article.

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