Informed Consent and the Use of Transvaginal Synthetic Mesh

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In 2008 and again in July of this year, the U.S. Food and Drug Administration (FDA) issued safety communications regarding the use of transvaginally placed surgical mesh. These FDA communications have been the subject of much discussion in the literature. One issue raised by these communications and in the medical literature is the matter of informed consent. Informed consent is an established bioethical principle in modern health care, but it is evolving. The legal interpretations of informed consent are also in flux. A review of contemporary ethical and legal elements of informed consent is presented as it relates to the use of medical innovation, with a focus on transvaginally placed surgical mesh.

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In 2008 and again this year, the U.S. Food and Drug Administration (FDA) issued a safety communication regarding serious complications associated with the use of transvaginally placed surgical mesh.[1,2] Although the 2008 FDA announcement included warnings on mesh use in both the repair of pelvic organ prolapse (POP) and urinary incontinence, the most recent announcement focuses only on its use in the setting of POP surgery. Despite nearly equal numbers of medical-device reports to the FDA for mesh used in POP repairs as in incontinence surgery, the FDA "continues to evaluate the literature for stress urinary incontinence surgeries using surgical mesh and will report on that usage at a later date."[2] These warnings have sparked considerable debate among physicians treating female pelvic floor disorders. As noted in the FDA warnings and in the professional literature, one issue is the matter of informed consent.[3–5] Citing a lack of credible treatment outcomes for these products,[6–8] some maintain that informed consent cannot be obtained.[4]

Current surgical treatments for female pelvic floor disorders may or may not use synthetic mesh, yet its use is not new. Gynecologists have used surgical mesh to repair POP for at least 30 years. These early applications were in the setting of an abdominal sacrocolpopexy[9]; yet the use of vaginally placed artificial mesh in the 1990s, before industry support, came with hope of improvements in invasiveness, durability, and operative time. One of the earliest industry-developed uses of transvaginally placed mesh was the ProteGen Sling (Boston Scientific). The rise and hard fall of this procedure are described elsewhere,[10] but this procedure was the predicate for the tension-free vaginal tape (Ethicon Women's Health and Urology). Despite differences in the materials used, medical application, and surgical technique, tension-free vaginal tape was the predicate device for various industry-based procedures designed to repair POP. What is referenced in this brief genealogy is the FDA's 510(k) process that "clears" products for human medical use based on predicate devices. This has been the topic of numerous lay and professional articles, including a recent Institute of Medicine report that called the process "flawed."[11] On the matter of informed consent and transvaginally placed mesh, an important message from this genealogy is that no mesh used in gynecology is FDA-"approved" with human safety or efficacy data.

The concept of patient informed consent does not appear in any classical documents on medical ethics.[12] The philosophical notions of individual dignity, autonomy, and self-determination referenced in informed consent arise from the Protestant Reformation, with subsequent application to medicine in the 20th century.[12] Informed consent litigation often is

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cited to begin with the 1914 case of *Schloendorff v Society of New York Hospital*. The judge in that case believed that treatment consent was mandatory because, "every human being of adult years and sound mind has a right to determine what shall be done with his own body."[13] Such a statement references self-determination, but, although the bioethics community and the courts mostly agree on the importance and generalities of informed consent, the details are ill-defined and evolving.

Patients do not consent to a variety of surgical materials and techniques used everyday. Surgical mesh is a material much like suture that could be used with varied results by different surgeons or with different techniques. Why should a material such as mesh elicit anything unique in regard to informed consent? When is a material or technique a substantial fact that needs to be disclosed to a patient? What is in view in the most recent FDA safety communication regarding mesh is a surgical approach because mesh used in an abdominal application is not cited. The matter of informed consent in regard to surgical mesh use in gynecology, however, should not be seen as narrowly restricted to only its use in prolapse surgery or in transvaginal placement. That would be missing the forest for the trees. Nothing in discussing the ethical and legal considerations of informed consent is specifically unique to transvaginally placed surgical mesh. The nature of informed consent should be blind to the thing disclosed, yet that nature is becoming harder to understand in an age of increasingly transparent treatment outcomes.

The purpose of this article is to provide the reader with a background that will assist in navigating the question of what constitute those substantial facts that deem disclosure. In regard to informed consent, the dilemma in using surgical mesh in gynecology or any medical innovation is that, although its use may be legal, it also can be unethical. Teasing apart the related ethical and legal aspects of consent can reveal that adoption of this (or any) innovation can be right and wrong, legal and illegal. This duality underscores the complexity this article aims to explore.

BACKGROUND

Based on the quantity and quality of clinical and theoretical evidence, as well as the risks and benefits of alternative therapies, all medical care can be sorted into three categories: 1) effective care, 2) preference-sensitive care, and 3) supply-sensitive care.[14] Effective care includes those medical services that are supported by well-articulated medical theories with strong clinical evidence of efficacy. Preference-sensitive care is where two or more treatment alternatives exist with differing risks and benefits, yet the ratio of those risks and benefits does not favor a best option. Given few comparative efficacy data favoring any one kind of treatment (to include at least pessary, physical therapy, surgery or observation), the care of POP should be considered preference-sensitive.

Care that is determined by the supply of clinical resources available is supply-sensitive, and it accounts for more than half of all Medicare spending.[15] Unlike the case in effective care or preference-sensitive care, demand for supply-sensitive care increases with increasing capacity of the local health system. A timely example of supply-sensitive care appeared in a recent study showing that hospital acquisition of a surgical robot increased the number of patients having radical prostatectomies.[16] The message with supply-sensitive care is that, with more doctors, more beds, or more robots, there is more treatment but not necessarily better clinical outcomes for patients. Conceivably, industry-developed surgical procedures increase the supply of surgeons treating what that procedure aims to remedy. In the treatment of POP, this predicts that more industry-developed procedures render more surgeons, and with more surgeons more surgeries. Acknowledging that the supply of POP surgeons appears to be less than the projected demand[17] does not necessarily assert that disease demand is driving care given the known variation in surgical care (women in the south are nearly twice as likely to have POP surgery as are women in the northeast[18]) and the large number of asymptomatic cases. The goal of marketing is to drive demand. Whether POP awareness qualifies as marketing is debatable, but, in the context of informed consent, any supply-oriented care nevertheless raises questions about the intent and voluntariness of treatment.

The widespread adoption of transvaginal synthetic mesh systems for the treatment of POP is based on generally poor measurable outcomes of traditional surgical repairs of pelvic floor dysfunction.[8] Whether or not all these measures are clinically relevant is an important question[19] that could meaningfully alter how poorly or well traditional repairs perform.[8] It is also unclear what effect individual surgeon technique has on surgical outcome. Nevertheless, the perceived outcomes of traditional repairs and the poor reproducibility of these repairs across diverse surgeon experience drove the demand for industry-developed "kit" repairs.

The rapid evolution of industry-developed surgical kits has hindered investigation; new versions are introduced before a study can be rallied or com-

pleted. Recently, however, randomized surgical trials have been conducted comparing traditional surgical prolapse repairs with a synthetic mesh kit. The results of these studies do document more complications and adverse postoperative events relative to traditional repairs but differ on whether there were improvements in subjective or objective POP outcomes.[20,21] There is evidence supporting the use of transvaginally placed surgical mesh for at least anterior vaginal wall prolapse repair.[6,7,21] If transvaginal mesh does render some beneficial therapeutic outcomes in the hands of some surgeons, are the safety concerns regarding mesh best directed at a surgical technique, or should they be directed at how some surgeons approach the adoption of medical innovation? In either case, the matter of informed consent is relevant.

INFORMED CONSENT AND BIOETHICS

As already mentioned, informed consent is a 20th-century concept.[12] Classical documents on medical ethics are silent with respect to any notion of informed consent. For example, the Hippocratic Oath demanded physicians perform their duties "calmly and adroitly, concealing most things from the patient … revealing nothing of the patient's future or present condition."[22] This view of things has given way grudgingly to state legislation designed to increase patient involvement in medical decision-making.[23] After World War II, the Nuremberg Code highlighted the concept of consent in human research, although it must be recognized that there are important differences between treatment and research consent. A clinical consent balances benefit and burden, whereas a research consent does not. Although the intervention proposed in a clinical consent carries risk, it is balanced against a perceived, more likely therapeutic benefit. Research interventions offer no known therapeutic benefit over standard care, otherwise there is no equipoise. A research participant accepts the risks of involvement without known benefit, hence the greater imperative to disclose those risks. Research ethics also spawned the ideas of Principlism with the Belmont Report in 1979, these ideas in time filtered into clinical practice. In research or clinical settings, informed consent gives a nod to the principle of autonomy, acknowledging that individuals are self-determined and free to decide what constitutes the good life with the liberty to act accordingly.[24]

Autonomy is the easiest of the four principles to understand and recognize; however, it is not the only principle relevant to informed consent. Beneficence, nonmaleficence and justice all temper the limits of autonomy. Physicians should not only respect patients but also seek their good and avoid their harm. Likewise, according to justice, individual good is balanced against societal good.[25] In the case of transvaginally placed surgical mesh, it may offer benefits valued by some physicians, but the possibility of individual patient harm must be in balance. In regard to justice, one might argue that simplifying pelvic surgery, as in industry-developed surgical kits, undermines surgeon skill that in turn harms individual health vis a vie societal health. In a real sense, informed consent offers a pause to consider these and other ethical issues for the patient and physician.

At a basic level, the elements of informed consent can be understood to be disclosure, competency, and choice. Adding understanding and voluntariness is a further refinement.[25] Some emphasize the importance of avoiding deception or coercion, although avoidance of coercion could be seen as operationalizing respect for autonomy.[25] Given the difficulties in defining or measuring a patient's understanding, the legal considerations of informed consent have focused on disclosure.[26] Voluntary choice (ie, choice without coercion) is what is in question if disclosure and understanding are in doubt. In matters of mesh, what should be disclosed?

Heather Gert proposes a model of disclosure that centers on avoiding surprises.[27] Essentially, this model presents disclosure as more comprehensive than traditionally imagined and not just about those facts and values that instigated a patient's choice. I would want to know how long I will wear a cast or be out of work, even though that information does not necessarily influence my treatment choice. What comes as a surprise to a patient ("I have to wear the cast how long?") may not be a surprise to the physician; hence, such information should be disclosed. A surprise to both the patient and physician is not material to disclosure. The simplicity of this model is appealing, but what surprises a physician varies with experience and expertise, making materiality illusive. Gert's criticism of two other disclosure models (the Reasonable Person model, which will be discussed later, and Howard Brody's Transparency model) identifies the same problem of defining materiality.[27] Furthermore, all models suffer from hindsight bias–after an adverse event, what is material can change.[28]

Avoiding deception is foundational to the morality of informed consent according to Gert, Culver, and Clouser.[29] Failing to inform a patient of an act on them constitutes deception.[27] What is disclosed should be adequate, where adequacy is defined as that which "any rational person would want to know before making a decision."[29] This definition is akin to

the legal paradigm used in defining the reasonable patient, but what defines rationality? Predicting another person's values defies the contemporary study of values (ie, axiology).[12] Rationality, therefore, is defined by the individual, and disclosure short of "full information introduces the possibility that a patient will make some choice other than the one closest to their own ranking of harms . . . Thus partial disclosure can, from the patient's point of view, cause significant avoidable harm, which explains why less than full disclosure on the part of the physicians is deceptive and morally unacceptable."[29]

Insofar as the moral work of Gert, Culver, and Clouser's view of the "common morality" is done through the avoidance of intentional harm (Gert, Culver, and Clouser's view of harm is understood very broadly to include death, pain, disability, loss of freedom, and loss of pleasure), the moral justification of informed consent on the grounds of deception is understandable. It is self-evident that, short of full information, the completely efficient decision occurs only by chance and is unrecognizable. The information deficit between patient and physician cannot be mitigated fully; therefore, physician good intent aligned with good action (validated by published and personal evidence) is the only recourse. Intent, however, is not measurable, and good action often is limited by inadequate validation. Acknowledging that the treatment of pelvic floor problems should be preference-sensitive, the distribution of treatment should be random and, to the extent it is not (as has been shown for POP across the United States[18]), can reflect distorted physician intent and thus compromised patient voluntariness. This possibility is tempered by other competing explanations, but the possibility nevertheless raises concern, as does the infrequent evidence validating good action.

Returning to the matter of using synthetic vaginal mesh in the repair of POP, according to the model of avoiding surprises, given the widespread awareness of the FDA concerns about the use of synthetic mesh, any application of it for the treatment of a pelvic floor problem should be disclosed. Any application of mesh would include uses not mentioned by the 2008 or most recent FDA warning, such as mid-urethral sling surgery or abdominal sacrocolpopexy. Furthermore, if Dr. Weber's and others', including the FDA's, conclusions that there is insufficient evidence regarding the use of transvaginal synthetic mesh are not disclosed, this can constitute deception. Admittedly, such deception is not likely overt; nevertheless, not providing information that is clearly relevant to the treatment decision is an omission that can, in effect, deceive a patient. Per Dr. Weber, "what remains unknown is the true magnitude and consequences of (the general risks of mesh placement) and other complications. Therefore, patient's have no way of balancing the unknown magnitude of these risks against the potential benefits." This statement aligns closely with what Gert, Culver, and Clouser have said regarding avoiding harm and the moral problem of deception.

There are sincere concerns with disclosing "any" application of any medical innovation. There are differences in the type of suture used across traditional suture-based prolapse repairs, but do these differences deem disclosure? Should a patient be given a choice regarding a product wherein the knowledge necessary to weigh its risks and benefits exceeds the expectations of a layperson? These are difficult questions. As noted above, there always will be knowledge deficits between physician and patient, between physician and physician, and between medical device manufacturers and physicians. Better validation of efficacy mediates these relationships, but too little of this has been gathered so far. Professional ethics also mediate these relationships, but this has not been a focus in the debates surrounding the use of transvaginal mesh. Besides, "ordinary" differences across surgeon technique do not provoke FDA safety communications, hence this alone deems disclosure. Individual surgeon awareness and disclosure of his personal outcomes as well as those published mollifies the threat of deception. This ideal speaks to both good intent and good action. Collection of individual surgeon outcomes, as will be noted later, is a significant challenge.

The ethical theory behind informed consent is complex and diverse but finds its footing in the notion of respect for persons. Today, at times, the notion of autonomy has overshadowed other important principles in ethics; nevertheless, its application in medicine, starting only in the 20th century, has been both welcomed and troubling. The consideration of this topic thus far has touched only on the matter. Nevertheless, what can be said in regard to the use of transvaginally placed synthetic mesh, a surgical innovation in gynecology, is that claims against it in regard to informed consent do have some legitimacy in current bioethical theory. That theory manifest in law will be discussed next.

INFORMED CONSENT AND THE LAW

As early as 1767, there are court discussions regarding about what the "reasonable physician" should inform a patient.[30] As already mentioned, though, informed consent litigation begins with Mary Schloendorff in

1914.[22] Schloendorff underwent a hysterectomy, having consented only to an "ether examination." Judge Benjamin Cardozo writes in this case, "a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages."[13] Today, assault and battery in the context of health care delivery generally applies only when no consent has been obtained in a nonemergent clinical setting.[22] Current informed consent litigation focuses on negligence, which is the failure to perform what is seen under like circumstances to be the duty of a reasonable person.

The term "informed consent" first was used in the 1957 California case of *Salgo v Leland Stanford Jr. University*.[22] The Salgo court concluded, "a physician violates his duty to his patients and subjects himself to liability if he withholds any facts … necessary to form the basis of an intelligent consent by the patient to the proposed treatment."[31] This decision initially appeared to establish a patient-based standard for disclosure but ultimately referenced physician discretion.[32]

The 1972 Washington, DC, case of *Canterbury v Spence* was landmark.[32] Jerry Canterbury was 19 years old when he underwent a surgery to correct a ruptured disc. Dr. Spence performed the surgery that left Canterbury with walking difficulty, urinary incontinence, and bowel paralysis. The suit maintained that these risks were not disclosed, and, indeed, Dr. Spence confessed that, when asked about the surgical risks, he replied, "not any more than any other operation."[22] Defending this position, Dr. Spence maintained that communicating the risks of surgery might dissuade a patient from pursuing needed therapy. Notably, this argument is a common justification for limiting the scope of informed consent, yet it undoubtedly threatens self-determinism. Supply-sensitive care can be an expression of medical paternalism that, although well-intentioned, upholds a view of health not defined by the patient but imposed by the physician. Physicians can act as patient surrogates in making health decisions and not undermine patient autonomy, but those situations need to be understood explicitly by both physician and patient.

The court ultimately found in favor of Dr. Spence, but not before ushering in the objective patient-based standard. Later, a twist on this theme was established by the Oklahoma Supreme Court in the 1979 case of *Scott v Bradford*.[32] In this case, the court pushed disclosure to the subjective patient-based standard. The difference between these two patient-based standards is in who is the reference for disclosure adequacy. In *Canterbury v Spence*, a hypothetical objective patient is referenced, whereas in *Scott v Bradford*, the individual patient in question is the reference. (The subjective patient-based standard best aligns with the moral theory of Gert, Culver, and Clouser, yet what individuals value is not static. We do not know what we do not know; hence, sorting values often is understood only in retrospect.) Operationalizing both of these standards is difficult, but the difference is, in theory, significant.

Approximately half the states in the United States recognize the physician-based (or malpractice) standard, whereas the other half recognize some kind of patient-based (or material risk) standard.[32,33] The differences in these disclosure standards are substantial. An editorial in the *Journal of the American Medical Association* featuring an unpublished trial highlighted the failings of the physician-based standard.[34] In that case, a physician was litigated successfully for practicing evidenced-base care because he was referenced against a physician community that did not.[34] On the other end of the care spectrum, evidenced-care patterns can be so honored as to restrict patient choice and plausibly undermine informed consent.[35]

What a plaintiff needs to prove to litigate an informed consent suit successfully depends on the disclosure standard. In those states that recognize a physician-based standard, expert testimony is required to show disclosure was outside of the "standard of care." In states in which the patient-based standard is recognized, it must be shown that knowledge of the risk in question would have changed the patient's treatment choice. From here, plaintiffs must demonstrate three additional elements: 1) the physician failed to disclose what he had a duty to disclose (ie, was negligent), 2) harm occurred as a result of the therapy choice, and 3) had disclosure been more complete, to include the risk of the harm endured, a different choice would have been made.[33] A plaintiff can have a difficult time successfully demonstrating all of these elements, particularly outside of a procedure. Indeed, 88% of informed-consent cases relate to surgical procedures, with nearly 90% of those being related to failure to disclose pertinent risks.[33] Along these lines, the current and past FDA warnings on transvaginal mesh identify risks[1,2] that should be disclosed.[3] The other approximately 10% of cases, however, involve consent topics that show how informed-consent litigation is trying to conform to bioethical theory, casting a new and different light on the use of medical innovation.[33]

TWO INFORMATIVE CASES

In addition to the cases discussed by Mucowski et al,[3] the following two related cases are relevant to how informed-consent litigation is evolving. The first case asks whether all surgeons are equally physically capable of performing a given surgery. The second case asks whether all surgeons are equally skilled at performing a given surgery. Both cases poke at the awkward question of whether surgeons are equivalent. The extent to which surgeons are not equivalent affects informed consent. To be clear, there are many more than two cases that have relevance to the ways informed-consent litigation is evolving, but these two are particularly disquieting.

Hidding v Williams (1991): Physician Capacity

In general, the court view of disclosure is that it be increasingly more candid and comprehensive. It is the expectation of the court that treatment specifics, alternatives, risks, and benefits are discussed in increasing detail. In situations where treatment is innovative, even more disclosure is required.[26] Along these lines, a physician's personal experience and past outcomes are seen as relevant to disclosure.[26] In the Louisiana case of *Hidding v Williams*, Dr. Williams was prosecuted successfully for failing to disclose his problems with alcohol. The adverse event that occurred to Mr. Hidding was recognized to be remote (1 in 200,000 cases), but the court found that, "failing to disclose his chronic alcohol abuse Dr. Williams violated the informed consent doctrine."[36] Leblang[26] expressed concern for what this ruling might say about any surgeon-related physical or mental capacity question in performance of a given procedure but states, "to date it does not appear that any appellate court has ruled on whether or not such a duty exists." In would seem, however, that, because a physician's capacity to perform surgery clearly could affect a patient's decision to pursue surgery with a given surgeon, a precarious precedent is set that echoes contemporary bioethics.

Johnson v Kokemoor (1996): Physician Experience

In 1996, Wisconsin plaintiff Donna Johnson sued Dr. Kokemoor after repair of a brain aneurysm.[22] The surgery left Johnson with incomplete quadriplegia. The suit maintained that Dr. Kokemoor was not surgically negligent but that he did not disclose the risks of surgery adequately. Those risks included to what extent risk might have been less if other, more experienced surgeons performed the surgery. The Wisconsin Supreme Court ruled in favor of Johnson, concluding that Dr. Kokemoor was obliged to inform how surgeon experience might mitigate the surgical outcome.[22] Six years later, the New Jersey Supreme Court ruled in a similar case that "background and experience (are) part of the informed consent disclosure."[22] In 2010, a Wyoming case reiterated this same theme.[33]

Linking with contemporary bioethics, these cases follow the theme that individual physician capacity and experience with the treatment proposed is material to disclosure. "These cases seem to foreshadow a universe within which healthcare providers could be required to reveal a wide variety of personal information to patients."[22] It is understandable to expect disclosure of physician-specific treatment outcomes, but this necessitates that physicians track and record such things. Tracking treatment outcomes is only the beginning; it would need to be decided how those outcomes are recorded and how they are communicated meaningfully to a patient. There are many hurdles to recording and reporting individual clinician treatment outcomes meaningfully, and, given dwindling reimbursements, it is not clear how this ideal could be implemented in all medical practices. Furthermore, clinician personal information potentially includes diverse topics that, with disclosure, might undermine patient trust in their physician.[22] These details remain to be clarified. Of note, what the FDA and others[3] recommend physicians disclose does not include physician-specific treatment outcomes. In light of poor population-based outcomes[6–8,20] and claims that individual surgeon experience matters in regard to the risks of transvaginal mesh use,[37] physician-specific treatment outcome disclosure appears warranted.

IMPLICATIONS AND RECOMMENDATIONS

Conflicts of interest are never eliminated; they are at best managed. Physicians are rewarded for what they do to patients, and that reward easily can become the overriding endpoint. This obvious conflict of interest has plagued medicine through history, pressing the development of professional codes of ethics. There are many reasons for a physician to adopt medical innovation into patient care that have nothing to do with promoting the patient's good. The place to start in navigating ethical conduct as it relates to medical innovation is to ask, "why do I want to use this innovation?" If the answer to this question is anything but "for the patient's good," a bias may be at work that needs to be managed. The next question for the physician to ask would be, "but how do I know it

is for the patient's good?" The answer to this question will take significant effort to identify what is collectively and personally known regarding the predicted outcomes in using this medical innovation as it specifically relates to a given patient. Should there be no collective or personal evidence for the innovation, this is a setting of equipoise and research is the only ethical way forward. Should there be some evidence collectively but none personally, this is a setting for disclosure. These two questions resonate with good intent and good action and with those sentiments that we all review in decision making–what are the facts, and how do I value them. These two questions are not easy to answer, and the answers are never static; however, considering them in the bright light of professional oversight improves the honesty of our responses.

Use of transvaginally placed synthetic mesh as an innovation started with good intentions–better treatment outcomes for women with POP. What is not always morally clear is the execution of that intent. The clinician must intend to avoid deception so that voluntary treatment choice, particularly in the setting of preference-sensitive care, is honored. Weber's concerns regarding informed consent in use of transvaginal synthetic mesh have merit. Mucowski et al's rebuttal[5] also has merit insofar as these products can be used legally and informed consent can be performed. Informed consent can be obtained in the absence of adequate clinical evidence, but this setting is research because risk is not balanced against known benefit. Patients cannot easily attain what physicians know about medicine, and physicians cannot know what patients value. This informational asymmetry requires that both the physician and the patient are intentional about clarifying to the other what will render the most patient-centered treatment choice. It is recognized that patient-centered care will, at some point, need to be balanced against societal needs to uphold distributive justice. That topic, however, is beyond the scope of this article.

Although Mucowski et al[3] are overall reassuring to physicians who chose to use these products, this review of bioethical theory and current consent litigation should cause introspection. To comply with both the ideal bioethical and legal senses of informed consent, physicians would know the evidence regarding the products they use and would likewise be prepared to follow and disclose their own outcomes in use of these adopted products. Indeed, Britain's National Institute of Clinical Excellence recommendations on the use of transvaginal surgical mesh include ensuring patients understand the uncertainty about long-term results and complications associated with these products and physician auditing and review of clinical outcomes of patients in whom mesh has been used.[38] To follow these recommendations speaks of good intent, reflecting the principle of beneficence that girds the fiduciary relationship between patient and physician. It also reduces the possibility of unintended patient deception, upholding respect for persons or autonomy. These issues of informed consent are not unique to the use of transvaginal synthetic mesh. All of medicine is constrained by these same issues and controversy. As patients become more independent of physician-based medical information in an age of greater transparency of treatment outcomes, litigation likely will continue to shape informed consent to a closer approximation of bioethical theory with good and bad effect.

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