2017

Inform and Consent: More Than Just "Sign Here"

Jody L. Madeira
Indiana University Maurer School of Law, jmadeira@indiana.edu

Kathryn Coyne
Wright State University

Ami S. Jaeger MD
BioLaw Ethics Institute

J. Preston Parry MD
University of Mississippi Medical Center

Steven R. Lindheim MD
Wright State University

Inform and consent: more than just "sign here"

Informed consent, which blends law, medicine, and bioethics, is a multifaceted process to obtain patient permission and enhance patient understanding before health care interventions. Insufficient informed consent may even constitute battery or medical malpractice, for reasons articulated in the landmark 1914 New York case *Schloendorff v. Society of New York Hospital*. Adoption of the informed consent doctrine was sluggish but reached a groundswell following the Nuremberg Code, the well-known 1972 case *Canterbury v. Spence*, and news coverage of the Tuskegee syphilis study. The result was the 1978 Belmont report, which remains a gold standard for ethics and health care and identifies three core principles in patient care and research (1). These include respect for persons (i.e., autonomy), beneficence, and justice. Applying these principles to medical care requires practitioners to carefully consider patient needs and appropriately discuss the balance of risks, benefits, and alternatives with patients. Through informed consent, practitioners ensure the Belmont report's legal obligations and ethical guidelines are met, improving patients' rights and autonomy.

Assisted reproductive technology (ART) procedures have numerous ethical and medical considerations, including self-determination, affirmed through proper informed consent. Because procreative therapy is more elective than emergent, and multiple treatment paths may be reasonable, autonomy through informed consent is all the more important with ART. However, clinicians are increasingly responsive to productivity concerns, and it can be easy to emphasize rote consent procedures over understanding for efficiency's sake, leading to rapid communication of facts without adequate time for patients to process information or ask questions. Informed consent within ART is unique because procreative autonomy is intended to create offspring that have no say in the process. Some elements remain similar to "standard" medical procedures: patients consented for ART are educated about the nature of the proposed treatment, including potential benefits, risks, and alternatives, before voluntarily proceeding (2). Because ART procedures have multiple medical risks, ethical considerations, and fundamental legal consequences like establishing and relinquishing parental rights, informed consent discussions are often inseparable from written affirmation of intent. Given the complexity and length of most informed consent documents, the American Society of Reproductive Medicine (ASRM) has created a model template to streamline the process for ART patients/couples (2). While ASRM has encouraged the use of this standardized consent form, there are no universal informed consent requirements for ART facilities. Many states, however, require specific consent language for third-party procedures.

Regardless of format, informed consent document(s) can have unintended or unanticipated consequences. The most serious of these consequences is that completing these forms may become little more than a rote exchange or ritual, rather than a meaningful exchange. If patients feel they need to sign these forms to access treatment, the process becomes transactional—a mere opportunity to "step up and sign." If this occurs, interpersonal dynamics within informed consent could muddle the content and meaning that these forms were intended to convey and perhaps undermine consent's effectiveness and entire purpose. Thus, informed consent documents may embody a host of contradictions. Foremost, they stand for two processes that are fundamentally at odds with one another: [1] a meaningful educational interaction that facilitates understanding and protects the patient and [2] a purposeless bureaucratic or legalistic ritual that ostensibly protects doctors and not their patients. In addition, they brim with information on risk and harm, but their orderliness and standardization may inadvertently lull patients into complacency.

Many reproductive endocrinologists, health psychologists, and attorneys have expressed concern over whether patients understand the balance of ART's risks, benefits, and alternatives. Strong, collective effort in our field to promote understanding has not eradicated the concern that many women and their partners undergo ART without truly knowing or appreciating the implications of ART for personal health and the health of children born through the process. Multiple questions often arise. Could lax informed consent requirements or lengthy, jargon-filled documents detract from patient understanding? Do patients sign consent papers without reading them and without asking questions? Are patients simply overwhelmed with information? Are consent documents dismissed as bureaucratic or one-sided, knowing that the documents can't be negotiated and are thus irrelevant? Do patients find medical jargon describing ART too complex or intimidating? Are patients so eager to conceive a child that they discount the gravity of the risks or low probability for a desired outcome? Do such concerns also weaken informed consent's legal protections for medical practitioners?

In other disciplines, medical practitioners have begun to employ a variety of multimedia patient education and consent tools to improve patient comprehension. These tools range from DVDs to narrated computer applications to computer tutorials complete with quizzes, which can be accessed in clinical settings or from personal computers or mobile devices (3). Older studies of multimedia aids have yielded equivocal results regarding their superiority to traditional paper consents, since poorly designed aids (those that are too tedious or long) can negatively impact patient education (4). More recent research including randomized studies has linked multimedia interventions to greater patient enjoyment; improved patient knowledge, comprehension, and recall; improved physician-patient relationships; lower anxiety; and faster learning (5). Multimedia interventions can penetrate beyond the boundaries of traditional paper consents, incorporating audio elements and narration, visual cues, animation, and diagrams. Patients can even create individualized consent experiences, obtaining more information through additional content.

In addition to enhancing patient understanding, multimedia platforms may prove to be more efficient than traditional paper consents, improve doctor-patient relations, and possibly conserve valuable practice resources. Applications

can rapidly reinforce information through quizzes offering immediate patient feedback, allowing physicians to identify and target particularly confusing topics. Efficient interventions may conserve time formerly spent conveying basic information. A multimedia intervention may also help in ensuring consistency across providers and patients, potentially decreasing the feeling that consent is a bureaucratic routine while simultaneously encouraging patients to be more involved with their care. Moreover, research suggests that digital mediums likely strike patients as less bureaucratic, enhancing trust for patients who tend to disregard paper consent forms on the grounds that they safeguard physicians' legal interests over patients' educational needs (5). Done properly, these can meet the systematic, expeditious, and cost-effective standard advocated by ASRM (2).

One potential downside to the multimedia process is that practitioners may view these tools as substitutes for interpersonal interaction with patients. These aids should not substitute for effective communication inherent to the doctor-patient relationship; rather, they can help both parties prioritize issues, promote dialogue over monologue, and assess and refine understanding. Having gone more than 15 years into the new millennium, technology now permeates medical care, from robotic surgery to enhanced imaging and electronic medical records. Given the known disadvantages of the traditional paper process, it may be time to leverage technology for informed consent as well. Furthermore, research suggests that on average, ART patients are more technologically savvy than the general population and may be more receptive to these approaches. Like any useful tool, multimedia informed consent will require appropriate design and application to be effective. As medicine strives for greater efficiency and better outcomes, informed consent through systematic, validated approaches offers this opportunity.

Jody Lynee Madeira, J.D., Ph.D.[a]
Kathryn Coyne, M.S.[b]
Ami S. Jaeger, J.D.[c]
J. Preston Parry, M.D., M.P.H.[d]
Steven R. Lindheim, M.D., M.M.M.[b]

[a] Maurer School of Law, Indiana University, Bloomington, Indiana; [b] Department of Obstetrics and Gynecology, Wright State University, Boonshoft School of Medicine, Dayton, Ohio; [c] BioLaw Ethics Institute, Santa Fe, New Mexico; and [d] Department of Obstetrics and Gynecology, University of Mississippi Medical Center, Jackson, Mississippi

http://dx.doi.org/10.1016/j.fertnstert.2017.03.022

You can discuss this article with its authors and with other ASRM members at https://www.fertstertdialog.com/users/16110-fertility-and-sterility/posts/15697-23749

REFERENCES

1. Cassell EJ. The principles of the Belmont report revisited. How have respect for persons, beneficence, and justice been applied to clinical medicine? Hastings Cent Rep 2000;30:12–21.
2. Practice Committee ASRM. Revised minimum standards for practices offering assisted reproductive technologies: a committee opinion. Fertil Steril 2014; 102:682–6.
3. Jones KP. Informed consent in assisted reproduction technology. In: Carrell DT, Peterson CM, editors. Reproductive endocrinology and infertility: integrating modern clinical and laboratory practice, chapter 4. New York: Springer Science+Business Media; 2010.
4. McGraw SA, Solomon MZ, Maschke KJ, Benson JT, Irwin DE. Clarity and appeal of a multimedia informed consent tool for biobanking. IRB 2012;43: 9–19.
5. Madeira JL, Andraka-Christou B. Paper trails, trailing behind: improving informed consent to IVF through multimedia applications. J L Biosci 2016;3: 2–38, 28.