Paper Trails, Trailing Behind: Improving Informed Consent to IVF Through Multimedia Applications

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Paper trails, trailing behind: improving informed consent to IVF through multimedia applications

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ABSTRACT

Though intended to educate patients on the risks, benefits, side effects and alternatives within medical treatment, informed consent documents may have unanticipated consequences for patients. Patients may regard these forms as little more than a ritual to access treatment. Or patients may perceive that these forms exist to protect doctors rather than to contribute to a meaningful, patient-protective educational interaction. To rehabilitate the informed consent project, this essay considers the baggage that informed consent documents have acquired through practical use, explores patients’ and providers’ lived experience of informed consent, and considers whether a multimedia consent application would be a viable solution to the various difficulties that currently erode perceptions of and confidence in the informed consent process.

In a culture like ours, long accustomed to splitting and dividing all things as a means of control, it is sometimes a bit of a shock to be reminded that, in operational and practical fact, the medium is the message. This is merely to say that the personal and social consequences of any medium—that is, of any extension of ourselves—result from the new scale that is introduced into our affairs by each extension of ourselves, or by any new technology.1

—Marshall McLuhan

What does it mean in informed consent to say that the medium is the message? There have only been two dominant mediums in informed consent since its inception:

1 Professor of Law and Louis F. Niezer Faculty Fellow, Indiana University Maurer School of Law, Bloomington, Indiana. J.D., University of Pennsylvania, 2003; Ph.D., Annenberg School for Communication, University of Pennsylvania, 2007.

conversations and documents. Informed consent is conventionally understood to have four dimensions: providers’ act of delivering information on risks, benefits and side effects to patients; patients’ efforts to understand this information and deciding whether to consent to treatment on its basis; and documenting this decision. McLuhan did not intend ‘medium’ and ‘message’ to bear their conventional definitions. A ‘medium’ is any extension of ourselves from which change emerges; all inventions and innovations are McLuhan media. A ‘message’ is the ‘change of scale or pace or pattern’ that new innovation introduces into human affairs—not an innovation’s content or use, but the change in interpersonal dynamics that it brings. Thus, ‘the medium is the message’ means that ‘we can know the nature and characteristics of anything we conceive or create (medium) by virtue of the changes—often unnoticed and non-obvious changes—that they effect (message)’.

In the process of carrying out these activities, however, innovations such as informed consent documents 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; if patients feel they need to sign these forms to access treatment, they become transactional, merely opportunities to ‘step up and sign’. If this occurs, these interpersonal dynamics in informed consent medium could create new informed consent messages in the McLuhan sense—muddling the content that these forms were intended to convey, and perhaps undermining the entire project. Informed consent documents embody a host of contradictions. Foremost, they stand for two processes that are fundamentally at odds with one another: (i) a meaningful, patient-protective educational interaction that facilitates understanding, and (ii) 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.

This essay considers the consequences of this heavy legalistic baggage acquired from contexts and cultures of use, explores the lived experience of informed consent, and considers whether a multimedia consent application is a viable solution to informed consent process problems. In essence, does changing the informed consent medium resurrect its message? To answer this question, the authors are conducting the first randomized controlled trial of a web-based multimedia informed consent application, EngagedMD, in a major American fertility clinic. This clinic is the first to incorporate multimedia consent into its protocol.

This study will assess how IVF consent documents and EngagedMD impact patient anxiety, recall and comprehension, patient comfort or satisfaction, and provider/patient relations. EngagedMD consists of 13 videos, 5–7 min in length, each of which is followed by a brief quiz (see Figures 1 and 2 for sample screenshots and Figure 3 for a list of videos and lengths). Patients must watch a video before taking the matching quiz, and the application ‘scores’ their answers as true or false; if patients answer a question wrong, a notice pops up with the correct answer and a

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3 *Id.; McLuhan supra* note 1, at 8.

Figure 1. Screenshot from an EngagedMD patient video.

Figure 2. Screenshot from an EngagedMD patient video quiz.

Figure 3. List of EngagedMD videos and running times.
brief explanation. Patients can complete the application anywhere and from any device on which the Internet is accessible. The application’s ‘backstage’ feature allows doctors and nurses to check patient progress through the videos and generates a final report on quiz performance. Patients can also send questions to their provider at any time when completing the program. The randomized controlled trial will enroll 400 participants who are first-time IVF patients, 200 assigned to a control group receiving standard consent forms, and 200 to an experimental group receiving both forms and access to EngagedMD. Participants will be asked to complete four online surveys at certain times: before receiving consent forms, after receiving and completing consent aids, shortly before egg retrieval and shortly before the beta pregnancy test that concludes the IVF cycle. Approximately 50 participants will be interviewed two weeks after their cycle ends. The study also includes interviews with physicians and nurses before and after clinic adoption of EngagedMD concerning the meaning of informed consent and perceived advantages and disadvantages of consent forms and the multimedia application.

This essay is the first to provide a theoretical and tentative empirical assessment of how diverse informed consent mediums can and do affect the effectiveness and experience of informed consent to assisted reproductive technology (ART) procedures. Part I sets forth the various considerations necessary to evaluate whether consent documents in fact are laboring under burdensome bureaucratic baggage. It first provides a theoretical overview of general informed consent definitions and concerns before turning to the role of consent documents in particular, discussing prior research on similar forms of documentation, and describing their unique qualities. Part I closes by exploring the ‘dark side’ of consent documents—how they come to position users in ways that are perhaps not so helpful to the informed consent project, and that may actively imperil it. In Part II, this essay describes the actual lived experiences of IVF patients and care providers, focusing on whether they regard informed consent as important or redundant, whether it is affected by the doctor–patient relationship, who it protects, and whether conversations or documents are more effective mediums (or whether both are equally effective). Part III turns to multimedia consent, first discussing prior research on multimedia consent interventions in other areas of medical practice and then describing professionals’ assessments of an actual IVF multimedia consent application prior to its adoption in a major fertility clinic in the USA. The essay concludes by discussing preliminary results on patients’ and providers’ reactions to the IVF consent application following its adoption, which suggest that this application has great promise for overcoming many of the current limitations of document-based consent to IVF, including its perceived bureaucratic ritualization and perceived legal protection of medical providers.

1. UNDERSTANDING THE PROJECT OF INFORMED CONSENT IN ART

A. Informed consent doctrine

Before wading into the issue of whether consent forms are flawed mediums and multimedia applications are a viable solution, it is first essential to have a working familiarity with informed consent definitions and concerns. Informed consent to medical treatment is both a legal and ethical imperative. Typically, courts and medical literature
have proposed a definition of informed consent-as-disclosure, which Beauchamp and Childress criticize as 'unduly influenced by medical convention and malpractice law' that therefore 'incorporates dubious assumptions about medical authority, physician responsibility, and legal theories of liability, all of which focus on the obligation to make disclosures rather than the meaning of informed consent'. This informed consent definition originated in legal doctrine and has 'been primarily a requirement of disclosure based on a physician’s general obligation to exercise reasonable care by providing information'. Critiquing this standard, Beauchamp & Childress contend, 'from the moral viewpoint, informed consent has less to do with the liability of professionals as agents of disclosure and more to do with the autonomous choices of patients and subjects'. These two dimensions of informed consent—legal doctrine and moral viewpoint—are inherently in tension with one another; these stresses and their implications for the lived experience of informed consent will be discussed throughout this essay.

Beauchamp and Childress themselves propose that informed consent consists of (i) the threshold elements or preconditions of competence to understand and decide and voluntariness in deciding; (ii) the information elements of disclosure of material information, recommendation of a plan, and patient understanding of these two concepts; and (iii) consent elements of a decision in favor of a plan and authorization of the chosen plan. What care providers must disclose is 'a core set of information', including:

(i) those facts or descriptions that patients or subjects usually consider material in deciding whether to refuse or consent to the proposed intervention or research,
(ii) information the professional believes to be material,
(iii) the professional’s recommendation,
(iv) the purpose of seeking consent, and
(v) the nature and limits of consent as an act of authorization.

Ideally, therefore, the informed consent process educates patients about the risks and benefits of a medical procedure, allowing patients to make informed decisions about whether or not to undergo treatment. When correctly executed, the informed consent process may protect physicians from claims of battery, promote patient autonomy, encourage innovation of safe and high-quality procedures, help deliver patient-centered medical care, and improve the patient–physician relationship. Finally, information itself may constitute emotional support for patients, conferring a sense of control. However, some patients may find information to be emotionally threatening due to its content or ambiguity.

Traditionally, informed consent occurs in a predictable sequence of acts. First, a patient is provided information in the form of documents that describe the treatment

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5 Tom L. Beauchamp & James F. Childress, Principles of Biomedical Ethics 79 (5th ed. 2001).
6 Id. at 81.
7 Id.
8 Id. at 79.
9 Id. at 81.
procedure, risks, and benefits, either with or without an explanatory conversation with a care provider. Second, the patient signs a legal form, indicating consent to the treatment. Ideally, prior to signing, the patient is also given an opportunity to request clarification or to request changes to the existing treatment procedure. Informed consent documents may be read in a number of environments—in the waiting room, the patient’s home or the provider’s presence—and at a variety of times—from weeks prior to treatment to the day of treatment. Legal scholars typically recommend that patients be given plenty of time in advance of the procedure to read forms and ask questions; however, sometimes this is not feasible (such as during emergency treatment).

Unfortunately, ample evidence suggests that the traditional informed consent process frequently fails to significantly improve patients’ baseline comprehension of treatment procedures, risks, and benefits. As a result, some patients may be consenting to medical treatment about which they are not properly informed. In such a situation, a court may find that a physician failed to obtain informed consent from the patient prior to treatment.

Previous studies have identified reasons why the traditional informed consent process fails to increase patient comprehension. First, patients may have trouble understanding medical documents and consent forms that include technical or legalistic jargon. This problem is compounded if patients have a low reading level or if English is not their native language. Therefore, one informed consent expert advocates for medical consent forms to be written at the eighth grade reading level. Unfortunately, physicians may be unskilled at simplifying medical terms for the lay person. Also, some medical information may be impossible to describe without using some technical terms. In such situations, it is particularly important for the physician to give patients the opportunity to ask questions prior to signing the consent form.

Second, many consent forms are lengthy, tempting patients to skim over rather than carefully read the text. The average informed consent document is 12 pages long. Physicians feel pressure to include as much information as possible in documents in order to conform to regulations. For example, under Federal law, researchers in clinical trials must provide participants with information regarding the eight elements mandated by the Food and Drug Administration, as well as information required under HIPAA. Physicians may also assume that the more information they provide, the less likely the patient will be to initiate or win a malpractice lawsuit. Finally, physicians may feel an ethical duty to provide patients with as much information as possible. Unfortunately, more information is not always better for the patient, because lengthy forms may tempt patients to skim the text or to sign the consent form without reading it at all.

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13 See Kenneth Getz, In Search of Informed Consent Improvement, APPLIED CLINICAL TRIALS MAGAZINE, Nov. 2007, at 42.
14 Id.
15 Id. See also Elizabeth Cohn & Elaine Larson, Improving Participant Comprehension in the Informed Consent Process, 39 J. NURS. SCHOLARSH. 273, 273 (2007).
Third, patients may assume that informed consent documents are primarily designed to provide legal protection for the doctor rather than crucial information for the patient. As a result, patients may merely skim the documents, assumes that reading them would be a waste of time. Relatedly, patients have become desensitized to signing forms in doctor offices, especially forms that appear legalistic in nature.

B. The role of consent documents

With a working understanding of informed consent fundamentals, we can delve more thoroughly into the implications of documents as an informed consent medium. In his foundational article ‘What is a Document’, Michael Buckland describes several perspectives on how best to define that medium. Archivist Suzanne Briet asserted that ‘a document is evidence in support of a fact’, ‘any physical or symbolic sign, preserved or recorded, intended to represent, to reconstruct, or to demonstrate a physical or conceptual phenomenon’. This means that a document is considerably broader than a paper document; it could even encompass an antelope—one that is not wild, but has been captured, housed in a zoo, and subjected to study. According to Ron Day, documents have indexicality—‘the quality of having been placed in an organized, meaningful relationship with other evidence’.

Informed consent documents can also be understood as a cog in a larger bureaucratic project. Together with informed consent conversations, they comprise a major medical practice. Yet, few have considered the various socio-cultural components of informed consent documents, focusing instead on how documents affect recall, comprehension, and recording purposes. Working on subject matter that offers a particularly appropriate comparison for consent forms, Lynch et al. focus on paper trails in evidentiary chains of custody, observing:

Paper trails are an important element of chains of custody, as they stand proxy for other materials and actions: they track the movements of samples, certify that required protocols were followed, and identify responsible agents and agencies at each step of the processing of evidence. Vernacular accounts often refer to the paper trail of records as the chain of custody.

Note that here, the documents—paper records or consent forms—stand for the very phenomenon they are supposed to document. Lynch et al. note that such trails are ‘bureaucratic records [that] stand as documents of identification, certification, and organizational memory: a signature, appropriately inscribed on a form by the relevant official, performs witnessing’. Papers documenting a chain of custody are critical to the integrity of this evidence: ‘The integrity of the chain is forged and secured through a complex arrangement of technical devices and organizational practices that serve to record, certify, and practically ensure...that a naturalistic reading of matching evidence coherently emerges from the assemblage’. Similarly, in informed consent, document signatures, in particular, ‘certify the integrity’ of consent, documenting that standard procedures were followed—at least, until their authority is challenged. They help to

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19 Id. at 134.
20 Id.
establish the coherence of informed consent as a practice, aid understanding and decision making, and serve as confirmation of both.

Moreover, standardization can dull perceptions of risk. In informed consent, documents and their contents are seen as authoritative and are rarely questioned. As Navaro-Yashin observes, ‘[i]n most legal transactions within the euro-American paradigm, documents which include writing in them are taken as references for truth or authenticity’.21 Although consent documents are flooded with the language of risk and inadvertent harm, their legibility, uniformity, and authoritativeness may nullify the very dangers they describe: ‘if handling documents has a soothing effect...then documents can also provide an aura of propriety and possibility’.22 As Jacob explains, ‘an aesthetic of mechanically reproduced printed forms, as opposed to handwritten forms, does give the comfort of consistency and repetitiveness and allows the reader to be off guard’.23 Consent forms’ very existence connotes legitimacy and competence; ‘the mere production of documentary accounts describing what one does is considered ethical in and of itself, and the growth of auditing practices have ’fostered the production of self-descriptive documents as evidence of normatively good behavior’.24

From her fieldwork in an American hospital transplant unit, Jacob observes, ‘professionals appeared very bureaucratically tactical in making sure that forms, as material objects, looked clean, organized, well-designed, and legible...through documents, the hospital bureaucracy was beautifying itself for its eventual interlocutors’.25 Consent forms are thus engineered to address and engage with patients in certain ways. For example, they are designed to encourage people to read them, not for those patients who choose not to read them. Rather, in constructing consent forms in certain ways, ‘[s]pecific ways of reading, understanding, and signing forms are expected...the consent form makes for a person who is self-reliant and reflexive but who, in essence, is profoundly obedient’.26 Ironically, these obedient people are not the patients in the crosshairs of medical concern; the focus instead is on the ‘disobedient’ or irresponsible patient who does not read the forms even when instructed to do so. Consent forms lose efficacy because they cannot rule out certain types of patient behaviors, such as lack of engagement and inappropriate eagerness to sign—an inherent limitation of that medium. Routines engender rote compliance, even if they are important.

C. The dark side of informed consent documents
It is strange to conceive of something as seemingly innocuous or blasé as a consent form having a ‘dark side’. Yet, it is clear that most researchers have overlooked documents as subjects of research; Bruce Latour deemed documents ‘the most despised of all ethnographic subjects’.27 If anything, consent forms have been somewhat invisible as

21 Yael Navaro-Yashin, Make-Believe Papers, Legal Forms and the Counterfeit: Affective Interactions Between Documents and People in Britain and Cyprus, 7 ANTHROPOLOGICAL THEORY 79–98, 94.
23 Id. at 254.
24 Id. at 251.
25 Id. at 252.
26 Id. at 255.
the subject of research. Referring to them as ‘consent’s blind spot,’ Mary Andrée Jacob notes, ‘the consent form documents, in contrast to the idea of consent, is rarely taken as a problem in itself.’

28 The scholars who go under consent, or inside the black box of formalized contracts, often assume too much that the interesting aspects of consent are its hidden components that need to be uncovered before they can be critiqued, Jacob explains, ‘Even law and economics scholars discussed elected ‘trickery’ of standard form contracts’. 29 This approach acknowledges that ‘even the simplest of forms speaks to multiple audiences and is produced by multiple hands, with often quite different interests and concerns at play’. 30

When one actually does explicate informed consent documents, it is apparent that they have a dark side. It is imperative to acknowledge and discuss it before we can try to move past it, perhaps by transitioning from the document medium to another medium—not forsaking the entire informed consent project. To posit that consent forms have a dark side is to assert that consent documents do more than connote authority and communicate risk. Like other objects, documents are more—and tell us more—than is at first apparent. Roland Barthes notes that objects ‘function as the vehicle of meaning: in other words, the object effectively serve some purpose, but it also serves to communicate information: we might sum it up by saying that there is always a meaning which overflows the object’s use’. 31 Similarly, Bernd Frohmann observes, ‘documents invite us to speak, to make statements about the manifold of phenomena for which the document-as-thing provides evidence. The idea of relationship between the document-as-thing in the production of statements led us to the concept of things that restrict, limit, and control speech rather than engender it’. 32 In other words, particularly from a social constructionist perspective, a document’s relevance ‘is now generally considered to be situational and ascribed by the viewer’. This implies that documents’ content can be facilitated or undermined by forces outside its four corners. Somewhat surprising given its bureaucratic connotations, Donker Duyvis posits that the content of documents can be imperiled by its form:

33 Buckland, supra note 31.

Thus, whatever is spiritual about the informed consent message—its interactive qualities, its engagement—can get lost in the bureaucratic baggage as context comes to govern content.

As a tool of informed consent, documents become weakened by bureaucratic baggage acquired in a reputedly adversarial and litigious culture replete with rumors of

28 Jacob, supra note 22, at 250.
29 Id.
30 Donald Brenneis, Reforming Promise, in DOCUMENTS: ARTIFACTS OF MODERN KNOWLEDGE 65 (Annelise Riles ed., 2006).
31 Id.
medical malpractice. The key to understanding this dark side—and perhaps remedying it—is assessing why patients so often purportedly fail to engage with these documents. Medical professionals must walk a thin line between potentially conflicting roles as healers and as bureaucrats. One would think that it would be incumbent upon medical professionals in their role as healers to reject bureaucratic conceptions of consent documents. But if anything, the opposite is true; most providers are more likely to discuss informed consent’s problems than sing its praises. But it seems that since consent forms are the standard of care for informed consent, there are no plausible alternatives. Thus, medical professionals are forced to become (at least temporarily) bureaucratic purveyors of consent documents, the efficacy of which they doubt. After all, like bureaucrats who have ‘their own accountabilities and vulnerabilities in the organization’, they ‘wish to make sure their work is accountable and that [it] provides “plausibility’. Should there be a problem, providers ‘may later be called to interpret what these documents are about’.

But how did documents come to acquire this bureaucratic baggage in the first place? Contract scholars discuss a fairly recent trend towards acknowledging that the concept of consent has feet of clay. The ‘normative power’ of the idea of meeting of the minds is losing ground; Margaret Radin asserts that the ‘idea of voluntary willingness first decayed into consent, then into assent, then into the mere possibility or opportunity for assent, then to merely fictional assent, then to mere efficient rearrangement of entitlements without any consent or assent’. Consent—at least in some contexts—has come to seem fictional:

Consent seems obviously fictional in a great many transactions, however, and that is one reason I say that consent is vestigial. Consent is fictional when the terms are filed somewhere we cannot access, as in airline tariffs. Consent is fictional when almost all of us click on-screen boxes affirming that we have read and understood things we have not read and would not understand if we did. Consent is fictional on websites whose terms of service state that just by browsing the site, whether or not one ever clicks on the terms, one has agreed to whatever the terms say, now or as they may be changed in the future. Consent is fictional when the contract ends, as one I saw recently did, with ‘By reading the above you have agreed to it.’

Since it is a form of consent, it is logical that informed consent may seem rather vestigial as well. One of the authors has been literally confronted with this attitude; while Madeira was presenting her research in informed consent in the IVF context, a doctor in the audience interrupted her, stating that informed consent did not exist. Professional doubts about the validity of informed consent as a process or even its base reality intimate that consent forms, at least to some practitioners, may be ‘make–believe papers,’ with ‘performative and phantasmic quality[ies]’. Here, ‘make–believe’ implies ‘fictional reality,’ where ‘fantasy is conceived not as antithetical to some hardcore notion of the real, but as part-and-parcel of reality’, where some practitioners pay lip

34 Jacob, supra note 22, at 251.
35 Id.
37 Id. at 1231.
38 Navaro-Yashin, supra note 21, at 79.
service to idealizations of informed consent that are very different from their actual consent experiences. Clarke, too, has written about ‘fantasy documents’— ‘documents produced by organizations outlining contingency plans in the event of mass disasters such as nuclear war or a massive environmental disaster— as ‘rationality badges’, that is, statements to the public that things are under control’. Just as some in their role as parents may feel obliged to pretend that there is a Tooth Fairy or Santa Claus, some practitioners may feel duty-bound by their professional roles, training, and legal strictures to go through informed consent rituals, though they doubt their efficacy.

Yet, the issue is not so much that the informed consent process is broken as it is that stakeholders’ perceptions of informed consent documents have become tragically skewed. Indeed, as discussed later, Madeira’s qualitative research with fertility patients undergoing IVF revealed that interview participants had much more positive views of the informed consent project writ large, believing that it was not bureaucratic and that it either protected patients or protected providers and patients equally. It is as if perceptions of informed consent documents are the bad apple that stands to ruin the bushel; if patients and providers lose faith in documents’ efficacy and protections, might not they also eventually come to scoff at the larger project of informed consent?

In a novel article, Navaro-Yashin posits that ‘the documents…of law and governance [are] capable of carrying, containing, or inciting affective energies when transacted or put to use in specific webs of social relation’. Navaro-Yashin examines the implications of citizenship documents produced for the Turkish Republic of Northern Cyprus (TRNC)—a state recognized only by Turkey, making TRNC documents invalid outside of that country. Turkish civil servants employed in the immigration office that issues these TRNC documents are ‘openly ironic, cynical and humorous about their practice’, and joke about what the documents are good for even as they issue them. Navaro-Yashin notes:

thus, in the very act of manufacturing and processing these documents, the civil servants involved in these transactions and authorized to carry them out returning the documents topsy-turvy, or on their head, by being ironical and cynical about them. The specific documents generated effects of pity, humor, and ridicule among their producers.

Navaro-Yashin’s case study of the TRNC documents parallels the contemporary treatment of informed consent documents in the USA; though embedded in the interpersonal, dialogic context of informed consent, these forms are simultaneously a legal obligation and a transaction that inspires skepticism in many practitioners and patients.

Informed consent processes and documents position their creators and readers in certain ways. Informed consent may be central to physicians’ and nurses’ professional status, with the quality of a professional’s consent process simultaneously helping patients to ascertain the professional’s value and showcasing their actual ethical and treatment values. Perhaps consent documents are even fetishized as a sanctioned and

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39 Id. at 80.
40 Riles, supra note 27, at 11.
41 Navaro-Yashin, supra note 21, at 81.
42 Id. at 89.
ritualized professional construct. According to Jacob, the consent form effectively creates a bureaucratic person from its user: ‘the consent form neither represents nor reflects the person who signed it but is rather an alternative term for the person herself. This person is not based on cognitive and humanistic understandings of the consenting individual but rather is constituted and preserved by legal and bureaucratic documentary proceedings’. Bureaucratic logic shapes and changes phenomena [with regard to its own hermeneutic of closure] fittingly, consent, too, offers a form of closure in the form of a decision made, a commitment undertaken.

Ideally, this closure is symbolized by a patient signature, perhaps followed by that of a witnessing medical professional. But theoretically, this signature is ‘not’ informed consent in itself, although the two have admittedly become conflated in contemporary practice. ‘Under mainstream legal discourse, the signature on a consent paper form is nothing more than a means of evidence of consent, whereas informed consent is and should be a shared process, an ideal practice’. Instead, as Jacob notes, signatures have come to be emblems of the depleted state of the contemporary informed consent process:

In an American Hospital transplant unit, touching, page turning, skimming through (but rarely reading), and signing of consent forms by most of my research subjects (both staff members and patients) was accompanied by a sense of getting it done, and quickly. For many, signing was only an activity performed out of necessity. Form filling may have been presented formally as a ‘discretionary move’, but for transplant donors and recipients, for example, it is rather a bargain about putting one’s mark on the document as soon as possible in order to get activated on the transplant waiting list or queue for a nephrectomy. The filling of forms is thought to be a means to achieve one’s objective. In the field, excessive time consumption was the main complaint expressed about ‘getting through’ consent.

Thus, for Jacob, ‘paper rarely succeeds in bringing about a reflexive pause and in slowing down the process’. ‘Rapid document reception and handling’ contributes to an atmosphere of ‘annoyance, indifference, sometimes mockery. Even when it happens rapidly, the moment of consent is always already too long’. Of course, this may not be a product of the informed consent context but a characteristic of the document medium. In his study of wardens’ compliance with completing paperwork such as warrant covers or intake records in a maximum-security jail in Papua New Guinea, Adam Reed notes that officials were scarcely jumping at the opportunity to complete these forms:

Among warders at Bomana jail the requirement to fill out documents is often met with ambivalence. They regard the activity as energy sapping and boring, and try to avoid the task if they can… In form filling it is even harder to locate a free response. Prisoners and warders at Bomana view the act as coerced from the start.

44 Jacob, supra note 22, at 250.
45 Id. at 253.
46 Id. at 256.
47 Id.
48 Id. at 258.
49 Adam Reed, Documents Unfolding, in DOCUMENTS: ARTIFACTS OF MODERN KNOWLEDGE 165, 169 (Annelise Riles ed., 2006).
To say that consent forms position and engage their users in certain ways implies that they have affective properties. Consent forms are ‘mundane documents’ and ‘engender routine responses, both from those filling them out and from later readers’. Therefore, ‘they and their consequences remain, in large part because of their very ordinaryness, analytically invisible’. Consent documents may appear dry and devoid of emotion, but they are actually useful tools for emotion management. Medicine positions itself as a rational (and likely emotionally repressed) space. Informed consent is charged with taking a rational, matter-of-fact approach to communicating information that is upsetting or that could induce emotional reactions (such as side effects or adverse outcomes). Moreover, information material to informed consent, including details of proposed treatment—often involves violence and bodily invasion, albeit in therapeutic form. Thus, consent documents attempt to sanitize or de-emotionalize information that is actually extremely emotive. Robert Cover’s infamous essay on ‘Violence and the Word’ is relevant to this latter point. When informed consent asks patients to consider what will happen to their bodies in certain procedures, and what could happen, it becomes apparent—to comprehend emotional subject matter within a decision-making context that is ostensibly rational. At the same time, informed consent distances patients and providers from this violence, through statistics that are general and not tailored to individual patients as well as through an impersonal, standardized, mass-produced, authoritative, and reassuring document format.

In fact, consent forms in their current form may be unable to accomplish their mission—to effectively motivate patients to think about procedures, side effects, and unintended consequences. True comprehension might require patients to be imaginatively or empathically engaged with details and possibilities—activity discouraged by consent form format and language. Although they are tools of emotion management, informed consent documents fail to engage most patients on an emotive level. It is hard for patients to empathically extend themselves into the consent document; bodies of text do not necessarily correspond well to bodies of flesh as images would. Reliance on rational statistical language bleeds affect out of documents, potentially nullifying connections between humans and the consent process. After all, we engage with and understand phenomena through affect, appreciation, cognition, and empathic extension of the self. If patients do not affectively engage with consent documents, it is difficult to say that they trust or respect them, their informative potential, or their protective capacities—a key source of rupture not only in the fabric of informed consent but also potentially in provider–patient relations.

Patients usually do not hesitate to take a critical stance toward consent forms that they believe are at least equally protective of doctors as of patients, and negatively reflect on both the forms and on the entirety of the informed consent project. This is dangerous; it is possible that the skepticism and cynicism with which doctors and providers view these consent forms also bleeds into and taints the informed consent process itself. The question is how to change this lived experience. Jacob asserts that scholars and practitioners should adapt their expectations and theories of informed consent to

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50 Brenneis, supra note 30, at 42.
51 Id.
match the rather blasé reality:

It might be helpful for scholars of health and research practices to stop fantasizing about choice and emphasize how ‘getting through’ and ‘being moved along’ are the lived experiences of consent. One can do this by giving subjection its due and by recognizing submission, formalized or not, as a relevant kind of agency, an expression of one’s subjectivity...facing consent forms’ air of inevitability, subjects deploy a different kind of discretion. The discretion of debating, changing, supplementing, or discarding the form is not available to them.\(^\text{52}\)

Jacob further suggests that patients’ decisions not to read may ‘be subversive ways...patients can rescue their eroded agency’.

This approach sounds in Foucauldian theory, and she in fact posits that ‘documents should not simply be viewed as tools, but also as texts, responsible for producing or objectifying the subjects that use them’.\(^\text{53}\) Patients’ reluctance to read and/or complete the forms becomes not boredom with a bureaucratic routine but a subversive response to the ‘hegemony of document technology’ and perhaps provider paternalism. We believe that this is not patients’ motivation in the vast majority of instances; they are far more likely to have not read forms because they feel that they already knew the information, were already educated about this material information by their physician, or were inclined to skim it by a lack of time, attention, or understanding. Moreover, in Madeira’s research concerning informed consent in the IVF context, patients never mentioned such motivations and were sometimes allowed to debate, change, and supplement the informed consent forms. Moreover, nothing ever prevents any patient from signing the forms without reading them and then discarding them immediately afterwards.

A better approach than changing our consent expectations to conform to the current lived experience of ‘getting through’ would be to actively try to change this unsavory and ineffective lived experience of informed consent altogether. Why would it be desirable to keep a practice that is dysfunctional and ineffective? If consent forms, like other documents, are affective, than changing the lived experience of informed consent necessitates changing practitioners’ and patients’ relationships with these documents. The first step towards doing so is ‘exploring documents’ messy and excessive potentialities, the multiple and contingent affects which they engender in their holders and transactors’.\(^\text{54}\) This necessitates engaging with what Navaro-Yashin terms the ‘affective underside’ of these forms, both acknowledging that consent forms are ‘cozily despicable...[and] provoke irony, cynicism, familiar contempt and wit’ and undertaking to change these affective effects. One possible solution which until now has not been implemented in fertility care is multimedia consent. Could informed consent carry different affective connotations when documents are not the medium? But another question must first be answered: what are providers’ and patients’ actual lived experiences of informed consent? Are such sweeping changes to informed consent really warranted? After all, prior research by Madeira suggests that IVF patients take the informed consent process seriously and do read and understand informed consent forms—although this

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\(^{\text{52}}\) Jacob, supra note 22, at 260.  
\(^{\text{53}}\) Reed, supra note 49, at 158.  
\(^{\text{54}}\) Navaro-Yashin, supra note 21, at 95.
tells us little about whether the consent experience could be improved, and whether
cynicism about consent’s viability has consequences.55

II. PATIENT AND PROVIDER PERCEPTIONS OF THE INFORMED
CONSENT PROCESS, DOCUMENTS, AND CONVERSATIONS

To illustrate the tensions inherent in the lived experience of informed consent pro-
cesses, including the consent mediums of conversations and documents, this essay will
now turn to the comments of patients and providers. These comments were obtained in
a qualitative survey with 130 male and female patients who had undergone IVF in the
past five years and 90 reproductive medical professionals (doctors, nurses, and men-
tal health professionals). This section will describe participant thoughts on whether in-
formed consent was important or redundant, whom the informed consent processes
protected, when the informed consent process began, whether informed consent was
affected by the doctor–patient relationship, and whether documents or conversations
were more important. Patients’ and providers’ remarks show that, while informed con-
sent is certainly fraught with numerous problems, including bureaucratic baggage, it
still has much perceived value in terms of promoting comprehension and deepening
doctor–patient relations.

A. Is informed consent important or redundant?

Patients had very nuanced opinions of whether the informed consent process was im-
portant or redundant. For some, it was a necessary evil that triggered the essential pro-
cess of educating patients about their procedures and medications. For others, the im-
portance of informed consent was theoretical; it did not seem immediately relevant
because they did not anticipate problems from their treatment cycles or provider re-
lationship. Many patients felt that documents were very useful references, particularly
when they had left the doctor’s office and had basic questions. Sometimes, certain in-
formed consent formats (most often documents) felt redundant, while others (usually
conversations) seemed more important and useful. And several patients felt that the
importance of informed consent depended on whether patients had realistic choices in
procuring treatment and the gravity of treatment procedures.

Some patients barely remembered the informed consent process. ‘Honestly, I
haven’t thought about the informed consent form since I signed it last July… I feel like
I’ve been through all these IVF cycles and IUIs, and I haven’t ever once gone back and
thought about the paperwork’, related Participant 72, ‘I think I’m just too wrapped
up with my own, dealing with my own emotions to think about like what paperwork
I signed’.

Some patients felt that informed consent was synonymous with paperwork and,
therefore, was redundant and bureaucratic. ‘It feels so bureaucratic, because you do it
at every doctor you go to; you have your HIPAA consent, you have everything, it feels
kind of like paperwork’, noted one participant. The trope of informed consent as a bu-
reaucratic ritual goes hand in hand with the idea that patients do not read the forms
but just sign them. In this vein, one participant asserted, ‘no one really reads them and
no one really takes them seriously’. Another participant went alleged that, not only do

55 See generally Jody Lyné Madeira, The ART of Informed Consent: Assessing Patient Perceptions, Behaviors, and
patients fail to read the forms, the informed consent project is flawed: ‘I don’t think
that people read them; usually, I think the people who actually acquire the signatures
usually don’t do a good job of explaining the significance of informed consent... I don’t
think informed consent is very valid in most cases’.

Most patients felt that informed consent was somewhat helpful. ‘You do need some
basic understanding and some signing before you move into a lot of this stuff’, cautioned
Participant 123; similarly, Participant 8 felt that ‘you’ve got to sign a contract of some
sort; you’ve got to... say that you understand what’s going on’. For Participant 70, the
process was educational: ‘I do think they’re important because there were a lot of ques-
tions that I hadn’t considered. There were some where I was like, ‘Wow!’ There were
things that my husband and I had to sit down and talk about because I didn’t know’. Participant 83 felt that informed consent is a matter of personal responsibility and au-
tonomy: ‘I think the patient should, if anything, be reminded of what they’re getting
into, reminded of what they’re responsible for, and what the doctor’s responsible for,
and to be aware of what the risks are. I think every patient has the right to know what
they’re getting into and to be able to make that choice’.

Several patients thought that informed consent was both redundant and important.
‘I think the bureaucracy part is [the forms are] very wordy. But certainly it’s important
that everybody understands that the patient understands’, observed Participant 104. Another participant stated that even though the forms are somewhat redundant and
bureaucratic, the forms may prompt important discussions.

The prospects covered in informed consent struck some patients as theoretically im-
portant but practically irrelevant at the time of signing. ‘To me they’re bureaucratic
because we don’t need them... but if things took a turn and lawyers got involved or
something, I’m sure things will come back up and our signatures will come back up’, noted Participant H79, ‘but now, I don’t see significance in the paperwork, not because
it’s not needed, but it’s just another step’. Fertility patients are not necessarily focused
at that time on the realm of ‘maybe’ in which the informed consent project resides, but
rather on the very real possibilities of conceiving. One participant said of informed con-
sent forms during the infertility treatment process: ‘That’s a sidestep, that’s secondary,
that’s something you don’t really worry about; it’s like a game show; you’re to the end,
and you’re almost about to win. The rest of it is secondary’.

Informed consent seemed to be essential with respect to some procedures, but less
important with others. One participant explained, ‘[in] giving blood or getting a flu shot
[informed consent] is more of a bureaucratic, redundant thing... It’s kind of rushing
through...versus elective surgery, where they’re going to sit you down and talk you
through everything’. The informed consent process seems more consequential when
patients actually feel that they can realistically choose whether or not to undergo a pro-
cedure. ‘I think... when they actually contain decisions... they are very important... but
if they’re just like, “Hey take this drug, here’s the multiple side effects and you could
die”, no one really reads them and no one really takes them seriously’, Participant 56
observed. ‘Like the ones I just signed before I had my C-section, I didn’t really have a
choice... I’m not going to not sign these and be stuck with this kid inside of me for the
next 25 years’, she continued, ‘but if they have decisions in them like “I want this many
embryos transferred”... then they’re important’. In other words, patients may feel that

Paper trails, trailing behind  •  17
the informed consent process is actually more relevant within infertility treatment than within other medical contexts.

Illustrating that informed consent is performative and embedded in a network of social relations and institutional processes, patients’ impressions of informed consent can be affected by what weight clinic personnel assign to the process, and how much time is invested in informed consent conversations. Participant 149 noted that while ‘they definitely emphasized that I had to read the whole thing and sign it’, the doctor ‘just blew through it’. Participant 135 felt that her relationship with the provider negatively affected the informed consent process:

If we had had a better relationship with our doctor, I would have been able to make a significantly more informed consent. His attitude was like, ‘It’s all there on that paper. Someone else is taking care of that kind of thing, for me; you can read what’s on that paper’... I just felt like I was not in a position to ask a lot of questions of him or get reasonable answers from him.

Patients bemoaned the litigious culture that made informed consent necessary—an approach which interposed even more distance between themselves and the evils that informed consent supposedly guards against. Informed consent violations had been experienced by ‘other’ people who had been exploited by ‘other’ providers and experienced other harms. ‘Unfortunately there are some not good people in the world,’ Participant 130 opined. ‘I just wish we didn’t live in such a culture where the doctors are so afraid of being sued that they have to explain every slightly possible bad outcome in a consent form that you have to sign’, related Participant 89, ‘if you trust your doctor, you should know going into it that he’s going to do everything he can, and if something terrible happens from the procedure, it’s not that he did it on purpose...It’s a shame to me that we live in that kind of society but since we do, I think [informed consent] is very important. If I were a doctor, my consent forms would have every single thing that could possibly go wrong in them’. Thus, to many patients a culture of civil liability is responsible for informed consent, and doctors appear to be informed consent’s victims and not its violators. Finally, one participant was quick to point out that it would be impossible to proceed with treatment without signing the forms, regardless of how patients felt when they signed them: ‘we signed them because that was the only way to get it done’.

Patients undergoing multiple cycles learned firsthand that informed consent is a continual process that is not restricted to paperwork or one time conversations about risks, benefits, and side effects before a cycle. Following her first failed cycle, Participant 30 did not receive the information she felt she needed in order to make a decision about beginning another cycle. The patient received a phone call from a nurse about negative pregnancy results during which the nurse said, ‘So, [your doctor] would like to know if you would like to go again’. Reflecting on this conversation, the patient said, ‘That’s not how you make a decision about IVF; you don’t make a decision in a 30-second phone call... And so, there was no consent, there was no conversation’. In the fertility process, informed consent is particularly critical as the cycle develops, where factors such the number of eggs retrieved and fertilization rates can affect the decision to continue treatment.
Some professionals explicitly urge their patients to take responsibility for informed consent. One physician believes that as a patient, you are obligated to invest time and effort into understanding the treatment process. Another physician compared the doctor–patient relationship to a contractual relation:

It’s also incumbent on the patient, I think, to be responsible to ask questions and make sure that any concerns or lack of understanding are voiced...I think it’s almost like a two-way contract, in a sense. That there’s just a mutual understanding that everybody has a good sense of what’s going on, and is on board.

B. Who informed consent protects
In terms of ‘who’ informed consent protects, more patients felt that it protected the provider than the patient. Some patients felt as though they could not change the informed consent forms and that this meant that the forms were there to protect the physician: ‘I think it’s there to protect the doctor because it’s not like you can write in your own little clause’ (Participant 107). Participant 30 felt that the most important thing on the informed consent document was a signature, really a formality. ‘I am not convinced that that paperwork really showed that I was a well-informed patient, so to me, that’s...where it becomes [focused on] legality’, she continued, ‘I can fully admit that I don’t know what is in that paperwork, and I didn’t know what I was getting myself into really’. It is as if patients regard signed informed consent documents as a shield that the doctor can raise for protection against a civil suit. The mere format and authorship of the informed consent documents affected Participant H42’s perception of whom the form protected: ‘since it’s written by the hospital...I think it’s more for them...I mean, it’s got the...logo of the hospital on top of it....I don’t think they would do it unless they had some incentive in doing it’. One patient did not feel that she needed the protection of the informed consent process, so it was really there to protect the doctor.

On the other hand, several patients opined that the informed consent process protected both patients and physicians. Participant H68, an attorney, was confident that forms were there to protect both: ‘I’m a lawyer, so I think the doctor’s being protected, but I think it’s also protection for us... And I know most people don’t think about what happens if you get divorced and have a frozen embryo somewhere, but I know the legal implications of that and how critical it is. So it’s very important to have all of that decided up front’.

Patients who believed that informed consent protected physicians over patients described how it would be different if the converse were true. Participant 56 was one of very few patients who actually experienced an informed consent violation, and found it nigh impossible to pursue legal remedies even with a bona fide physician error:

[Informed consent] didn’t do much for me. It didn’t protect me. I still ended up with the triplets and absolutely no basis to have any retribution or whatever the right word is for that. I mean, I got free cycles but that didn’t really do much for me, honestly. So I definitely did consult a lawyer because I just needed to for my own psyche, because I needed to know what my options were. And they basically said ‘You have none because there’s no guarantee that you could carry a pregnancy to term anyway’ — and that was before I did. And I said specifically, ‘What about the informed consent I signed?’ And they said, ‘Eh, whatever’. And I was like, ‘No, there’s an informed consent [form] there [that]
spelled out O-N-E, one embryo should be transferred.’ And [the clinic] blatantly disre-  
garded both written and verbal consent. And we were told, ‘Oh sorry, you can’t pursue  
any justice based on informed consent.’…Why did I sign that then?

Some patients considered their ability to change terms when asked if these forms  
protected patients or doctors, which often raised comparisons to contracts of adhe-  
sion. Participant M3 reflected, ‘Ultimately any time that you’re not given an option  
to change…or negotiate the terms and conditions, obviously it’s meant to protect the  
person that’s handed you the paper…I think a lot of people don’t understand that they  
can negotiate terms and conditions… [whether] it be a lease, or any business situation.  
And this situation is, in most senses, a business arrangement’. According to this patient,  
many patients may feel uncomfortable suggesting changes because they do not want to  
‘create waves’. He wished that more patients knew their rights.

Others felt that the informed consent process protects both patients and providers  
but that doctors received the lion’s share of the protection. Nevertheless, the process  
may be reassuring; as one participant said, ‘Even though I’m sure most of the paperwork  
is to protect [the doctor] and not me, it still made me feel better I guess that he’s still  
legally obligated to do something for me since I’m giving him all this money’.

Ultimately, informed consent’s perceived legalities may prompt patients to accord  
forms less significance in medical treatment. ‘It’s about being sued, and so that’s why  
when I view it that way, I’m not paying attention as much’, Participant 140 explained,  
‘I’m like, ‘Oh yeah, I have to do this, this is their due diligence’. So I didn’t feel like it  
was as much of the medical process, which it should have been’. The legal terms of her  
informed consent documents did not seem equitable to some participants: ‘If some-  
thing serious were to happen, some huge error, I don’t feel that we’d…win. I feel that  
the clinics would win’. This is one of informed consent’s greatest ironies—a procedure  
that is meant to protect patients ends up making them feel more vulnerable, either be-  
cause the terms of the informed consent documents are biased in favor of the medical  
professionals or because no lawyers would take a pure informed consent case without  
other claims.

C. Is the informed consent experience influenced by the provider–patient  
relationship?

For most participants, the informed consent experience was influenced by their rela-  
tionship with their doctor. Holding a doctor in high regard made the process easier for  
some. Put simply, trust facilitated informed consent interactions, especially when cou-  
pled with standard consent forms. ‘I felt so at ease with him that it wasn’t hard for me to  
sign the documents. Obviously I read what I signed, but the fact that I trusted my doc-  
tor made it easy to sign the papers’, said one participant. It was as if the patient’s award  
of trust qualified as a kind of certification of procedure, doing away with much of the  
need for informed consent. A patient that has been well informed by her physician may  
regard informed consent documentation as duplicative: ‘the document signing was not  
really a major thing in our eyes. I think it was just a formalization of what we had already  
been told’. The manner in which informed consent is obtained can further enhance this  
trust. For example, one participant said she trusted the informed process because it was  
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guided by a motherly, supportive nurse who calls her patients ‘Sweet Pea’ and ‘wouldn’t  
lead me astray’.
Ironically, the trust that patients crave and doctors seek to encourage may actually undermine informed consent. For example, Participant 126 felt that trust rendered her more compliant: ‘the more trust I gave to the doctor, the more willing I was to be agreeable and understand anything, whether it was a particular test or a particular process of the procedure’. This compliance can even be extreme: ‘I think when you have trust in the doctor, “Yea, yea, yea, yea, yea”, you just sign whatever he tells you to sign because you trust this doctor and you like the doctor’. In this way, trust either facilitates or undermines the informed consent project, depending on how compliant trust renders a patient.

Informed consent documents struck some patients as fairly innocuous, not the type of legal form that required suspicion and close scrutiny. One patient said, ‘I didn’t really look at [informed consent] as being something [where] they were trying to pull a fast one on me. There are legal documents that I kind of suspect I need to look for a loophole, that they’re trying to pull something on me, but this just didn’t really seem [to be]...a confrontational kind of document [or]...all that contractual’. In the infertility context, patients are already predisposed to deprioritize informed consent in light of other weighty concerns over conception and will be even more likely to disregard the process if trust does away with self-protective instincts: ‘I didn’t feel like [the provider] intentionally had any reason to try to harm me. So it was just kind of like, “Let’s get on with this”’.

But if positive feelings towards providers or appreciation for a thorough informed consent process can improve the provider–patient relationship, dislike for providers and a detached, rushed or rote informed consent presentation can undermine this critical interpersonal connection. The informed consent conversation actually decreased Participant 130’s liking for her doctor: ‘I think it put a negative spin on our relationship. That was the first doctor I saw, and it was very rote: this is the risk chances, this is the worst-case scenario; you could go to the hospital and die. It was just matter of fact. There was no emotion behind it’. Similarly, the interpersonal disconnect that Participant kH43 felt in his provider relationship meant that informed consent seemed more bureaucratic: ‘[b]ecause of the lack of personal connection we had with the doctor...it felt like some red tape that [we] had to go through’. Finally, Participant 79 felt as if he scrutinized the documents more quickly and even changed them because he was angry: ‘We were already kind of angry…and [that] made us feel like we probably needed to read the informed consent closer. To make sure we were reading exactly what we were signing. And to be honest, I don’t know how often people actually do this, but we crossed off part of our informed consent, and said, “We don’t consent to this.” and actually edited it’.

Several patients asserted that if they did not trust the doctor, then they would have asked more questions during the informed consent process. A lack of trust also would have prompted them to spend more time looking over the informed consent documentation or to take the forms home before signing them. The documentation itself would also become more significant if the patient distrusted the doctor; as one patient said, ‘if I didn’t trust my doctor...I’d need to see [the information] in writing rather than just hearing it from him’. For Participant 107, the informed consent process would have been more difficult if she had distrusted the doctor: ‘I think then you would be second guessing every decision he made. I think it would be more emotionally stressful’. In essence, the process would be a lot longer, more tedious, and more adversarial.
Other participants felt that their experiences of informed consent were not affected by their provider relationships. For Participant 127, this is because she viewed entering the clinic doors as bespeaking consent: ‘the minute I walked into your office to talk to you, I’m giving you my consent. Unless I change my mind; I have that privilege as a patient, but...in my mind it’s assumed. I’m ready’. Some patients felt that they didn’t yet know the doctor well enough for that nascent relationship to affect the informed consent interaction. Still others believed that the informed consent process was so standardized that it would not have been affected by the interpersonal relationship with the doctor.

D. Are conversations or documents more effective informed consent mediums?
We have been gradually building towards the idea that informed consent is not always restricted to a matter of signing standardized documents—it is inexplicably intertwined with the doctor–patient relationship and interpersonal matters of trust and prior patient experience as well as clinic practices and routines. It is also obvious that patients experience conversations with their providers dealing with risks, benefits, side effects and alternatives differently than they experience documentation. Although informed consent as a process cannot be separated entirely into neat packages such as ‘conversation’ versus ‘document’ or ‘spoken’ versus ‘written’, it is possible to deconstruct the informed consent interaction a bit more thoroughly to gauge patients’ and professionals’ reactions to the mediums involved, and their characteristics, consequences, advantages, and disadvantages.

1. Conversations more helpful
Most patients felt that conversations were most helpful for several reasons: they could ask questions; conversations better matched their learning styles and clarified or added information; human interaction improved understanding; and conversation could provide more individualized information. For example, one Catholic patient appreciated the opportunity to ask questions related to her religious preference that were not addressed in the documents.

Conversations were obviously more advantageous for auditory learners. ‘I can learn things ten times faster in a 10-min conversation than I can by reading pamphlets and books and whatever’, one participant asserted. Conversations gave patients opportunities to ask questions. For some people, conversations are more memorable than forms because they are more interactive. Conversation also allows health care providers to explain information relevant to informed consent in less technical and more comprehensible language than the consent form. For some individuals, conversations may be less stressful than a slew of documents.

The physician’s physical presence during the conversation can underscore the importance of informed consent: ‘when a doctor’s sitting there...when he’s saying it, he’s experienced it, he sees it, he does it…It’s more real when it comes from the doctor that’s going to be doing everything’. Conversations could also add ‘gravitas’ to the consent procedure, preventing the patient from glossing over an important topic, especially if the patient has signed many bureaucratic forms in the past to which she has become desensitized. Speaking of her doctor, one patient said, ‘She’s been there a long time so I just felt like she was telling me... these things from experience rather than, “This is just something we have to tell you”.’
In addition, patients very much appreciated the humanity inherent in the conversation process: ‘Just the human...touch, the human tone. Almost like, “You can do this. It will be alright”’. Conversations do not feel as bureaucratic as paperwork. One participant craved the ‘reassurance’ available in conversation but not through paper; the physician can ‘calm you down if you needed to be calmed down’.

Conversations were assuredly not helpful, however, when the provider gave patients incorrect information. For example, one participant recalled being very distressed after she received incorrect information from her physician. It was also not helpful when providers thwarted opportunities for conversations that could enhance patient understanding, such as by not answering patients’ questions but directing them to look at paperwork instead.

Almost one-third of professionals believed that conversations were more important than documents. Reasons include patients’ inability to read or understand documents, the ability to customize explanations to best ensure patient understanding, the feeling that ‘real’ consent took place in conversation, and viewing documents as more of a formality or confirmation of consent. One Mental Health Professional observed that medical students were taught that the informed consent process occurs in conversation, whereas the documents merely reflect that consent had occurred. Informed consent interaction individualized the process: ‘I think the oral informed consent is really what gives it a...a more personal relationship,’ said one physician. Several professionals frankly acknowledged that ‘most of the time [patients] don’t take the time to go word by word through the consent form before they sign it’. Other patients are ‘desperate’ to begin treatment, so they sign without reading the form. Conversations allowed the health care professional to ensure that the patient understood the information prior to consenting.

Many physicians believe that patients are desensitized to documents as a result of bureaucratic elements of American culture wherein one must regularly sign standardized contracts, such as mortgages, leases, or end-user license agreements. Patients often do not carefully read through those forms, and if they suffer few consequences as a result, then they feel no need to carefully read through informed consent forms either. One physician said, ‘it’s very, very uncommon for patients to come in and say, “I see on page 12 you have this written. What does that mean?”’ Another physician believes patients fail to read informed consent forms because by the time the patient gets the document, the patient has already made up his or her mind to undergo treatment. In other words, even though the informed consent process should enable patients to make informed choices, sometimes the patient’s choice has already been made before the informed consent process even begins.

Professionals were also concerned with patients who could not understand the paperwork, especially if the language is technical, information is dense, or there are many pages. Some physicians and institutions try to revise the forms to make them more understandable for the lay person, but there is no guarantee that every patient comprehends the forms. On the other hand, conversation compels patients to think through the consent forms. ‘I think you can’t digest until it’s read out loud, because (especially when the cancer patients are coming to me), they’re not really paying attention’, said one lab technologist, ‘they really couldn’t care less, they have so many more serious things on their mind, but this is to me a very serious thing’.
Some professionals believed that the meat of informed consent occurred through conversation, whereas the signature on the document is a mere formality, evidence that conversations had occurred. Professionals’ different perceptions of consent conversations and documents represent clashing images of the provider–patient relationship, where an interactive, trusting, medical relationship is pitted against one that is suspicious, adversarial, and legal. Some health practitioners believe that these forms are relics of an adversarial, litigious culture. This is not a positive development. One physician observed that the ‘written part is to cover your back, unfortunately’. In fact, these forms may actually make it harder to meet the medical standard of care if they are difficult to understand and confuse patients instead of informing them.

Some professionals expressed skepticism regarding the legal validity of informed consent documents. After all, if different medical professionals follow different informed consent protocols, then the patient’s signature is virtually meaningless, as it does not guarantee whether the informed consent interaction included multiple mediums, forms with appropriate language, verbal explanations of provisions, and opportunities to ask questions. The signature on the document is in fact nothing more than a confirmation that on a certain date a patient picked up a pen and inscribed her name on a corner of 8 1/2 × 11 paper. Surely if a patient plaintiff sues her physician for an alleged informed consent violation, more evidence will need to be introduced about the exact practices that were followed. As one physician ruminated, ‘I’m not an attorney, but from what I understand, it really doesn’t matter if they sign it or not’.

2. Documents more important
A small group of patients felt that documents were more important than conversations. Visual learners preferred documentation over conversation. ‘Well what I teach is English’, said one participant, ‘so I’m a big reader and I read really fast and digest a lot of information...I think the conversation probably wasn’t as important to me as what I read because I digest information really well’. Some participants felt that the conversation was less detailed and thus less helpful: ‘the document contained more information that I could read later when I wasn’t so caught up in it I guess’.

Patients also believed that documents are helpful when conversations are brief or unmemorable. They serve as a valuable resource for patients, and can be reread when questions arise in the future. Documents are especially useful when patients have an opportunity to read them prior to conversations with providers, allowing the patients to formulate questions in advance.

Only a handful of fertility professionals believed that documents were more important than conversations for the informed consent process. They observed that patients could not be realistically expected to remember every factoid within the onslaught of information about IVF and treatment protocols. One physician explained, ‘It’s really natural if someone doesn’t get pregnant, they go through the grieving process...and I think at some point they pull those documents out and they go back through and [see] “Oh, this mentions here that this might happen.”’ Moreover, there might be something to the notion that documents carry more ‘gravitas’ than conversations over time because they outlive conversations. Additionally, when something is placed in document format (rather than conversation) it feels more serious. Finally, documents serve as testaments to current standards of practice, especially when different informed consent practices exist across clinics.
3. Both documents and conversation are important

Approximately one-third of patients felt that both documents and conversations were important. Most of these patients indicated that the mediums reinforced one another, going ‘hand in hand’. A common sentiment was that conversations filled in the gaps left by documents. One participant said the conversation ‘cleared up the big picture’, while the documents ‘let us understand the details better’. The opportunity to learn things through two different mediums, paper and conversation, makes the information more salient for some patients. ‘It just made it come alive a little bit more,’ said one participant regarding conversation about the informed consent documents. However, some patients felt that there were no real differences between the two formats. And neither format was particularly helpful if patients were already overly familiar with the information.

Two-thirds of fertility professionals thought of both conversations and consent forms as useful; each medium conveyed information for distinct purposes or to different people. As a result, conversations and forms reinforce one another. Finally, several patients were either predominantly visual or auditory learners, so both mediums should be provided. For one physician, the forms provide information that is crucial but more general in nature, while conversations allow providers to educate patients about how ‘their’ specific needs will be addressed. A similar and likewise popular response was to observe that forms satisfied legal requirements while ‘the conversation is important in gauging how [well] the patient understands’.

If informed consent consists of both education and confirmation, then one process—understanding—has to come before the other—signing. ‘They have to be equally important. You have to understand before you sign, otherwise I wouldn’t have a patient sign’, said a nurse. Therefore, she believes the conversation should occur before the patient receives documents. On the other hand, the document can serve as a useful guide for the patient to follow during conversation or may help the patient formulate questions.

The consent forms may contain the same information as conversations, but if a professional discusses both with a patient, the written form becomes a checklist that helps to ensure that the verbal presentation is thorough. Additionally, documentation allows for standardized conversation with room for individualized information when needed. This becomes especially important after the conversation takes place. ‘At least with a hard copy of a document if they question anything, obviously, you can go back and say, “It’s written here. You signed here”,’ said one physician.

E. Summary

Patients and professionals’ perceptions of informed consent are suffused with tensions—between medical and legal safeguards, between trusting and adversarial relations, between informality and formality, between comprehensibility and thoroughness, between understanding and time, between current optimism and potentially troubled futures.

Here, we begin to break down and complicate the stereotypical informed consent process—today, an event where a patient rapidly signs a one-size-fits-all, standardized and perhaps dense document brimming with legal jargon as a condition for seeing a physician or undergoing a procedure. This description could apply to a wide variety
of medical documents, from privacy notification agreements and HIPAA forms to surgical consents. Today’s informed consent forms have much in common with the ill-fated end-user license agreement to which consumers who purchase cell phone service or software must agree (ostensibly, after reading—a ludicrous assumption for most people).

Instead, an effective informed consent interaction is demonstrated not by a signed document, but by patient understanding. A necessary complement to provider explanations is patient questions. Informed consent then is a multi-medium interaction, and both parties can use interaction to tailor information to patients’ specific concerns. If health care providers come across as endeavoring to inform patients to assist them with decision making and not for self-protection, then the informed consent process cultivates and strengthens mutual respect and trust. Ideally, emphasis is not placed on the long-term value of consent documentation as a legal protection for medical providers; informed consent becomes divested of overtones of distrust and adversarial relations.

Patients’ and providers’ comments illustrate what happens when the educative and adversarial connotations of informed consent persist alongside each other. These dual purposes cannot survive in harmony with one another. Instead, like Dr. Jekyll taking over Mr. Hyde, consent’s adversarial properties overshadow and potentially nullify its educative dimensions. The result is that patients see informed consent as a product of a litigious culture and not patient reform, which propitiates a cynical and lackadaisical attitude towards the informed consent project. Cynicism may cause patients to skim over information provided, thus preventing them from becoming truly informed.

Some people might argue that when patients trust providers, then patients relax their vigilance, harming the informed consent process. However, most of the time patients’ trust in providers enables informed consent rather than undermining it. After all, if patients do not repose some trust in their health care providers, then why would patients believe they are being given accurate information on which to base treatment decisions? Conversely, if physicians do not trust patients, then how would physicians ever feel comfortable with patients’ assurances that they understood proffered explanations? Without trust, what value would a patient’s signature hold? Therefore, trust in the physician–patient relationship forms a bedrock of the informed consent process. Nevertheless, this research illustrates that consent documents are problematic and that many patients are sensitive to the bureaucratic dimensions of paperwork, causing cynicism about the informed consent project as a whole. Therefore, a multimedia intervention may be warranted.

III. MULTIMEDIA INFORMED CONSENT PROCESS

In order to increase comprehension and patient attention during the informed consent process, some researchers have designed and tested ‘multimedia informed consent’: a more engaging informed consent processes including video, computers, the Internet, and/or other forms of technology. Multimedia informed consent may be provided in lieu of, or in addition to, traditional informed consent documents.

A. A brief review of past research on multimedia informed consent

A number of studies have analyzed the impact of multimedia informed consent on patient comprehension (see Part I infra), none of which takes place in the ART
context. Researchers must be careful when drawing broad conclusions, because the topic of multimedia consent includes a number of diverse formats that are difficult to compare. For example, a literature search for ‘multimedia informed consent’ revealed the following formats of information delivery: a 13-min DVD featuring a series of dramatic vignettes; a 20-min self-guided, narrated presentation on a computer with short video clips; a 10-min computerized tutorial with a sequence of 2D and 3D images and animations; and computerized lessons that progress to new topics only when short quizzes are answered correctly.

Like document-based informed consent, multimedia informed consent may occur in a number of contexts. For example, information may be accessed on the patient’s home computer, in a computer kiosk at the physician’s office (with staff nearby to provide technical assistance), or on a tablet in the physician’s office. Multimedia informed consent may occur immediately prior to the procedure or far in advance. Additionally, Internet-based informed consent may occur at multiple points during treatment, including post-procedure education and patient support.

Most studies have been equivocal regarding benefits of multimedia informed consent relative to traditional document informed consent. For example, Cohn and Larson critically evaluated studies of multimedia informed consent comprehension over the last decade. After analyzing interventions with simplified documents, multimedia approaches, and in-person education, they determined that no single intervention was consistently associated with improved comprehension. Similarly, a randomized experimental study by Jeste et al. found little evidence that multimedia interventions improved comprehension. Instead, satisfaction with quality and effectiveness of information was high in both the traditional informed consent and multimedia informed consent groups, with no significant difference between them. In-person discussions are better at improving patient understanding relative to multimedia intervention or document informed consent. However, Jeste et al. suggest that multimedia tools would be beneficial if integrated with in-person discussion.

Few authors have found negative impacts of computer-based patient education. In one study, a minority of participants found a video-based intervention to be too tedious and long relative to document-based informed consent. Another study found that

57 See Kass et al., supra note 10, at 2.
59 See Dennis Gyomber et al., Improving Informed Consent for Patients Undergoing Radical Prostatectomy using Multimedia Techniques: A Prospective Randomized Crossover Study, 106 BJU INT. 1152, 1153 (2010).
60 See Deborah Lewis, Computer-Based Approaches to Improving Patient Education: A Review of the Literature, 6 J. AM. MED. INFORM. ASSOC. 272, 279 (1999).
63 Id.
64 Id.
65 Id.
66 See Lewis, supra note 60, at 279.
67 See McGraw et al., supra note 56, at 14.
the graphics involved in a multimedia intervention could be emotionally distressing. However, neither of these complaints are insurmountable, as videos may be shortened and graphics more cautiously designed. Some individuals lacking computer skills may be at a disadvantage in multimedia interventions; however, one study found that individuals without prior computer experience have few problems with multimedia interventions. Furthermore, if multimedia informed consent occurs in the physician’s office, then a nurse or other staff member nearby may be able to assist with usage difficulties.

Some studies have provided encouraging results regarding multimedia consent interventions. One comprehensive literature review of 66 studies of multimedia interventions ascertained that the literature supports the use of computers to educate patients. Other studies have found the following specific benefits associated with multimedia intervention relative to document-based informed consent: higher patient satisfaction with the informed consent process; greater enjoyment; improved knowledge and comprehension; better information recall; improved patient–physician relationship; lower anxiety; and faster learning. In particular, a randomized, experimental study with 135 participants found that improvement from baseline to early understanding was significantly greater among patients in the media intervention group


69 See Lewis, supra note 60, at 275 (citing V.Z. Ogozalek, The “Automated Pharmacist”: Comparing the Use of Leaflets, Text-Based Computers, and Multimedia Computers to Provide Medication Information to the Elderly, J. MED. EDUC. TECHNOL. 6 (1993)).

70 Id.

71 See Michael Rowbotham et al., Interactive Informed Consent: Randomized Comparison with Paper Consents, 8 PLoS ONE 1, 4 (2013) (study found that patients given informed consent program on an iPad reported slightly greater patient satisfaction and enjoyment than patients given paper informed consent); Clayton Cowl et al., Evaluating the Use of Computer-Based Interactive Technology for Improving Outpatient Procedure Education, AM. MED. INFORM. ASSOC. ANNU. SYMP. PROC. 1001 (2002) (patient satisfaction significantly increased in the interactive informed consent group versus in the standard paper informed consent group); Gyomber et al., supra note 59, at 1154; Tetzlaff et al., supra note 11, at 290, 291 (study found that live interaction informed consent was preferred to video informed consent, and video informed consent was preferred to text informed consent for all topics).

72 See Rowbotham et al., supra note 71, at 4.

73 See Tait et al., supra note 58 (study found that multimedia informed consent resulted in greater patient knowledge relative to standard informed consent process).

74 In a 130 person, randomized, experimental study of the effectiveness of multimedia IC relative to paper brochure IC, researchers found that multimedia IC resulted in more realistic expectations regarding the clinical trial. Interestingly, despite the more realistic (and pessimistic) expectations, multimedia IC did not lead to a decrease in trial enrollees relative to the paper brochure IC, perhaps because potential trial participants had already made up their minds prior to the IC process; Kass et al, supra note 10. See also Rowbotham et al., supra note 71, at 3 (study found that patients given informed consent program on an iPad had improved comprehension scores relative to patients given paper informed consent).

75 See McGraw et al., supra note 56 (participants in multimedia group demonstrated better recall. However, being able to recall information is not necessarily the same thing as processing and understanding information.).

76 See Lewis, supra note 60, at 279 (a literature review of informed consent studies found that multimedia intervention may lead to better communication between patient and provider).

77 See Gyomber et al., supra note 59; Cowl, et al., supra note 71, at 1001 (validated questionnaire found that patient anxiety significantly decreased in multimedia informed consent group relative to standard informed consent group).

78 See Lewis, supra note 60, at 275 (one study found that patient learning occurred 40% faster with interactive computer-based informed consent relative to standard informed consent).
relative to patients in the traditional informed consent group. Patients in the media intervention group had a significantly greater early understanding of risks and treatment options. The study was notable for its rigorous methods (including adequate randomization, high response and participation rates, blinded outcome assessments, and consideration of multiple potential confounders in the interpretation of results) and for its significant findings.79

Multimedia informed consent can provide specific benefits relative to document-based informed consent. First, visual cues, animation, and diagrams are easily integrated into multimedia formats, possibly promoting better recall.80 Animation conveys time and dynamic processes better than do static images, which is especially useful when conveying abstract principles.81 In particular, participants with lower textual abilities are better able to comprehend processes described through animations.82 Additionally, audio and graphics increase comprehension and decrease anxiety in individuals with low literacy skills, which is especially important in the medical context where technical and scientific terms are prevalent.83 However, one study found that the cognitive load for handling complex animations might distress low-visual-ability users.84 Also, videos and animations can effectively weave together a narrative of disparate topics, promoting recall.85

Second, computer interventions allow for individualized experiences. For example, a computer program may allow patients to click on underlined terms or topics to obtain more information if desired.86 Likewise, a computer program may include required information routes and optional information routes.87

Third, computer interventions may allow for immediate reinforcement of information, such as through quizzes that provide immediate patient feedback.88 One study reported increased comprehension when patient movement through a computer program depended on the patient answering quiz questions correctly. Quiz results may also help physicians identify topics that are particularly confusing to patients, prompting the physician to focus on these topics when meeting with the patient.89 Finally, Internet-based informed consent is particularly well suited to providing ongoing education and long-term patient support,90 such as by allowing patients to submit questions to their physician or engaging in real-time conversation with staff from home.

One must approach these results with some caution. Scholars have identified several study limitations prevalent in many multimedia informed consent analyses,

79 Tait et al., supra note 58, at 11.
80 See McGraw, et al., supra note 56.
81 See Kim, et al., supra note 68, at 345.
82 See Id. at 346.
83 See Lewis, supra note 60, at 278.
85 See Kim, et al., supra note 17, at 345 (narrative approach to information improves comprehension).
86 See Tait et al., supra note 10, at 10.
87 See Kim, et al., supra note 17, at 349.
88 See Lewis, supra note 12, at 274.
89 Multimedia IC can help medical providers identify and respond to patient needs. For example, the computer program could allow medical providers to see which topics or screens patients spend the most time on, suggesting that medical providers should discuss these topics in face-to-face meetings. See Kim et al., supra note 17, at 351.
90 See Lewis, supra note 60, at 278.
such as small sample size; failure to use randomized, experimental design; lack of blinding; and inadequate accounting of differences between demographic groups. Additionally, it is difficult to make meaningful comparisons between different types of multimedia informed consent, especially with regards to clarity, if the formats of information delivery are different. For example, multimedia informed consent may include videos with human actors, animation, graphics, games, and/or quizzes, formats which may be difficult to meaningfully compare. Disagreement also exists as to what ‘comprehension’ is and how it should be measured. Some studies test recall but not patients’ decision-making processes. As a result, some researchers are using cognitive interviewing, rather than surveys, to better understand how patients reason through information and make decisions. Finally, little research has been conducted about how patients’ psychological state at the time of consent affects information storage, retention, and recall of important information pre-treatment. Such research would be useful, considering that graphics in multimedia interventions may heighten patient emotions.

Previous studies of multimedia interventions provide clues as to how multimedia interventions should be designed in order to increase patient satisfaction and comprehension. First, video or computerized interventions should not take too long to complete or else patients may find the intervention tedious. For example, one group of researchers reduced their informational video from 20 min to 13 min after receiving criticism from a focus group. Relatedly, computer interventions and videos should not be too repetitive; repetition may increase information recall, but it may also cause boredom. Second, designers of multimedia intervention should strive to avoid patient fatigue. One option is to provide the most important information up front, rather than at the end of the intervention when patient attention typically starts to wane. Also, provision of two different information routes (one longer, one shorter) would allow patients who want more information to access it. Third, immediate feedback in the form of short quizzes and answers should be provided. Finally, any multimedia intervention should be aesthetically appealing; the more aesthetically appealing, the more likely a user is to find the computer program (and its information) trustworthy. Also, apparent usability may influence actual usability.

91 See McGraw et al., supra note 56, at 17.
92 Id.
93 Id.
94 Id.
95 Id.
96 Id.
98 See Ian N. Olver et al., Improving Informed Consent to Chemotherapy: A Randomized Control Trial of Written Information versus an Interactive Multimedia CD-ROM, 74 PATIENT EDUC. & COUNSELING 197 (2009) (study found that depression consistently influenced patient recall; more research is needed to assess how patients’ emotional states affect their ability to comprehend information during the informed consent process).
100 Id.
101 See Kim et al., supra note 68, at 346.
102 See Lewis, supra note 60, at 274.
104 See Kim et al., supra note 68, at 343.
B. Perceived advantages and disadvantages of an IVF multimedia web-based informed consent application

Doctors and nurses at a major fertility clinic that will be the first in the country to incorporate multimedia informed consent into its IVF program were asked a number of questions, including what the advantages and disadvantages of the multimedia application would be for professionals and patients. Because participants frequently listed the same factors for both professionals and patients, these factors will be discussed together for expediency’s sake.

1. Advantages for professionals and patients
The most frequently mentioned advantage of multimedia informed consent for professionals and patients was improved patient learning and understanding. One physician opined that the multimedia application was more advantageous than documents: ‘I think the process, the videos, the quiz; I think it’s just a completely different level of understanding for patients.’ A nurse agreed: ‘when you’re talking about an egg retrieval, some people don’t even know their own anatomy...I think fear is the biggest part of this... and not really understanding what things look like? And if you can visualize what it is, it kind of lowers that anxiety’.

Another physician praised the application as a huge step forward in patient comprehension: ‘That’s why I think this process...is probably more important than any other informed consent that’s ever been done, because you’re actually using it as a teaching process, interaction, making sure they understand the process’. Regarding length of time spent in the multimedia informed consent process, one physician says, ‘I would still use the same amount of time in giving informed consent to my patients. So I don’t think it would save much of that time...You really only have about 20 min when you’re presenting any type of process, and once you get past that, the patient is not listening’.

One consequence of enriched learning is that the multimedia application would make the risks of the medical procedure feel more real to the patient. One nurse admits that she was ‘a little taken aback watching it... all the stuff about death and bleeding and needing transfusions. I’m thinking, I’ve been here almost six years and I’ve not run into too much of any of that...But it’s an informed consent. That’s what an informed consent is’.

Professionals appreciated the ability to seamlessly incorporate a quiz into the multimedia consent application, potentially improving patient accountability. A physician asserted, ‘I think that if you’re making them do a quiz with each one, they have to have read through it; they’re not skipping over or just signing off on something’. Additionally, physicians liked the ability to identify common and individual misunderstandings based off of quiz results. Such feedback allows physicians to modify their conversations or information delivery in order improve comprehension. Not surprisingly, greater patient accountability may translate into more effective legal protection, both for patients and providers. As one physician explained, ‘Well, if I missed it, the video is going to cover it’. Similarly, another physician asserted, ‘If somebody had to go through that visual video kind of a thing and answer questions...and then c[a]me back and sa[id], ‘Well, I didn’t understand it’, we’ll say, ‘Well, here’s evidence that you went through this whole thing. You had plenty of chances to ask questions’.

Some physicians believed the multimedia informed consent process would standardize the provision of comprehensive information. One physician said, ‘I know on a good day, I will probably cover 80% of the issues with a patient and on a bad day maybe 50%. So, at least I know that, using [multimedia], every issue that I want the patient to have heard, they will have been exposed to in a very digestible form’. Another physician said:

I think it complements the written document, but it’s [a] much more in-depth explanation. I think all of us, as physicians, probably have varying presentations about what the complications really are, and I think if you have a uniform way of presenting it, and everybody’s on the same page and we cover the same things, it’s very difficult for the
patient to miss something that’s important and then come back and say, ‘Well, I didn’t understand’.

Professionals also believed the multimedia application would be more efficient. According to one professional, multimedia informed consent would translate into fewer patient questions about IVF in general: ‘Less time on the phone and email. We answer a lot of questions…about the process, about everything in general, and I think if we can defer to the Engaged MD first, and then the patient can generate questions and then we can supplement, it would save a lot of time’.

Professionals and patients also observed that multimedia informed consent would be geared towards patients with visual or auditory learning styles. ‘It’s automatically a little bit more engaging than just a paper document is. I’ve noticed that, if I can watch a video about how to do something versus reading a page about it, I’ll watch the video’, noted one physician. Another physician agreed:

For a lot of people, it’s hard for them to visualize what’s actually happening. So if you can show them what’s happening, with the egg retrieval, and you show them what’s happening in the lab, and how things are identified in the lab, and how things are manipulated in the lab, and the ICSI procedure and the embryoplasty procedure, most people don’t have an idea of how that’s actually done…The patients would really like that.

Professionals were very confident that multimedia informed consent would be more comfortable for patients. One physician observed, ‘I think that the consent process has been flawed along the way, just because it’s too cumbersome and there’s too much to read, and our consent forms now, because of the attorneys, are probably 20, 30 pages. I think [multimedia informed consent] is a really great, better way for the patient to be consented’. For one nurse, it was critical that patients could complete the multimedia application at home: ‘any type of video that you do at home, you can do it at your leisure. I think convenience is the number one thing’. Another physician thought it would give patients more control: ‘if people have an understanding, have more control over their lives, and what’s happening with them, their comfort increases. That’ll decrease [the] potential that they’re going to look at things in a negative fashion’. One professional thoughtfully noted that patients would appreciate that the clinic had gone to such cost and effort patients of risks and benefits.

Patients could use the multimedia application as a reliable resource to review if they had questions during the treatment process. As one nurse explained:

If they have a question specifically about egg retrieval, they can go and view the entire process in its entirety, instead of Googling it at 11 pm at night. We’re not available at 11 pm. So if they’re anxious enough where they cannot go to sleep because they have a question, real information is available instead of Googling and going to MommyAndMe.com; they can really go to real sources of information and get accurate answers.
Many professionals did not believe that incorporating multimedia consent would have any disadvantages for them. ‘I don’t think there’s a disadvantage to this’, 2 EMNurse commented, ‘I think this is just a great tool to help us. I think it can’t hurt us’.

Some professionals added, however, that the application would impose more follow-up responsibilities, mostly on nurses and other staff. ‘One of the potential downsides of this, is physician/nurses making sure that we follow-up with the patient, to make sure that their questions are answered. And then it needs to be documented’, one physician explained, ‘if some clinical teams aren’t as diligent as they should be, there could be unanswered questions, though. So that just takes a little extra work on our side. One nurse was mindful of the fact that these responsibilities would also be added to patients’ duties: ‘the patients have such a huge checklist of things that they need to complete, that
this is one more thing to add to that basket, but we have to remind them to sign consents anyway’.

Professionals were also careful to note that they would still have to have informed consent conversations with patients. One physician emphasized:

You still need to give the informed consent to your patients, because you know their personality, and you don’t want someone to rely too heavily on that... Make sure you hit all the bullet points with the patient, and then explain what they have questions about briefly, and then say, ‘Now do the informed MD because there’s a lot of information on there, and it may answer those questions more thoroughly than we can in this short time. And then come back for what’s left over. And between myself, and the nurse, we’re going to pretty much make sure you, you could have everything you can.

Another physician was concerned that professionals would use the videos as a crutch in order to avoid conversation: ‘It shouldn’t really be something that takes the place of a consultation, but I would fear that maybe being an unintended consequence, that I go from saying, “Okay, I’m gonna have this chat with my patient”, to “Oh, we’re gonna do IVF, just watch the videos”’. In other words, the multimedia application should supplement conversation rather than replace conversation.

When it came to patients, however, the vast majority of professionals noted that the biggest disadvantage was the time commitment required to complete the multimedia application—an interesting concern, given the time that many if not most infertility patients spend in online research or reading about infertility, often from unreliable sources. In the words of one physician:

You could probably blow through a consent form... in a very shoddy way pretty quickly'. Another physician asserted, ‘I think time is the biggest thing. Signing a consent with me, whether they understand it or not, takes 10 or 15 min, because at the end of the day, it needs to be signed. With this, it is going to take a little over an hour, because there’s no skipping ahead... it’s either done or it’s not. So it is gonna take some time and some dedication from the patients’ perspective.

Another physician had an even stronger reaction and wondered if the clinic might not lose patients who were irked at spending additional time:

The big disadvantages that popped into my head when you said ‘An hour 30’ or ‘An hour 45 minutes,’ I thought to myself, ‘Holy god, that sounds horrible’. That just seems like a tremendous amount of time. I don’t sit in front of my computer for an hour and 45 minutes to do anything. And I worry that that is gonna be a huge turn-off. I try to put myself in the position of the patient, if I was going for... some sort of elective cosmetic procedure, and my doctor told me, ‘Before we’ll proceed to the procedure, you have to complete two hours of videos and quizzes’, I might be like, ‘All right, buddy. See ya!’ I just don’t have that kind of time. And there’s a big split between what patients want. Some patients say... ‘I’m not here for a relationship. I’m here to have a transaction of information and get on with my day’. And there are people who, on the other hand, want every little bit... I think those patients probably would think this is great.
On the other hand, a different physician disagreed, stating, ‘I don’t think a patient going through IVF is going to be unhappy about having a fantastic educational tool’. After all, thorough comprehension is the basis of true informed consent.

A few professionals worried that patients may feel overwhelmed by multimedia. For example, one nurse feared that multimedia might cause information overload or cause stress in cases of language barriers, lower socio-economic status or lower levels of education. Similarly, a handful worried about access issues or the impact of technological knowledge deficits. For one nurse, the same patients who may be more likely to become overwhelmed might also have trouble understanding or accessing the application, especially if they lack a readily available computer.

IV. CONCLUSION

This essay has examined whether the consequences of consent forms’ legalistic and bureaucratic baggage derailed the informed consent train, before it even leaves the station so to speak, and explores how a different engine—a multimedia consent application—could affect the lived experience of informed consent.

At this point, EngagedMD has been incorporated into clinic practices at the fertility clinic that is serving as the study site. This innovation has great potential to spread rapidly through the industry; though individual clinics could certainly implement EngagedMD, there is a trend towards consolidation in the reproductive medical industry, or clinics could receive such services if they are offered through corporations like IntegraMed that provide several services for fertility clinics such as ‘clinical and business information systems, marketing and sales, facilities and operations management, finance and accounting, human resources, legal, risk management, quality assurance, and fertility treatment financing programs’.¹⁰⁵

Thus far, preliminary results suggest that patients and providers do feel that this is an entirely different intervention. In a limited survey of 68 patients conducted in April of 2015 by the EngagedMD designers, patients ranked EngagedMD second only to their doctor as an effective information source (see Figure 4). Moreover, the majority of patients strongly agree that the application educated them about the IVF cycle, made them more comfortable, enhanced their ability to converse with their medical team and ask informed questions, made them feel more in control of their medical decisions, and made them better prepared to sign consent forms (see Figure 5).

Patient comments substantiate these preliminary statistics. One patient noted, ‘Overall I thought it was a great tool. Having been through IVF at another clinic that did not have a similar program, I found that even I was able to learn a thing or two that I hadn’t known previously’. Another noted that ‘it covered topics that I either wasn’t aware of (and without awareness couldn’t ask my doctor or nurse for more information) or that I knew about generally but didn’t have a detailed understanding of...that information...helped give me realistic expectations for my upcoming IVF cycle’. A third asserted, ‘I loved the visuals that went along with the nurse’s instructions. I could watch the videos on my computer, and on my iPad which was very convenient’. Moreover,

most physicians feel that EngagedMD is more efficient and effective in several dimensions than consent documents alone (see Figure 6).

As the EngagedMD randomized controlled trial begins, it is interesting to consider the ways in which it may change patients’ and providers lived experience of consent. Perhaps this new application will be free of the baggage attached to documents and rituals of reading and completion; perhaps patients will feel that this format more effectively protects them. Of particular interest is whether patients feel that they do have to invest more time to complete the EngagedMD application, and whether they feel that that expenditure was productive. Survey instruments and interviews will also endeavor
to capture patient reactions to unexpected developments in their IVF cycle, such as cycle cancellation due to poor response to follicle stimulating hormones or other drugs or ovarian hyperstimulation. These results will show more conclusively whether or not EngagedMD—a more sophisticated multimedia application that others tested thus far in other care contexts—can succeed where documents are failing. The results will be relevant to the fields of law, medicine, and ethics.

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