

**TERMINATING THE PAPER TRAIL:
EVALUATING THE EFFICACY OF A MULTIMEDIA INFORMED CONSENT APPLICATION IN
REPRODUCTIVE MEDICINE**

Jody Lyneé Madeira

I. Introduction

In September of 2015, an odd post appeared in the “Infertility Support and Discussion” page of the “DC Urban Moms and Dads” web forum. A patient of Shady Grove Fertility Clinic in Washington, D.C. began a post about an unusual topic: her informed consent experience. Instead of typical consent documents, she had been asked to complete EngagedMD, a multimedia e-learning application designed to facilitate patient education and informed consent consisting of 13 video modules describing the in vitro fertilization (IVF) process. She noted, “Am I the only one who thinks this is bizarre?”¹ Several fellow patients replied, voicing a variety of opinions; while some resented having to complete the modules, others found it comprehensive and useful: “Some of the stuff is really simple, but some people go in without understanding the basics of IVF, so at least this allows the clinic to provide some fundamental info.” Another poster observed, “I actually like the module. Yes it was long but it helped inform me. . . . And it was helpful for DH [Dear Husband] to watch with me. . . . It is the first time that I haven’t felt like there is total information asymmetry in what I know vs his understanding.”

Just a few years ago, these patients would never have had an opportunity to evaluate a product such as EngagedMD. Instead, they would have received a lengthy packet (or binder) of paper consent forms to review and eventually sign. While a handful of e-learning applications exist in other medical fields, EngagedMD is the first designed and utilized to attempt to solve common informed consent problems in Assisted Reproductive Technology (ART), such as

ensuring consistent consent presentations and that patients read or understand consent documents. This chapter is the first to describe patients' reactions to EngagedMD, incorporating both quantitative and qualitative responses. Though designed to improve patients' consent experiences, these applications also seek to reduce provider liability and improve clinic efficiency, increasing profits in the process.

In exploring this technology, this chapter confronts the “dark side” of informed consent forms—the idea that consent documents fail for reasons other than poor patient recall and comprehension, especially patients' emotions² and their perceptions that these forms are bureaucratic and protect physicians at their expense.³ Currently, little research exists on patients' lived experience of informed consent, despite common speculation about its ineffectiveness. There is a critical need for more systematic empirical evaluation of both patients' consent experiences and the efficacy of diverse informed consent aids and mediums. Investigating these issues within ART is particularly interesting because patients must confront unique ethical, legal, and medical decisions.

This chapter is the first analysis of whether patients regard applications such as EngagedMD as more or less effective or enjoyable compared to other consent aids like documents and conversations. It is based upon 6,333 IVF and IUI patient online survey responses⁴ assessing whether they were satisfied with EngagedMD and viewed it as an effective informed consent aid. This survey included both multiple choice and open-ended questions assessing patients' opinions as to informed consent's importance, their satisfaction with EngagedMD, and its efficacy as compared to other consent aids. This chapter analyzes the results of several quantitative items as well as three qualitative questions: “How important is it

that you are properly educated about your care,” Did the EngagedMD program answer any questions that you otherwise would have had to ask your medical team,” and “Tell us why you did or did not like learning about your procedure from the EngagedMD eLearning system?” Thus, this chapter also reaches broader questions, like how these technologies transform how patients receive and use information and impact doctor-patient relationships.

This chapter analyzes the results of several quantitative items as well as three qualitative questions: “How important is it that you are properly educated about your care,” Did the EngagedMD program answer any questions that you otherwise would have had to ask your medical team,” and “Tell us why you did or did not like learning about your procedure from the EngagedMD eLearning system?” In Part I, this chapter will address EngagedMD’s history and design goals. In Part II, it will discuss patients’ responses to quantitative questions after completing EngagedMD before their IVF or IUI (intrauterine insemination) treatment cycles. In Part III, this chapter will explore patients’ written responses to open-ended questions concerning whether they felt it was important to be properly educated about their care, whether EngagedMD answered questions they would otherwise have asked their providers, and why they did or didn’t like completing the program.

II. A Brief History of EngagedMD

EngagedMD is largely the brainchild of Dr. Michael Levy, a reproductive endocrinologist (RE) who is President and Director of IVF at Shady Grove Fertility Clinic, the largest fertility clinic in the United States, with over 7,648 cycles annually.⁵ Interested in finding a more effective and appealing alternative to traditional paper informed consent forms, Dr. Levy initiated a

partnership in 2013 with two entrepreneurs, Taylor Stein and Jeff Issner, to design an interactive multimedia application to educate patients about IVF processes.⁶

The final product, EngagedMD, was implemented in 2015 at Shady Grove as a supplement to, not replacement for, patient-provider consent interactions. It consists of 13 videos followed by brief quizzes; incorrect answers generate “pop up” responses that give the correct answer and a brief explanation. Providers can track patients’ progress through the video modules, and can view their quiz scores so as to ensure that areas of confusion are clarified at subsequent consent consultations. As of mid-2017, EngagedMD is in use at Shady Grove Fertility Clinic and several practices across the United States, including Stanford University, University of Michigan, RMA of Texas, Fertility Centers of Illinois, and South Florida Institute for Reproductive Medicine. At Shady Grove, all new patients must complete the EngagedMD modules to proceed with treatment, regardless of whether they have never before undergone IUI or IVF or completed treatment cycles at other clinics.⁷

EngagedMD is marketed as a product that more effectively educates patients about treatment processes and risks, offers subscribing clinics better risk protection, and allows practices to improve efficiency and even patient volume. These goals are evident in a recent screenshot from EngagedMD’s website (see Figure 1), which lists several commercial and care objectives: increasing patient satisfaction, mitigating legal risk by ensuring full patient compliance, and saving time and increasing patient volume. To persuade clinics that EngagedMD is a smart business decision, its website includes a cost calculator, where curious providers can input factors like patient volume, length of appointment time, length of consent

packets and so on to obtain estimated “total patient education and informed consent costs,” as well as net savings with EngagedMD.

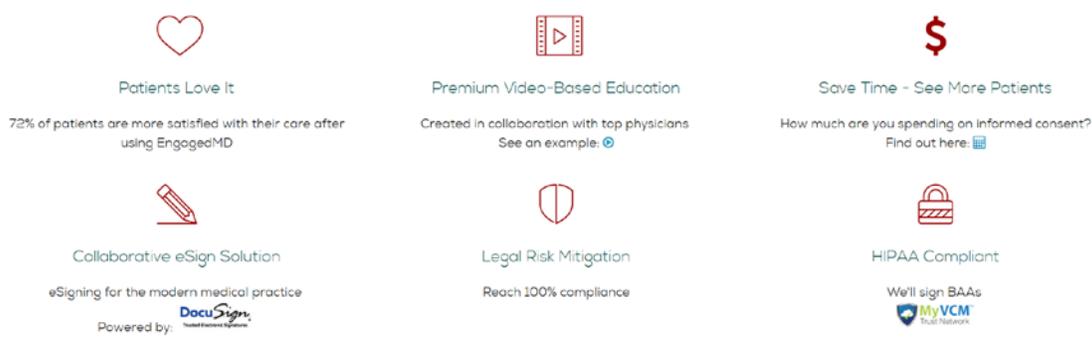


Figure 1: A screenshot from EngagedMD's website describing the application's benefits.

Informed consent is charged with fulfilling both medical and legal goals: educating patients and protecting physicians from lawsuits from allegedly misinformed or under-informed patients. But little research exists as to how well multimedia consent aids fulfill either of these goals, particularly on e-learning applications' effectiveness in comparison to consent documents and other aids, how such tools should be designed, what patients think of them, and how they impact medical treatment and relationships. Instead, most existing scholarship focuses on issues like recall and comprehension, ignoring how these aids impact patient satisfaction, treatment experiences, treatment relationships, and clinic efficiency. Recall and comprehension are critical issues, but do not reflect the sum total of what informed consent is, or what it should be. Although often reduced to signatures on consent forms, informed consent is as much a relationship as an educational opportunity or bureaucratic ritual. If informed consent is viewed too narrowly, its interactive qualities and potential for engagement can get lost in bureaucratic baggage.

III. Patients' Reactions to EngagedMD: A Statistical Snapshot

Patients were surveyed as to their overall informed consent preferences and experiences. Most patients had a healthy attitude towards informed consent; 84% (n=2906) felt it was “very important” they were properly educated about their care, and 15% (n=510) viewed it as “important”; 1% (n=41) were “neutral” on the question. Critically, only 8 patients out of 3,465 thought being informed was unimportant. Most patients (56%, n=1,929) would prefer to receive educational materials “as early in the process as possible”; other popular choices were after the consent consultation (27%, n=935) and before the consultation (10%, n=338).

Most survey respondents were either patients (48%, n=3,145), both patients and partners (42%, n=2,783), or partners (5%, n=341). The vast majority (72%, n=4,723) of the 6,532 patients completed the IVF modules; the remainder completed IUI training. In general, EngagedMD was received very favorably. Patients overwhelmingly reported that they enjoyed learning about their procedures from EngagedMD (96% (n=5285) vs. 4% (n=244)).

Patients also evaluated EngagedMD very favorably based on particular program features. The majority of patients—94% (n=4616)—felt that the videos had an “appropriate level” of detail; only 4% (n=179) felt they were too detailed, and 2% (n=117) found them insufficiently detailed. Relatedly, 90% (n=4,398) found it to be an “appropriate length,” whereas 10% (n=500) judged them too long. A resounding 89% of patients “strongly agreed” or “agreed” that quiz comprehension questions helped reinforce key concepts (46% SA (n=2404), 43% A (n=2241)). Patients also felt it was intuitive to use (93% either “strongly agreed” (54% (n=2,805)) or agreed (39% (n=2,028))).

Patients felt that EngagedMD positively influenced their informed consent experiences. The vast majority—83%—also felt that it enhanced their ability to sign informed consent documents (42% strongly agree, n=2,084; 41% “agreed,” n=2048). Of remaining participants, 10% (n=478) were neutral, and only 4% (n=208) “disagreed” or “strongly disagreed.” In addition to improving written informed consent, most also felt that EngagedMD enhanced their ability to converse with their medical team. Eight-five percent of patients “strongly agreed” (38%, n=1875) or “agreed” (45%, n=2231) with this statement, 11% (n=558) were neutral, and only 4% (n=196) “disagreed” or “strongly disagreed.” Similarly, 86% reported that it enhanced their ability to ask informed questions of their medical team (42% SA, n=2076; 44% A, n=2157; 9% N, n=459; 4% D or SD, n=178). EngagedMD also preemptively answered questions that patients would have asked their medical teams; 50% (n=1744) reported that it answered many questions, 44% (n=1525) stated that it answered one or a few questions, and only 6% (n=196) did not find that it answered any questions. In general, 93% “strongly agreed” (53%, n=2596) or “agreed” (40%, n=1952) that EngagedMD educated them on treatment risks.

Patients also felt that EngagedMD was a highly effective information source as compared to consent documents, internet-based sources, staff training, and physician consultations, as illustrated in Figure 3 below.

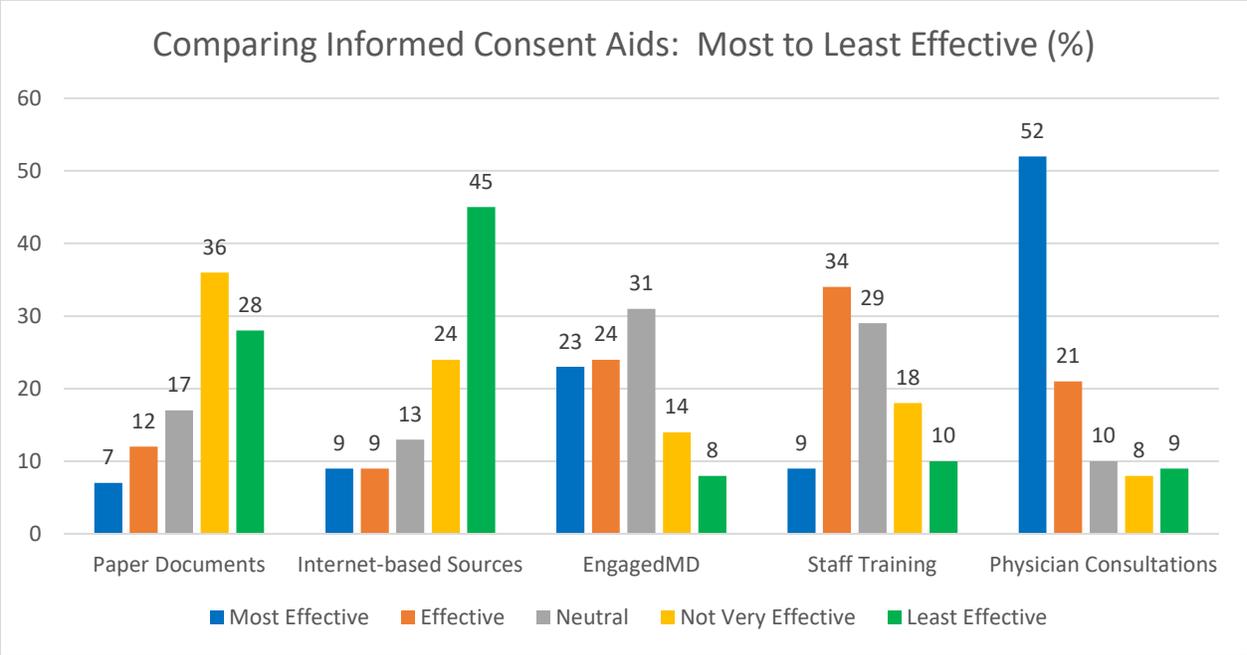


Figure 2: Chart Comparing Informed Consent Aids' Efficacy

Only 19% of patients ranked documents, the traditional and most commonly used informed consent aid, as their most effective (7%, n=353) or second-most-effective (12%, n=594) information source. Strikingly, 54% ranked them as either the most ineffective resource (36%, n=1831), or the next-to-most-ineffective resource (28%, n=1434). Internet-based sources, too, were rated low in effectiveness, with only 18% of patients ranking them most effective (9%, n=459) or second-most-effective (9%, n=458); 69% evaluated them as the next-to-most-ineffective resource (24%, n=1236) or the most ineffective (45%, n=2277). It is unfortunate, however, that patients regarded consent documents and internet-based resources so comparable in effectiveness. In contrast, 47% of patients ranked EngagedMD as most (23%, n=1179) or second-most (24%, n=1233) effective; 22% of patients felt that it was the next-to-most-ineffective resource (14%, n=693) or most ineffective resource (8%, n=391). Patients viewed interpersonal nurse or staff training sessions as comparably effective to EngagedMD;

43% of patients found them most (9%, n=463) or second-most (34%, n=1705) effective resources, and 28% found them next-to-most ineffective (18%, n=920) or most ineffective (10%, n=529). Patients clearly preferred physician consultations; 73% ranking them most (52%, n=2626) effective or second-most (21%, n=1090) effective (8% next-to-most-ineffective, n=400; 9% most ineffective, n=449).

Finally, patients overwhelmingly felt that EngagedMD improved their overall treatment experiences. In general, a resounding 97% (n=3360) of patients asked that question felt that the EngagedMD educational videos were a helpful addition to their medical consultations.⁸ Moreover, 72% (n=3294) reported that EngagedMD made them more satisfied with their care; only 1% of patients felt it made them less satisfied. Using EngagedMD also increased patients' positive treatment expectations.

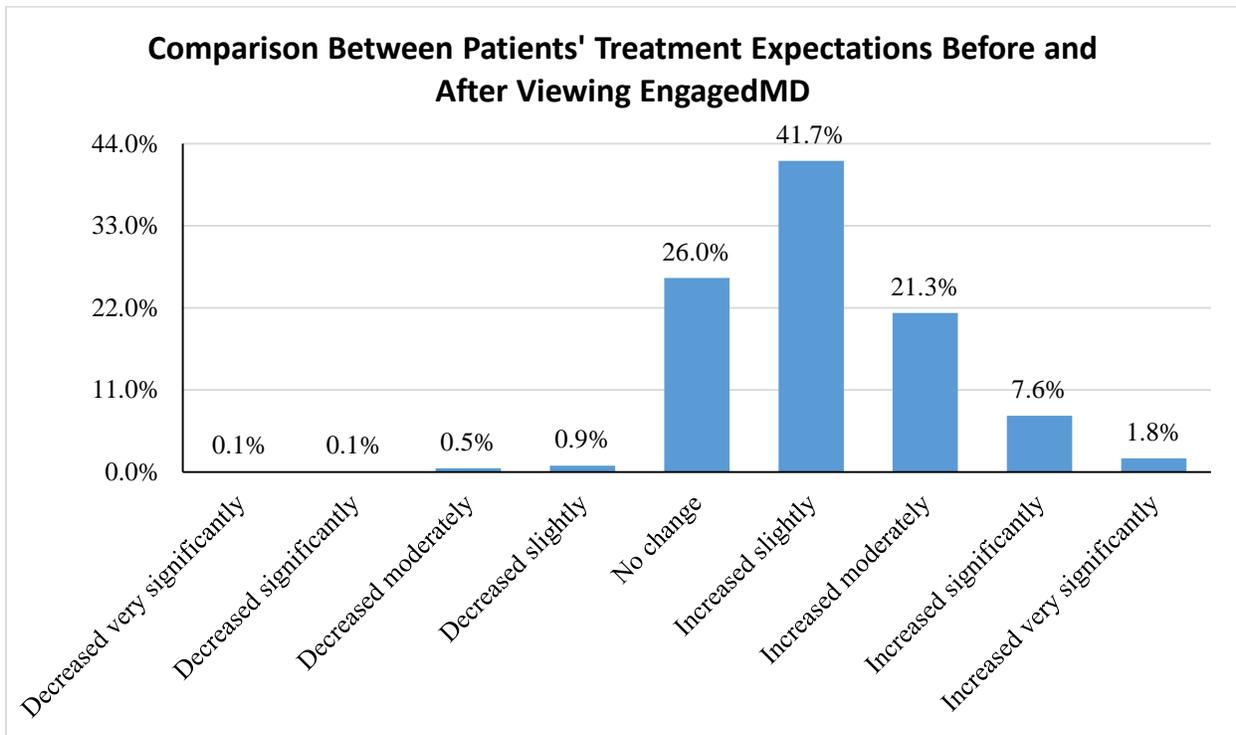


Figure 3: Chart comparing patients' treatment expectations before and after viewing EngagedMD

Before completing EngagedMD, 10% (n=279) of patients strongly agreed that they knew what to expect during treatment, while 44% (n=1271) of patients agreed, and 27% were neutral. But after completing the application, 57% (n=1654) strongly agreed that they knew what to expect, and another 38% (n=1086) agreed. Likewise, most would recommend EngagedMD to a friend or colleague; on a scale of 1 through 10, 35% (n=1664) chose “10,” and 85% (n=XX) ranked it 7 or higher. Seventy-nine percent of patients felt that it made them feel more in control of their medical decisions (36% SA, n=1799; 43% A, n=2108) (14% N, n=714; 5% D or SD, n=237), and 70% (34% SA, n=990; 36% A, n=1074) reported that it made them more comfortable pursuing treatment (20% N, n=601; 8% D or SD, n=221). Surprisingly, 48% even “strongly agreed” (24% SA, n=692) or “agreed” (24% A, n=718) that EngagedMD played a part in their decision to pursue treatment (19% D or SD, n=564).

IV. Patients’ Opinions About EngagedMD

A. What Importance Did Patients Place on Treatment Education?

A resounding 93% of patients (n=934) believed they should be informed about ART treatment. When asked to explain their answers to the question, “How important is it that you are properly educated about your care,” a few noted this question seemed “stupid” (Patient 782) or “dumb” (Patient 3453). Patient 1447 observed, “I can't imagine anyone answering anything else? It's literally a life and death decision- it's imperative to have all the facts,” whereas Patient 1613 merely replied, “Duh.”

Patients listed several benefits from being informed, including knowing material information and understanding treatment processes and protocols (38.5%, 387/1004), making

informed decisions (20.5%, 206/1004), information's inherent positive value (15%, 152/1004), preserving the health of one's self, partner, or offspring (9.8%, 99/1004), being prepared (6.9%, 70/1004), and the sanctity of creating life or the significance of conceiving (5%, 53/1004). Other infrequently mentioned reasons included treatment's complicated nature (1.8%, 18/1004) or expense (1.8%, 19/1004), care responsibilities (13/1004), and asking better questions (12/1004).

Knowing material information was important because, in the words of Patient 550, "I feel its [sic] very important to be fully aware of all possible risks and outcomes that could happen with this process. It may only be a 30 minute procedure but there are many potential side affects [sic] that could happen to anyone. No one is an exception." Information can help protect patients: "my body is going through a severe change in hormones and jump start processes. I like to know all side effects and research the procedures prior to accepting this process before putting my body through such procedures. This module was helpful" (Patient 2786). Moreover, knowledge might improve treatment outcomes, as Patient 1060 observed: "it's important to know the process so that I can help create a better outcome if my full compliance and knowledge will assist with enabling me to do so."

Consequentially, information could also help with treatment decision making: "I am a highly educated individual who cares about the health of my spouse, while wanting to have biological children. The more information we have, the better risk assessment we can do and the better decisions we can make together" (Patient 1218). According to patients, information "puts both partners in a position to make the most educated and collaborated decision possible" (Patient 2166), and "is important to a successful cycle" (Patient 2459). Infertility

treatment may entail unique choices and outcomes, as Patient 2161 remarked: "It's a multi-step, surgical procedure with moral questions attached to it. There are many levels of decision making at play here, and it's not something that can be considered lightly." Counter to stereotypes of "desperate" infertile individuals, several patients described engaged and "rational" decision making processes, and their desire to be "an engaged, prepared patient" (Patient 3282): "we are making decisions about risks that may affect our future children so it is important to be well informed. There also needs to be a good basis for judging cost vs. benefit" (Patient 2686).

For other patients, information and being informed had intrinsic value, and was an important part of treatment in its own right. Patient 385 enthusiastically noted, "info is always good!" Several remarked that "knowledge is power" (Patient 3729). Many patients affirmed, "I want to know everything" (Patient 155) or stressed, with more *gravitas*, that "information is [a] matter of life and death" (Patient 552). Quite a few candidly admitted enjoying information acquisition; Patient 2243 confessed, "I'm a bit of a science geek." But information was especially critical for patients who had experienced prior miscarriages, as had Patient 1762: "We have already been through two losses, we still don't have answers as to why its [sic] happening. So now its [sic] very important for me to gain as much info as I can."

Thus, it is not surprising that patients regarded information as a way to safeguard health and wellbeing: "My health and my future baby's health are dependent on this process and making smart decisions" (Patient 2362). Being educated allowed patients to increase their chances of success; Patient 2732 stated, "I want to make sure that I am 100% informed about what is going on with my (the patient) body as well as my partner. I want to make sure that we

can have a great success rate and being educated is one of the greatest things you can do.”

Some were particularly focused on understanding particular elements of treatment: “since I'll be introducing hormones and chemicals into my body, I want to make sure I understand what it is I'm injecting” (Patient 3720).

Patients also equated being informed about treatment to being prepared for undergoing procedures. As Patient 627 noted, “Knowing every risk is very important to me. The process helps me better understand how I need to mentally, emotionally and, physically prepare myself.” Because patients were seeking to conceive, the stakes were particularly high: “Anytime you are willing to bring another life into this world education/preparation is key” (1904). Patients termed the choice of whether to undergo treatment as a ‘major life decision’ (Patient 1607) and a “potential life-changing journey” (Patient 3282)—even “the biggest decision and most important thing in our lives” (Patient 2027). Some also regarded preparation as part of their patient responsibilities. As Patient 2318 stated: “Being properly educated not only empowers me to make an informed decision about my care, but also helps my treatment team ensure I'm prepared for the treatment I consent to.” And the best preparation was *accurate* information: “I like to go into something knowing what to expect. A lot of this information is available from other sources, but I'd rather get it from the program I'm participating in so I know it is accurate” (Patient 3629). The complex nature of IUI and IVF underscored the importance of information and preparation: “This is not a simple process. It is very complicated and precise. If we could have a baby on our own we most certainly would, since that is not an option it is important to us both that this process occur as efficiently and successfully as possible” P3377).

Information and preparation also make sense given the high financial investment that fertility treatment often requires—what Patient 802 termed “high stakes \$\$.” In light of these risks, patients like 3844 “want to make a well informed decision both clinically and financially.” And weighing these risks and making treatment decisions requires that patients take responsibility and even view themselves as “informed consumer[s]” (Patient 2816). These responsibilities could be quite extensive; as Patient 3281 noted, “often the patient ends up having to be the one to make sure everything is being done on time” (P3281). Taking responsibility meant assuming an “active role in the education piece” (Patient 3399).

Taking an active role required patients to ask providers questions. Patient 2279 emphasized, “It's important for a patient to be her own advocate, as she is most familiar with her body and her experiences. While a medical team has an expertise, I think it's important for patients to ask questions to make sure they get the most personalized treatment.” Patient 472 noted that information-seeking allows patients to “be prepared for the steps ahead and also ask the necessary questions to be comfortable with the process.”

Information covered in EngagedMD could also have emotional effects (noted by only 94 of 1004 patients). These emotional consequences are linked to the strong emotions that treatment cycles themselves can induce; patients described treatment as “an emotionally draining and physically demanding process, without the promise of a pregnancy” (P151) and described it as “intense” (P2688), “intimidating” (P3720), and “nerve racking” (P3077). With so much information to absorb, patients could find it hard to “take it all in” (P1074).

Fortunately, positive emotional effects were most frequently mentioned (59/94): “You need to know what's going into the body and have all the known questions answered as

accurately as possible. It's also not only physical but emotional as well" (P2317). Understanding treatment processes could "relieve stress" (P534), help patients to be "calm" (P2324), "reduce[] uncertainty," and "lower . . . anxiety" (P531). It might even make them more comfortable (P1039) and confident (P1144), reducing regret (P1605). Being informed helped patients cope with treatment procedures and the accompanying uncertainty (P1913, 2309), preparing them to be "emotionally ready" for treatment outcomes (P3456). Being better informed allowed patients to formulate more realistic expectations (29/446): "It helped prepare me for what is ahead" (P1109). In particular, this helped female patients understand what treatment involved on several levels. As Patient 3703 remarked, "I like that the information was in depth on how the female body works normally and then with IVF. Gives me a better idea of what to expect."

Information, then, could help them maintain control (5/94): "Life is made up of decisions and risk. To be informed gives some measure of control over the situation when making decisions" (P2759). Information could also "shape[] reasonable expectations" (P798). Finally, being informed could convey support to a partner undergoing treatment; Patient 2112 observed that it was "very important for me to know how the process works, and even more important for my wife to know that I'm engaged." Conversely, it could allow a patient to gauge how much interpersonal support she would need: "Being fully aware of this process better helps my understanding of it and what support I will need from my husband" (P3028).

Despite the value that most patients placed on information, others pointed out that sometimes knowledge was problematic. Information could be "overwhelming" (P93), and "some things are best kept unknown" (P1535). Sometimes, as for Patient 3673, "the risks in this much detail increased my anxiety and concern." Patients' apprehension might even

threaten the informed consent project altogether: “the information is intimidating and was on the verge of wanting to know and not wanting to know for saving emotional stress” (P3418). And there were other educational methods besides EngagedMD. Patient 156 commented, “this questionnaire is a formality, our doctor did a great job of explaining this already,” and Patient 3301 noted, “I trust my doctor to raise a concern or discontinue any dangerous treatment.” Patient 1538 felt that she already knew the information: “in all honesty I felt that I could have tested out of all these modules without the videos. Also, I am a visual learner, and would have much rather read articles than have a video.”

Finally, many patients asserted that patient education (or lack thereof) affected the quality of physician-patient relationships. Many patients’ reflections suggested there was a healthy distance between themselves and their providers. Patient 1726 remarked, “The doctors [sic] office is a business and in the business of making money and selling this program. Where the doctors brush over risks, this spells it out. Where the doctor brushes over the intensity of the procedure, this spells it out.” And Patient 356 interpreted access to EngagedMD as a sign of care within the caretaking medical relationship: “I’m glad to see that the doctors want us to be educated about what we are going through. I also think all of this will be discussed with our doctor with each phase of the process.” Acknowledging that clinics are businesses suggests that patients are wary lest providers have ulterior motives that are not in their best interests—here, glossing over treatment risks. Thus, EngagedMD is simultaneously part of and a check on the commodification of fertility care.

Patients link being informed to positive treatment relationships. As Patient 696 remarked, “It is important to know what is entailed in every step of every procedure, what

medication side effects/indications are, and how I can play an active role in my care to make this process easier for both myself and the reproductive team.” Patient 3843 more explicitly recommended that patients become advocates: “I want to be fully informed and advocate for myself with my doctor.” And Patient 3293 believed that being informed was a patient’s responsibility: “patients can take responsibility as well. Doctors and medical professionals are limited by the scope of their practice.” Information helps patients retain control to the extent possible, rather than ceding it—and thus all responsibility—to their providers. Through active participation, patients develop an appreciation for informed consent processes and the continuity of the consent obligation.

B. Did Patients Feel that EngagedMD was a Helpful Addition to Consultations?

The vast majority of patients judged EngagedMD to be a helpful addition to their medical consultation because it was more informative, answered patients’ questions and helped them to identify new ones, presented information in several different formats, and could be viewed repeatedly at times and locations of patients’ choosing.

There were several reasons why most patients (446/769) found EngagedMD more informative than other consent aids. Several patients (77/769) asserted that EngagedMD provided more detailed information. For example, Patient 1588 observed, “First consultations were mostly data (reading of baseline tests) and an idea of counting days or what an injection cycle would look like. The videos went into much more detail about the science behind the process and what to expect during each phase.” EngagedMD might be more thorough than a RE consultation: “After speaking with our doctor briefly about which treatment plan was best

for my husband and I, it was great being about to learn more detailed information about the entire IVF process and protocol involved” (3804).

EngagedMD also improved many patients’ understanding of treatment information (43/446). Patients’ remarks suggest that understanding is an iterative, progressive process: “Sometimes we think we may understand everything completely after a consultation but then we realize there were still things we didn't know or fully understand until after watching the educational videos” (254). EngagedMD could help patients organize information. Patient 1759, for example, observed, “During our appointments we ask a lot of questions and that scatters the info presented. In this educational medium, everything was presented in a logical order that I was easily able to stop, restart, and still fully understand.” Relatedly, several patients credited the application with “filling in gaps in knowledge” (14/446).

EngagedMD videos also answered patients’ treatment-related questions. In response to the question “Did EngagedMD answer any questions you would otherwise have asked your medical team,” patients overwhelmingly reported that EngagedMD answered “many questions” (50%) or “one or a few questions” (44%), as Figure 5 illustrates.

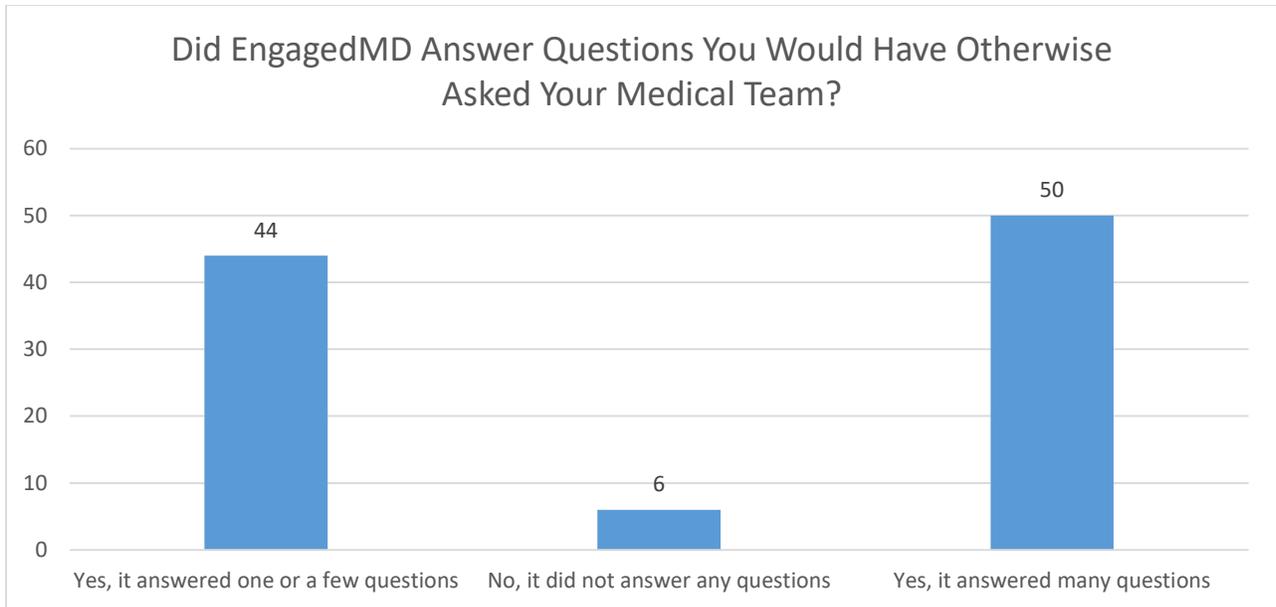


Figure 4: Chart showing whether patients felt EngagedMD answered their questions

EngagedMD’s strengths corresponded to and supplemented medical consultations’ weaknesses, in particular their brevity and impermanence. Patient 696 felt that, unlike providers, EngagedMD was always available: “The medical team is always busy, and doesn’t always have the time to explain everything detail for detail. They give a very brief response to your questions while trying to rush to the next patient. So, these video modules help answer unanswered questions. It answered questions I would not have known to ask.” Patients were happy to learn basic information before their physician consultations: “They answered a lot of the basic questions, making the eventual consultation more productive” (Patient 1229). Crucially, patients perceived EngagedMD as reputable and trustworthy: “They had a very good summary of all that we thought we needed to know. We did not have to go looking for this information on the internet from disparate sources.” Patient 1124 noted, “it’s better to be informed by the doctors, rather than googling on my own, or reading forums,” and Patient 1322 emphasized, “There’s a lot of misinformation on-line with the creation of blogs.”

Seeing and hearing treatment information was useful to many (90/769), since “everyone has a different learning ability, whether it be visual, auditory, tact[ile]” (Patient 696) and “charts and graphics help” (Patient 927). In particular, “the animations were very helpful in visualizing some of the more abstract concepts” (Patient 914), especially useful for patients who would be unconscious during certain procedures: “I appreciated the video footage of egg retrieval and ICSI” (Patient 3075). Even patients who read their consent forms felt that EngagedMD was helpful: “I previously read all of the materials provided, however visualizing the process I feel like I learned even more” (Patient 2148). The visual details could be more engaging than written material. As Patient 3310 explained, “visuals always help with explaining concepts. If someone just tried to talk through the AMOUNT of content that was in the course, I would have tuned out or missed something.”

Moreover, patients appreciated that they could repeat EngagedMD’s modules as often as necessary (70/769). Redundancy was a boon, not a burden: “the consultation is very dense in information. This is a good review” (P1271). It even had emotional benefits: “the videos helped reinforce the concepts already explained to me. I was able to review them at my own pace and not be overwhelmed with a bunch of information thrown at me at once” (P2243). Patients could use the modules to “catch up”: “I was able to replay and take notes of things that may have been forgotten after meetings that I’ve had in the past with my doctor and nurse.” Simply hearing details again could make a difference. Patient 881 remarked, “I was also given a booklet which contained the same information, but I think it’s important to hit the patient with as many different ways of getting the info as possible, to make sure she gets the info in the format that will resonate the most with her.” Patients even used EngagedMD to

educate partners and others; Patient 1539 was “so glad to have . . . the ability to go and watch it again and show friends and family so that they understand.”

The quizzes that followed each EngagedMD video were intended to positively reinforce that unit’s information. Patients differed as to whether the quizzes were useful or irritating. Patient 1035 remarked, “I also enjoyed doing the questions afterwards. Kept me on my toes.” Some felt that quiz questions “helped [] understanding” (P1139) or “tied it all together” (P1636). Sometimes patients’ reactions depended on whether they had undergone IUI or IVF before. Patient 3667 resented having to view EngagedMD when she had already undergone a prior cycle: “This would have been very helpful initially but it is frustrating that I'm forced to watch it and take a test 3 years into the process.” Other patients disliked that they had to complete quiz questions and EngagedMD modules to proceed with treatment: “I felt it was condescending and belittling. Not because of the content but because it's required. It makes you feel like passing a test is required to getting pregnant” (P1430). According to Patient 2759, the quiz provided insufficient motivation to take responsibility for treatment: “This is not the way to get patients to remember important information. I will remember the info because it is important to my health, I don't need a quiz to measure my attention skills.”

Similarly, patients also enjoyed the ability to view EngagedMD when and where they were most comfortable (67/769), allowing them to control the learning process. Patient 2158 explained, “When meeting with the medical team, I feel like I'm a product on a conveyor belt. Information is explained very fast when I met with the nurse. She didn't ask if I had any questions. The video was very helpful and I could go at my own pace.” Knowing that they could later review the information helped patients to relax during their physician consultations:

“there is so much to know about the treatment process, it would be an excessive burden to try to cover during a consultation - both for the doctor to provide and the patient to absorb. These videos allowed me to learn all the details I needed, at the pace I needed to take it all in” (P2318). EngagedMD gave patients breathing room: “it gave me time to read and think things through while in a relaxed state of mind” (Patient 3835). Being comfortable and able to concentrate improved patients’ learning: “This module allowed me to take my time to really listen and learn about what this treatment means for me. Being in the comfort of my own home helped me to better absorb the information” (P464).

EngagedMD also provided more specific information on several topics, including risks (25/446), statistics (11/446), physical effects (7/446), and medications (6/446). Patient 2613 stated, “After watching the video, I am more aware of the potential risks involved. Makes me a little more nervous, but it is better to know so you can ask your doctor questions and processes to consider.” Patients also appreciated gaining more insight into treatment statistics. Including those on “multiples and age of mother” (P1041) and the “comparative charts of absolute and relative [probability]” (P3792). Even basic information about reproductive biology might be useful for those patients who “have no clue how their own body works let alone know how an IUI works.”

Patients believed that they should see this material as early as possible—certainly before the first consultation: “This should have been sent prior to having a consultation if not immediately right after we got the sperm analysis back!” (Patient 1663). These highly-detailed modules may be less effective than if reviewed later, according to Patient 322: ““Unless the training is provided BEFORE the first visit, it adds too little. Doing this AFTER pple [people]

already had their visit and probably did a lot of research by themselves is quite a waste of time” (P729). Sometimes patients would have found it useful before making treatment decisions. Patient 3601 said, “it gave me MUCH more information than my doctor shared with me to date. Some of which I wish I had known before paying them and committing to the treatments.” This information might have prompted patients to make different decisions: “I think that I would like to have watched all fertility treatment option videos, prior to paying for the IVF process. Perhaps, then, I might have chosen a different procedure to begin with” (3031).

In addition to educating patients, the EngagedMD modules had other positive impacts, including preventing patients from becoming overwhelmed (17/769) and reducing anxiety (2/769), making them think about treatment information and choices (6/769), encouraging discussion with partners (8/769), and reinforcing confidence in decisions (3/769). For Patient 150, “It's important to be able to see and hear it from another person and remove the anxiety of a busy and rushed office visit.” Viewing these modules helped patients discuss treatment option and decisions and prompted reflection: “[it] made my partner and I take time to really evaluate and learn about the process we are launching into” (Patient 93). For patients like 1319, this additional reflection and discussion “also made me feel better about my decisions.”

Of course, this novel informed consent aid could also affect treatment relationships, for better or for worse. Most patients noted that EngagedMD improved treatment relationships by supplementing consultations. Patients’ remarks often assumed that the medical team did not have time to meet all informational needs, usually due to short appointment times: “they don't tell you much during consultations” (P386). Patient 241 felt EngagedMD was efficient because “now the team doesn't have to take extra time away from other patients that need help to

explain what is going to go on.” Patient 3844 found it more informative: “I just learned in a better summary over the past 45 minutes or so what I have only pieced together in the past year working with my doctor and nurses.” Or patients may be reluctant to ask questions in consultations: “sometime I have questions and don't want [to] interrupt; this I could pause and repeat the info.” And EngagedMD could effectively help in situations where providers weren't necessarily helpful: “While our current doctor is great at illustrating and explaining, we have had communication problems in the past with another doctor. This helps to bridge the gap in the doctors' individual personalities.”

Used inappropriately, however, EngagedMD could harm treatment relationships, particularly when used as a *substitute* for informed consent conversations. The application is designed to *supplement* informed consent consultations, allowing patients to penetrate beyond basic information to discuss other issues with their providers: “I believe in online education but this doesn't replace 1:1 discussions with my Dr. I think completing this video series helps me now that I've made my decision to YES do IVF. This helps me w/ what to expect and know” (Patient 2796). Patients deserve interpersonal consent discussions, but some providers might use the application to satisfy their consent responsibilities. Patient 698 was unhappy when this happened to her: “They were given to me not as a supplement, but as my only source of education- there was absolutely nothing personal about it. This should be a secondary supporting resource, not the primary tool for educating patients.” Used incorrectly, EngagedMD seemed impersonal: “Removed the face 2 face interaction. Feels like I and it are just boxes to check” (Patient 2677). Some would have preferred interpersonal interaction, like Patient 2851: “I would have rather heard it from a person than a video. The video felt like a

hassle to complete and made it feel like the staff couldn't be bothered to take the time to talk to us." And interpersonal interactions can be customized to patients' needs: "it would be better to have this conversation with a doctor or nurse familiar with our specific situation, who knows what their recommendations to us will be" (Patient 3860).

A handful of patients might find some material offensive or inappropriate. As Patient 3664 noted, "It's inappropriate and challenges the boundaries of marital relationships to require couples to watch these videos in exchange for treatment. In some marriages, couples may not talk about menstrual cycles, etc., and it's not appropriate for the medical profession to determine normative behavior between couples." Although it is always difficult to portray information in neutral ways, Patient 3664 is correct that e-learning technologies present information less neutrally than other consent aids. In this vein, Patient 3282 felt that EngagedMD's visual portrayals of the treatment process were problematic in many respects:

(1) yes, there are risks involved in IVF, but it'd be helpful to be given some hope as well--to highlight the positive statistics as well as the negatives (and risks); (2) it was extremely unhelpful to see only one heterosexual couple portrayed through all the modules. Could gay couples be included? And, at the very least, could the male partner in the video seem more engaged in the process? . . . [I]t'd be nice to have a "healthy model couple" shown as representatives for going thru this journey...rather than continually showing a woman clearly struggling emotionally alone in different scenarios- at night and in the bathroom and on the phone. Partners want to be and should be engaged in this process--and should be represented as such.

Moreover, patients found EngagedMD unhelpful for other reasons. Some may have already completed a treatment cycle before viewing these modules (20/769). Patient 748 explained, "It honestly was a waste of my time. I've done IUIs before and it doesn't make sense to watch these videos after I already know what is going on." Or patients could have previously

learned this information from providers or personal research (46/679). “The information in the module had been reviewed with us twice within the office at time of the treatment consultation, once by the doctor and once with the assigned nurse. This was supplemented by personal research both before and after the consultation,” Patient 2003 related. Too much repetition could irritate patients like 2526: “This duplicated most of the information I was given. I would also prefer a printed format that I could complete more quickly (by reading) than having to sit through 45 minutes of a video presentation. I am actually quite annoyed that I had to do this, on top of a thorough Q&A session with my provider and nurse.” Accordingly, those like Patient 3135 deemed it “redundant and a waste of my time” (9/769).

Others found EngagedMD too long (6/769), overly informative (6/769), too technical (6/769), or even at odds with other information (6/769). Patient 69 deemed EngagedMD “pretty boring. WAY too drawn out. Elementary in some places and overly focused on clinical issues I don't care about in others. Overall, I needed a glass or two of wine to get through it.” Similarly, Patient 1847 found it “almost too detailed - the science is a little difficult to understand, and there is too much to digest. I felt a little overwhelmed.” EngagedMD may well increase these patients' anxiety: “We felt the videos were helpful, but also a bit scary and intimidating--particularly, the portions about the potential complications during and after IVF. I think the modules may have been more effective had they included all factual information and saved the scarier portions for an in-person consultation.” Patient 3042 thought many patients might lack basic physiological knowledge necessary to understand the modules: “you should offer an even more basic pre-pre-education module for folks to brush up on basics-- at the level of 'what is a hormone.’ Those with minimal science or biology background (and those who

haven't thought about it in many years!) really might be left behind.” But others found the modules condescending. Patient 3664 objected, “I don't need a genetics lesson or menstrual cycle lesson as I went to college and have advanced degrees.”

Ultimately, most patients preferred EngagedMD to consent documents, most often due to personal preferences. Patient 3151 said, “The modules were much helpful and easier to understand than reading documents.” Sometimes patients preferred other informational formats, like documents: Patient 2190 commented that it would be “more effective and efficient for me to just read the information rather than having it fed to me as a video” (P2190).

V. Conclusion

In general, EngagedMD appears to have great potential for improving informed consent interactions. Patients prefer it to nearly every other form of consent aid, except physician consultations.

As to whether consent documents and their perceived weaknesses have tainted the entire informed consent project, the answer appears to be “no.” Patients enjoy being informed, and realize that information contributes to treatment experience, emotional and physical well-being and safety, and cycle outcome. And they conceive of informed consent broadly, more a process than ritual, and acknowledge that consent interactions can affect treatment relationships as well. Thus, it appears that this new tool has the potential to change patients’ lived experience of informed consent for the better, and that it might be free of the baggage that patients currently assume is inherent in paper consent forms.

Though this project lacks a control group of patients who did not receive EngagedMD, patients’ reactions to this e-learning technology are interesting and meaningful in their own

right, suggesting that such applications overall are beneficial and can improve treatment experiences. These responses shed light on patients' relationships with information, with techniques for information acquisition, and with information providers, contradicting conventional assumptions about informed consent—that patients do not want to know, or can't understand, certain treatment information. Moreover, they suggest there is a “sweet spot” in how much patient education patients receive. Few people want to know everything or nothing; rather, most want to be well-informed. They are hungry for details, but not eager to gorge on them, and hope to participate in their care as partners but are respectful of providers' expertise.

These responses also highlight the emotional consequences of informed consent, which vary from the predictable to the paradoxical. On one hand, patients are expected to engage emotionally with consent information to understand risks, etc. Fear is a counterproductive educational tool. Engaged patients' attention so that they appreciate and thoughtfully consider risks is one thing; increasing anxiety unduly is another. Reaching that informational “sweet spot” is surely tougher than it first appears. Increased attention and sensitivity to these emotional consequences illuminates several paradoxes that must be unraveled to improve consent processes. Information is both a guarantor of safety and a trigger for anxiety, a preparation tool and a destabilizing force, a coping mechanism and a stress inducer. Most significantly, these responses illustrate that patients are information consumers. Patients realized that EngagedMD is a product, were aware of the commercial value of a provider's time, realized the incentives for providers to use EngagedMD improperly, and yet still liked it.

These emotional consequences play out against a backdrop of institutional practices, such as fairly short appointment times, that introduce additional tensions. While patients want to learn from physicians and feel that interpersonal consultations are valuable, the brevity of such appointments may mean that their questions go unanswered. Or clinic environments may seem intimidating or impersonal, making it difficult for patients to discuss their most intimate concerns. EngagedMD is designed to at least partially remedy those deficiencies, and appears to be an effective supplement, so long as it is not used to replace face-to-face consent conversations.

Finally, these results emphasize how various conceptions of patient autonomy are in tension with the medical profession's definition of "quality," which focuses not on whether a consent instrument is customized to patients' needs and made the process comfortable, but whether disclosure is standardized so that every patient receives the same information at the same time. From providers' perspective, disclosure that is not standardized increases the risk that serious biopsychosocial consequences could follow, and so there are clinical circumstances where patients' decision making style does not matter.

Perhaps the most important conclusions that can be drawn from this research are that there should not be a one-size-fits-all approach to consent, and that there appears to be no effective substitute for treatment conversations. EngagedMD's chief advantage in terms of improving patient care experiences is likely that it allows patients to better prepare for their provider consultations and makes these interactions more efficient, freeing up time to discuss deeper matters beyond basic information. Future research include whether consent conversations actually improve after EngagedMD is implemented, and whether or how often

providers use EngagedMD as a substitute for consent conversations. Future evaluations, including randomized controlled studies, will provide more information on whether such applications improved shared decision making or undermine it.

¹ <http://www.dcurbanmom.com/jforum/posts/list/498760.page>

² JODY LYNEÉ MADEIRA, TAKING BABY STEPS: HOW PATIENTS AND FERTILITY CLINICS COLLABORATE IN CONCEPTION (forthcoming, 2017).

³ Jody Lyneé Madeira & Barbara Andraka-Christou, *Paper Trails, Trailing Behind: Improving Informed Consent to IVF Through Multimedia Applications*, J. OF L. & THE BIOSCIENCES 3(1): 2-28 (2016).

⁴ This survey was created by the EngagedMD design team, but it lacked any identifiers tying it to that company. Patients at IVF centers subscribing to EngagedMD were asked to complete this survey following their treatment cycles. Since all patient patients surveyed completed EngagedMD, there is no control group (a randomized controlled study is in process).

⁵ David Sable, *The Biggest IVF Clinics, Infertility by the Numbers, Part I*, FORBES (April 15, 2016), at <https://www.forbes.com/sites/davidsable/2016/04/15/the-busiest-ivf-clinics-infertility-by-the-numbers-part-1/#39e2a6f67936> (last accessed April 20, 2017).

⁶ I met Dr. Levy during a prior research project; at that time, we discussed ways to use technology to improve the informed consent process. He contacted me in the summer of 2014 to describe the EngagedMD project and place me in touch with its developers, whom I have since worked with to evaluate the application. It was through these connections that I gained access to this research data.

⁷ This is not the only example of required information in reproductive medicine;

⁸ Although the entire population includes 6,333 patients, a few questions were deleted from the survey at various stages, leaving a population of approximately 3, 643 patients.