Inform and Consent: More Than Just "Sign Here"

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OBJECTIVE: Assisted reproductive technology (ART) presents complex ethical and medical considerations that make informed consent difficult. We assessed patient experiences and perceptions regarding the informed consent process.

STUDY DESIGN: A quantitative online survey of patients who had undergone autologous in vitro fertilization (IVF). Survey questions evaluated consistency and perceptions regarding informed consent importance, redundancy, and protections.

RESULTS: Posters containing a link to the online survey were posted in 6 participating clinics, and messages were posted online in fertility forums such as those on resolve.org. Of the 262 responses, 249 were complete who had done at least one IVF cycle and were included in the analysis. More than 86% of respondents read the entire informed consent form (23% "somewhat carefully" and 46% "very carefully"). Nonetheless, some respondents described the consent process negatively, such as "too long" (18%), "something to get out of the way" (44%), "overwhelming" (34%), "unhelpful" (5%), and "difficult and confusing" (21%). Patients under 35 years reported discussing selective reduction more often (87%) as compared to those over 40 (69%). In an age- and income-adjusted model, age and income were not associated with reading forms carefully; reading carefully was significantly associated with the number of IVF cycles.

…these findings suggest that medical and legal safeguards are inadequately balanced with comprehensibility, thoroughness, and patient engagement.

CONCLUSION: These findings show that, although patients report reading and understanding IVF informed consent forms, they are less likely to read forms as they complete more cycles. Classic approaches to informed consent need to be reexamined. (J Reprod Med 2020; 65:213–219)

Keywords: assisted reproductive technology; comprehension; decision making; disclosure; ethics, medical; female; guidelines as topic; humans; in vitro fertilization; informed consent; legal liability; medical liability; patient education as topic; patient

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preference; personal autonomy; physician-patient relations; policy making.

Informed consent is an essential part of fertility care; in this process, providers educate patients about a proposed medical treatment's risks, benefits, side effects, and alternatives, answer their questions, and obtain their permission to proceed. The 1978 *Belmont Report* set the benchmark for core principles such as patient autonomy, beneficence, and justice.[1] Initially developed for human subject research, these principles are now applied to clinical medicine and are foundational guidelines for informed consent.

Published research on informed consent frequently questions its efficacy given impaired patient recall and comprehension or failure to read consent materials.[2] Additionally, there is a paucity of data on how patients experience the informed consent process; existing studies suggest that many patients view informed consent—particularly signing consent forms—as merely an obstacle to treatment.[3-5]

Though informed consent in assisted reproductive technology (ART) involves many of the same processes (procedural risks and benefits) as those of other medical fields, ART procedures are unique in proposing ethical, medical, and legal opportunities and challenges to other individuals besides patients: potential children.[6] Certain treatment choices, such as the disposition of cryopreserved embryos, donation of reproductive material, and posthumous procreative planning, are novel and may require a two-part consent process. Patients' treatment needs and desires might be influenced by religious or moral considerations as well as physiological needs.

Many reproductive endocrinologists, mental health professionals, and attorneys have expressed concern over whether patients find the ART consent process overwhelming or lack recall and comprehension given complex procedures.[7,8] These concerns have prompted professionals to strategically simplify these documents, including the American Society for Reproductive Medicine (ASRM), which has created a model template.[7] Moreover, third parties have developed web-based patient education and electronic consent platforms, such as EngagedMD.[9]

To date, no research study has conclusively answered whether ART patients are underserved by current consent procedures, whether they are uninformed or underinformed about ART consent issues, how they experience consent, and what effect consent processes have on the doctor-patient relationship. To explore these questions and identify areas of improvement, we assessed patients' informed consent experiences and perceptions.

Materials and Methods

This prospective survey study was reviewed and approved by the Indiana University–Bloomington Human Subjects Institutional Review Board.

A quantitative 197-question online survey-based study was disseminated to women and men who had undergone autologous in vitro fertilization (IVF) in the past five years using forums, electronic mailing lists, and blogs focusing on infertility and ART treatment. Posters containing a link to the online survey were posted in 6 participating clinics, and messages were posted online in fertility forums such as those on resolve.org. In total, 262 subjects responded and were recruited in the study. The survey was administered by posting links to a Qualtrics survey on online fertility-related forums such as those maintained by RESOLVE and circulated on Internet blogs and listservs.

Lacking a previous validated survey in the literature for exploring the IVF experience, author J.M. developed the questionnaire to assess key concepts. To ascertain that questions were comprehensible and minimize bias, the survey was reviewed for clinical accuracy by two reproductive endocrinologists, and it was pretested on 10 patients who were then excluded from the respondent population.

Questions evaluated informed consent experiences and attitudes, including perceived importance and protections. Survey questions included both closed-ended and open-ended questions. Primary outcomes were patients' overarching experiences and perceptions of informed consent. Secondary outcomes included how the patients' responses were related to demographic characteristics such as age and income, and the number of previous IVF cycles.

Statistical analysis was performed using SAS 9.4 (SAS Inc., Cary, North Carolina). Data were expressed as mean ± SD. Chi-squared and Fisher's exact tests were used to examine the association among categorical variables of interest. In a general linear model, logistic regression analysis was used to determine the effect of demographic pa-

rameters on response characteristics. Backward selection of parameters was applied, using $p<0.05$ and $p<0.10$ for entry or deletion, respectively. Logistic regression was used to determine these variables as determinants of responses. Statistical significance was assessed as $p<0.05$.

Results

Of the 262 respondents who completed the survey, the analysis included 249 respondents who had completed at least one IVF cycle. Out of the 249 patients, about 56% (n=136) were <35 years, 30% (n=72) were 35–40 years, and 14% (n=35) were >40 years. The majority (95%, n=231) of respondents were female, and 90% (n=213) were Caucasian. In total, 33% (n=71) had undergone one IVF cycle, 32% (n=69) had undergone two IVF cycles, and 36% (n=78) had undergone three or more IVF cycles. Table I shows survey participants' descriptive characteristics.

Respondents signed informed consent paperwork either as multiple separate documents (e.g., individual embryo disposition, cryopreservation, and IVF consent forms) (86%, n=183) or a single (14%, n=30) document containing all consent elements. Providers requested that patients sign consent forms either upon receipt (77%, n=162/211) or at a later session after encouraging patients to read the informed consent document (23%, n=49/211). About 82% (n=168/206) reported that they were required to sign consent forms before a particular witness, including a nurse, physician, clinic staff member, or notary public. While 79% (n=125/158) of patients who signed the forms at one time completed them before a witness, 91% (n=42/46) of patients who signed the forms at a later session completed them before a witness. However, this association was not statistically significant (p=0.059).

Of those that responded (see Table II), the majority (87%, n=175/202) reported reading their IVF consent forms. Most read them thoroughly, with 46% (n=94/204) stating they read the forms "very carefully," 23% (n=47/204) stating they read them "somewhat carefully," 21% (n=43/204) stating they read them with "average attention," 7% (n=15/204) stating "not very carefully," and 3% (n=6/204) stating "not at all carefully." Thus, at least 90% of patients read informed consent documents with at least average attention.

Overall, 98% felt that their documents were of at least average comprehensibility. Using a Likert scale from 1 ("very easy to understand") to 5 ("very confusing"), 35% (n=72/203) described them as 1 or "very easy to understand," 44% (n=

Table I *Survey Respondents Demographics*

Demographic	Frequencies (%)
Age group (n=242)	
≤35 years	136 (56.2)
36–40 years	72 (29.7)
>40 years	34 (14.1)
Gender (n=242)	
Female	231 (95.4)
Male	11 (4.6)
Race (n=238)	
Caucasian	213 (89.5)
Asian	13 (5.5)
African-American	3 (1.3)
Hispanic	13 (5.5)
Education (n=237)	
<4-year college degree	30 (12.7)
4-year college degree	96 (40.5)
Master level degree	71 (30.0)
Doctoral or professional degree	40 (16.9)
Annual income (n=234)	
<$100K	186 (79.0)
$100K–$125K	21 (9.0)
>$125K	27 (11.5)
Religious preference (n=229)	
No religious preference	122 (53.3)
Protestantism	39 (17.0)
Catholicism	39 (17.0)
Evangelicalism (Christian)	11 (4.8)
Judaism	10 (4.4)
Hinduism	3 (1.3)
Islam	1 (0.4)
Buddhism	1 (0.4)
Political preference (n=232)	
Republican	45 (19.4)
Democrat	65 (28.0)
Independent	32 (13.8)
Conservative	16 (6.9)
Moderate	27 (11.6)
Liberal	39 (16.8)
Libertarian	8 (3.4)
No. of ART cycles (n=218)	
1	71 (32.6)
2	69 (31.6)
≥3	78 (35.8)
No. of infertility years (n=234)	
<1 year	18 (7.7)
1 to <3 years	82 (35.0)
3–5 years	62 (26.5)
>5 years	72 (30.8)
No. of pregnancies from ART (n=178)	
1	84 (47.2)
2	64 (36.0)
≥3	30 (16.9)

89/203) as 4 or "understandable," 19% (n=38/203) as 3 or "average," and 2% (n=4/203) as 2 or "confusing." When asked to select from a list of specific terms describing their consent forms, 92% (n=163/177) of patients described the documents as "easy to understand," and 92% (n=128/139) also described them as "clear." A majority, 87% (n=180/206), affirmed that there was not any part of the consent form that they thought was confusing or difficult to understand, and 87% (n=181/208) were not surprised by anything about the IVF consent forms. Some, however, criticized other aspects of their informed consent documents: 18% (n=39/213) felt the forms were too long, 34% (n=73/213) found them overwhelming, and 5% (n=11/213) deemed them unhelpful. With respect to taking the consent process seriously, 95% (n=201/212) replied that "yes," they had done so. However, 45% (n=94/211) felt that consent forms were merely something to "get out of the way."

Respondents commonly discussed issues covered in the consent documents with their medical team; 82% (n=174/211) of patients recalled such conversations. However, the informed consent forms themselves were discussed less frequently (59%, n=125/212). Among the informed consent topics that IVF patients most frequently discussed with their physician or nurse were the likelihood of twins, triplets, or higher order multiple births (93%, n=197/211) and the risks and complications from multiple births (81%, n=171/210). While there was no significant difference in when different age groups discussed the likelihood of multiple births (p=0.209), complications from multiple births were more likely to be discussed with women under 35 years (87%, n=104/119) and women aged between 36–40 years (77%, n=46/60), as compared to women over 40 years (68%, n=21/31, p=0.028). Only 50% (n=105/210) of patients reported discussing selective reduction prior to undergoing IVF, and this topic was more often discussed with respondents ≤35 years old.

Though the vast majority of patients (93%, n=197/212) felt that they could ask questions about their informed consent documents, comparatively few (48%, n=101/209) proactively asked questions. On the whole, respondents felt that their informed consent forms were "take it or leave it" documents. Most (85%, n=178/209) did not want to make any changes to their consent forms, while 86% (n=181/210) believed they could not negotiate such changes even if they had wished to do so, and, as such, only 11% (n=24/212) actually requested changes. Among those who requested changes, 78% (n=18/23) of respondents reported that the physician agreed to the proposed change.

Table II *Regression Tables*

Per 1 cycle increase	OR	95% CI
Not at All Carefully vs. Very Carefully	2.25	1.34–3.78
Not Very Carefully vs. Very Carefully	1.58	1.12–2.22
Read with Average Attention vs. Very Carefully	1.18	0.91–1.53
Somewhat Carefully vs. Very Carefully	0.96	0.73–1.27

CI = confidence interval, OR = odds ratio.

Among patients who discussed consent issues with medical providers (n=179), about 44% (n=79/179) felt that conversations were more helpful than consent forms, and 35% (n=63/179) thought conversations were equally helpful.

The vast majority of respondents (93%, n=196/211) felt comfortable after signing their consent forms. When asked to describe their perceptions of consent forms from a list of several terms, respondents reported feeling more confident (18%, n=36/198), more empowered (14%, n=24/198), as if a major step was completed (41%, n=82/198), and more committed (21%, n=42/198).

In an age- and income-adjusted model, age (p=0.13) and income (p=0.56) were not significantly associated with how carefully patients read the consent forms, but reading forms carefully was significantly associated with the number of IVF cycles (p=0.022). For each additional ART cycle, there was a greater likelihood that patients would read the consent forms "not at all carefully" (OR 2.19, 95% CI 1.25–3.85) and "not very carefully" (OR 1.47, 95% CI 1.00–2.18) versus "very carefully."

Discussion

Our data show that most patients undergoing IVF read and understood their consent documents. Consent forms' perceived informational value, however, was limited by both consent form characteristics (e.g., length and language protecting medical providers) and other factors in the informed consent process (e.g., consent protocols and emphasis on conversations with providers).

Furthermore, there was a greater likelihood that patients would not read consent forms, would not

read them carefully, or would not read them at all with each additional IVF cycle. This might not be a clinical oversight, but a natural behavioral tendency which no reforms will cure. Thus, it is incumbent upon providers to continue to engage with patients about informed consent each and every cycle, no matter how many prior cycles they have completed.

These results stand in contrast to prior research studies involving other medical subspecialties, which have identified multiple reasons why the traditional informed consent process does not increase patient comprehension or prompt patients to read forms before signing.[10] For instance, patients (particularly those with low literacy or non-native English speakers) may have trouble understanding technical or legal jargon,[11] lengthy forms tempt patients to skim rather than scrutinize consent documents,[12] physicians may be pressured to over-educate patients,[3] and patients often describe making consent decisions in non-ideal ways[2] or might already be resolved to proceed with treatment.[2]

To date, there has been little empirical research on ART consent forms; existing publications do not employ empirical methods and primarily cover consent in third party reproduction and embryo disposition contexts.[13-15] Researchers assert consent processes focus on information provision instead of "ensuring patient understanding"[16] and criticize embryo disposition consent processes due to poorly drafted documents, technical jargon, information inundation, inability to realistically consider death and divorce, changing disposition preferences, and "questionable signing circumstances."[15] Other studies have shown that many patients could not remember giving consent for embryo storage and an inability to recall chosen options or form characteristics.[17-19]

This paucity of empirical research on informed consent in ART is at odds with the heightened concern given to informed consent practices within reproductive endocrinology. For procedures like intrauterine insemination and IVF, fertility clinics commonly require patients to attend informational seminars or consent consultations with physicians or other clinic staff and give them lengthy consent packets. In 2008 the Society for Assisted Reproductive Technologies (SART) devised model consent forms to increase forms' efficacy and improve patient understanding,[7] but clinics are not required to use those forms.

Our results suggest that the issues which undermine ART informed consent are more complicated than lengthy or complex consent forms. Although most patients read consent forms, one-third still discounted them as "something to get out of the way." Moreover, most felt they were too long, and a minority deemed them overwhelming, unhelpful, or difficult and confusing. Over time, patients read forms less carefully as they completed additional IVF cycles. While physicians can try to minimize information overload by discussing the risks they feel are most relevant to certain patient groups, only half discussed selective reduction, and this topic was more likely to be discussed with younger women undergoing IVF than with older women.

These findings suggest that researchers' understandings of the informed consent process's dynamics and shortcomings are too simplistic, reducing the efficacy of suggested reforms. While professional concerns over patient recall and comprehension stem from desires to improve understanding and effectively protect providers from legal liability,[4,20] our findings demonstrate that, at least in IVF, recall and comprehension are not problematic.

The heart of the informed-consent process is the physician-patient relationship, which means that most patients will value consultations more than documents, which become a valuable resource to answer questions. Thus, physicians and clinic staff members can leverage their relationship with patients, and the trust therein, to re-engage patients, explaining what they have to gain through this process, and what they have to lose if they do not take it seriously.

The most efficacious reforms, then, will place greater emphasis on maximizing informed consent's conversational aspects. Patients' informed consent experiences are affected by many other factors besides whether they recall and comprehend material information, including their perceptions of who consent forms protect, and forms' informational value and bureaucratic qualities. Even if forms are both thorough and easily comprehensible, informed consent processes will still fail if patients believe that informed consent is not important, if they are overwhelmed, or if they do not ask necessary questions. Similarly, patients may trust their treatment team more than impersonal documents, which seem to exist primarily to limit legal liability. Patients will comply with advice to read and complete consent forms, and

are very likely to understand this information, but they prioritize physician conversations and may place higher value on information learned face-to-face. Because informed consent is embedded in and affected by the doctor-patient relationship (not merely legal requirements), patients like it best when physicians explain why certain information is crucially important for their personal well-being. Thus, our findings support renewed efforts to make informed consent more personal and meaningful, and less bureaucratic, to patients.[21] Doctors should explain to patients why forms are relevant, but realize that information delivered through interpersonal conversations is more impactful. Such patient engagement also allows treatment teams to most efficaciously assess patient understanding.

Web-based, multimedia patient education platforms such as EngagedMD[9] may play a key role in informed consent processes, providing patients with information through diverse mediums in the settings they find most comfortable and convenient. Post-video quizzes allow providers to identify weaknesses in patient understanding. If completed prior to physician consent consultations, these platforms may answer patients' basic questions and identify new queries, helping physicians and patients to use limited consultation time more efficiently. These platforms are currently available and could be a considerable improvement on conventional informed consent protocols. In practice environments where increasing appointment length is often impossible, effective solutions will assist in putting appointment time to its highest and best uses: building trust and effectively educating patients. However, Madeira et al suggest that such platforms should not be used as substitutes for informed consent interactions; this would impoverish patients' informed consent experiences.

Our study has several strengths beyond the large sample size necessary for reasonable statistical power. Because all surveys were anonymous, the patients were more likely to answer questions truthfully. Moreover, this survey's national distribution helps to achieve a wide geographic distribution of patient values, attitudes, and experiences. The potential weaknesses of our study include that it was drawn primarily from a self-selected online patient population that was 90% Caucasian, which might not reflect patient demographics. There is also risk of selection bias, as individuals who chose to participate in the survey may not represent the behaviors and views of all patients undergoing IVF. Additionally, we were not able to use a validated survey in this study as one that met the objectives of our research study did not currently exist. Survey-based research might be subject to errors such as coverage, sampling, nonresponse, and measurement. The survey's anonymity made it impossible to clarify patient responses. Further systematic examination of informed consent's interpersonal dynamics is warranted, particularly efforts that explore specific characteristics of informed consent documents or interpersonal consent interactions that make them seem overwhelming, discourage questions, and diminish informed consent's perceived importance.

Conclusion

In conclusion, this study is among the first to identify factors beyond recall and comprehension that undermine the efficacy of the informed consent process. Its findings raise important questions for future research, emphasizing the importance of maximizing quality interactions between the patient and treatment team, and prioritizing other issues besides recall and comprehension. Robust patient engagement will go a long way towards overcoming consent processes' conventional shortcomings. Moreover, these findings suggest that medical and legal safeguards are inadequately balanced with comprehensibility, thoroughness, and patient engagement. Efficacious reforms will need to include other measures beyond revising consent documentation. Incorporating web-based multimedia patient education and consent platforms may offer a readily available, cost-effective way to readily improve patient engagement given tight provider schedules. Reconsidering classic approaches to informed consent—and looking beyond informed consent forms to interpersonal consent interactions and how consent is situated in the care relationship—may improve ART patients' understanding and experiences.

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