Informed consent in gynecologic surgery

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Purpose of review
Informed consent is frequently used interchangeably with obtaining a signature on a form. This oversimplification shifts the value from the process of informed consent to the documentation. This review focuses on the recommended components of the consent process, barriers encountered, factors influencing patient satisfaction, attempts to improve the consent practice, and considerations in special populations.

Recent findings
The process of informed consent is key to promoting shared decision-making and patient autonomy. Several barriers exist to providing optimal consent including time constraints as well as educational, cultural, and language barriers. Innovative approaches such as audiovisual aids show promise in overcoming barriers and improving the consent process.

Summary
Patients seek expertise and knowledge to aid in making decisions that align with their care goals. Providers have an obligation to provide individualized and accessible counseling. Ongoing research is needed to optimize this process.

Keywords
informed consent, patient autonomy, shared decision-making

INTRODUCTION

Current emphasis on the informed consent process reflects the movement in medicine away from paternalistic medicine to a practice of shared decision-making prioritizing patient autonomy. The informed consent process is at the crux of this paradigm shift. Reference to informed consent in clinical practice is often used synonymously with obtaining a signature on a permission form. However, such oversimplification wrongly shifts the focus to documentation and legal ramifications rather than on the more collaborative and communicative process of informed consent rooted in the ethical principles of respect for patient autonomy and physicians' moral commitment to beneficence. In this review, we will highlight components of the consent process, barriers encountered, factors influencing patient satisfaction, attempts to improve the consent practice, and considerations in special populations. Specific medicolegal implications are beyond the scope of this review.

COMPONENTS OF INFORMED CONSENT

Essential components of the informed consent process described by Cocanour [1] include patient competence; patient understanding of risks, benefits, and alternatives; and patient consent given willingly. These components are necessary in the informed consent process and provide a theoretical basis but leave room for interpretation in clinical practice. Specifically, the degree of disclosure of risks, benefits, and alternatives in these definitions is ambiguous. Various standards have been used to define the depth of the conversation including the professional standard, the reasonable person standard, and the individual or subjective standard. Although the professional standard focuses on what a community of medical providers deems appropriate to disclose, the foundation of the reasonable person standard stems from what information a usual patient considers necessary to be adequately informed. The individual standard is the most tailored of the three ideals emphasizing the uniqueness of each patient encounter [1,2]. Court rulings have played an important role in defining these three

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Curr Opin Obstet Gynecol 2019, 31:240–244
DOI:10.1097/GCO.0000000000000550

KEY POINTS

- Informed consent is a process that relies on establishing a clinician–patient relationship that promotes shared decision-making.
- Innovative approaches such as audiovisual aids show promise in overcoming barriers and improving the consent process.
- Providers have an obligation to provide individualized and accessible counseling.

frameworks. Over time the legal system has largely shifted from prioritizing the professional standard to favoring the reasonable person standard [2]. All three standards emphasize important considerations in the informed consent process.

A study by Pucher *et al.* surveyed 200 patients postoperatively after elective surgical procedures (laparoscopic hernia repairs and cholecystectomies) with the aim of understanding patients' perceptions and priorities with the consent process. Study participants were specifically surveyed about the components of the consent process they valued most. Components highly ranked included consideration of the individual patient's situation, allowing time for questions, a good provider–patient relationship, and confirming patient comprehension. The survey also addressed attitudes surrounding risk. One practical preference that was drawn from this portion of the survey was that for risk disclosure in proportions such as 'one in 10 patients' rather than '10% of patients'. Overall the author's concluded that the consent process is highly individualized and should be tailored to the individual patient rather than one standardized approach [3▪]. This highlights that despite the standards that have been developed over time, patient–physician communication is still the fundamental principle.

Beyond the vital ethical elements of an informed consent process, many national organizations including the American College of Obstetricians and Gynecologists, American Medical Association, and the American College of Surgeons all provide guidance on the contents of the informed consent [2,4,5]. The guidelines are largely uniform with respect to the essential components of an informed consent discussion and include education regarding the diagnosis; presentation of available treatment options including expectant management; and disclosure of the risks, benefits, and anticipated outcome of each option; and explanation of the role of the various healthcare providers involved in their care (including trainees) (Table 1) [2,4,5].

Table 1. American College of Surgeons components of informed consent discussion

Expected course of illness
Proposed surgical intervention
Morbidity and mortality associated with proposed surgical intervention
Common complications of surgery
Risks and benefits of proposed operation
Perioperative expectations
Alternatives treatment options
Disclosure of surgical team members and role in surgical care

Adapted from [5].

PATIENT SATISFACTION

In benign gynecology, multiple treatment options including expectant management, medical therapies, and surgical interventions are often appropriate for an individual patient. Informed consent implies patients understand the breadth of options as well as risks and anticipated outcomes specific to each. This model of shared decision-making promotes patient autonomy which intuitively is associated with patient satisfaction. In a prospective observational study of 150 urogynecology patients planning surgical management, higher knowledge of the informed consent discussion, determined by survey, was associated with increased overall satisfaction with decision for surgery [6].

BARRIERS TO INFORMED CONSENT

Many barriers to providing optimal informed consent in medical practice exist including, but not limited to, language and cultural differences [1], low health literacy, and provider time constraints. In addition, some mandated requirements of informed consent, such as the 30-day wait period prior to a sterilization procedure for patients with Medicaid insurance coverage, create additional hurdles that disproportionately impact these women. Although the intention of this mandate is meant to protect women, a recent study interviewing patients who underwent postpartum tubal ligations both with Medicaid and private insurance concluded that the women in both groups had similar processes of coming to the decision for desired sterilization procedure. They make a compelling argument that different groups of women should not be subject to different standards [7▪]. An additional study on sterilization consent by Natavio *et al.* compared Spanish speaking women's knowledge of postpartum sterilization based on use of a standard Medicaid Sterilization Consent Form in comparison with a

low-literacy version. Participants who signed the low-literacy form had a better grasp of the permanent nature of the procedure [8]. Providers should make every effort to eliminate these barriers to ensuring an informed consent process. Efforts should be taken to use low-literacy forms. In addition, for patients whose primary language is not English, interpreters should be used, and ideally written forms should be in the patient's primary language.

IMPROVING THE INFORMED CONSENT PROCESS

A 2013 Cochrane review examined the impact of various interventions aimed at improving the informed consent process. The findings were limited by the diversity of interventions employed and outcomes measured. Overall the conclusions drawn indicate efforts at enhancing the consent process, and particularly patient comprehension, do achieve the desired outcome. No conclusions about best practices were able to be drawn [9]. A 2017 Cochrane review looking at the use of decision aids to facilitate the patient decision making process supports the use of such aids to improve provider–patient communication [10].

A randomized control study of women undergoing laparoscopy for pelvic pain looked at the use of a multimedia module versus standard consent concluding that women randomized to the multimedia module group had increased knowledge scores of the procedure and risks immediately following consent with similar anxiety scores. The authors conclude that the multimedia format helps facilitate patient understanding promoting patient autonomy in the consent process [11]. An additional randomized control trial assessing whether a video tool improves patient knowledge in the informed consent process for benign hysterectomy also showed improved patient comprehension in the intervention group. The face-to-face time with the physician was also decreased in the video intervention group with comparable satisfaction scores [12▪]. Audiovisual interventions and decision aids can help standardize information conveyed to patients and address barriers to informed consent.

With the acknowledgment of current pitfalls and barriers to the informed consent process the Agency for Healthcare Research and Quality has launched and studied the impact learning modules targeted to healthcare providers and leaders to provide education regarding the informed consent process and encourage quality improvement projects aimed at improving the informed consent process. Of clinicians who completed the pretest survey only 40% reported using teach-back when obtaining consent and 55% used decision aids. Another notable difference was what providers perceived they were counseling and patient recall of information. Although 95% of providers self-reported providing alternatives, only 55% of patients reported being counseled about options [13▪].

TEACHING INFORMED CONSENT

The Accreditation Council for Graduate Medical Education acknowledges the importance of teaching residents how to provide informed consent with the inclusion of informed consent as one of the milestones for obstetrics and gynecology residents (Fig. 1) [14]. Despite this expectation, gaps persist in resident education surrounding informed consent. A recent survey of US obstetrics and gynecology

Version 09/2013 The Obstetrics and Gynecology Milestones: Gynecology, ACGME Report Worksheet

Informed Consent and Shared Decision Making — Interpersonal and Communication Skills

Level 1	Level 2	Level 3	Level 4	Level 5
Understands the importance of informed consent	Begins to engage patients in shared decision making, and obtains informed consent for basic procedures	Uses appropriate, easy-to-understand language in all phases of communication, utilizing an interpreter where necessary Engages in shared decision making, incorporating patients' and families' cultural frameworks Obtains informed consent for complex procedures	Organizes and participates in multidisciplinary family/patient/team member conferences	Models and coaches shared decision making in complex and highly stressful situations Leads multidisciplinary family/patient/team member conferences

Comments:

Not yet achieved Level 1 ☐

FIGURE 1. ACGME obstetrics and gynecology milestones. ACGME, Accreditation Council for Graduate Medical Education.

residents published in 2019 suggests a need for improved education regarding the informed consent process. Of 281 residents surveyed the majority reported learning the consent process by observation rather than formal instruction and only a minority of respondents reported having been evaluated. When queried about specific practices only 53.0% of residents responded 'often' that they 'mention alternative treatments' a basic component of the consent process. In addition, unique to training environments is the role of the learner in the operating suite. Disclosure to patients the role of trainees is an integral part of the consent process; however, only 45.6% of respondents reported 'often' to that they 'explain exactly who will perform the surgery'. The gap in resident education was self-identified as 61.6% of residents surveyed expressed interest in more formal training [15].

SPECIAL POPULATIONS

The concept of vulnerable populations was first introduced in the Belmont Report in 1974 [16] and has since been variably defined in the contexts of medical research and clinical practice. One definition of a vulnerable population is 'a condition, situation or set of characteristics that interacts with the environment, context, system or society in a way that adversely affects their ability to obtain the resources necessary to attain and sustain good health' [17]. Patients may belong to a particular 'vulnerable' group, such as prisoners, racial minorities, refugees, socioeconomically disadvantaged, and minors. In other instances, a specific situation renders the patient vulnerable, for example inability to read, a stressful situation or a perceived power differential [18]. For these reasons, the clinician must recognize and account for vulnerability during shared medical decision making and the informed consent process.

Frequently, the question of decision-making capacity arises in the gynecological setting. Decision-making capacity is defined as a person's ability to make a decision regarding medical treatment and is comprised of four distinct elements: understanding, appreciation, reasoning, and ability to express a choice [19,20]. Without decision-making capacity, a truly informed consent process cannot reliably take place. Several instruments exist to evaluate a patient's decision-making capacity and should be employed whenever there is doubt regarding a patient's capacity.

In accounting for vulnerability and decision-making capacity, one additional dilemma may present itself – harmful stereotyping and implicit bias [21]. Adequately assessing the patient's individual characteristics and identity as they relate to a particular group forms an essential component of the clinician–patient relationship and subsequent decision-making. Traditional teaching in medicine encourages use of prior epidemiologic studies to determine a particular patient's likelihood of disease based on certain characteristics, such as socioeconomic status or race/ethnicity. When counseling or recommending treatments, the clinician should remain objective and present treatment options in a nonjudgmental and nonbiased fashion.

CONCLUSION

Informed consent is a process that requires a relationship of trust and two-way communication between providers and patients. Although several principal components of informed consent are widely accepted, the specific depth of disclosure and understanding is more fluid and varied based on the individual needs of the patient and treatment for which consent is being obtained. Gaps in the consent process have been identified and proposed interventions have been studied. The heterogeneity of such studies however makes it difficult to draw conclusions and further investigation can help optimize the consent process.

Acknowledgements

None.

Financial support and sponsorship

None.

Conflicts of interest

There are no conflicts of interest.

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- ■ of special interest
- ■■ of outstanding interest

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