Informed Consent Education in Obstetrics and Gynecology: A Survey Study

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OBJECTIVE: The practice of obstetrics and gynecology poses specific ethical challenges for informed consent (IC). Data regarding resident confidence with the IC process are lacking. Our objective was to evaluate obstetrics and gynecology residents' education, experience, and confidence related to IC.

DESIGN: This was a cross-sectional survey of obstetrics and gynecology residents. Descriptive analyses were performed using mean and standard deviation or frequency expressed as a percentage. The results were analyzed for statistical significance using chi-square or Fisher's exact tests for categorical variables and Student *t* or Mann-Whitney *U* tests, as appropriate, for continuous variables; all results yielding $p < 0.05$ were deemed statistically significant.

SETTING: Electronic survey.

RESULTS: Two hundred eighty-one trainees completed the survey. The majority of participants were female (84.3%) and from an academic training program (65.1%). Two hundred seventy-seven trainees (98.6%) reported that they had obtained IC for operating room procedures; the majority had first done this in the first postgraduate year (PGY) ($n = 258$, 91.8%). Trainees most commonly obtain IC for resident and general gynecology attending cases. Most trainees primarily learn how to obtain IC via observation of their coresidents and attendings. Nearly 90% of trainees have obtained IC for a procedure for which they were unsure of all the risks. One hundred seventy-three trainees (61.6%) reported that they would like to have more training in IC. Increasing PGY was significantly associated with increasing confidence in obtaining IC for gynecologic, obstetric, and office procedures (all $p < 0.01$). There were no differences based on PGY in frequency of reviewing who will perform the surgical procedure ($p = 0.75$), how trainees will be involved in the procedure ($p = 0.35$), review of alternative treatments ($p = 0.91$), or in documentation of the IC process ($p = 0.16$).

CONCLUSIONS: Based on the findings of this survey study, education related to the IC process is warranted and curriculum development should be the focus of future study. (J Surg Ed 76:1146–1152. © 2018 Association of Program Directors in Surgery. Published by Elsevier Inc. All rights reserved.)

KEY WORDS: communication, consent forms, gynecologic surgery, informed consent, medical education, physician-patient relations

COMPETENCIES: Patient Care, Medical Knowledge, Interpersonal, Communication Skills

INTRODUCTION

Over the past half century, the process of medical decision-making has transitioned from paternalism to an emphasis on "patient autonomy, transparency, and shared decision-making."[1] Legal decisions in the 1970s formalized the autonomous role of the patient and ushered in a new era of patient-centered care.[1] According to the American College of Obstetricians and Gynecologists, "informed consent is a process of communication whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care."[2] Regarding consent for surgical intervention, the process of informed consent (IC) is of even greater

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importance as the patient becomes incapable of participating in the decision-making process once anesthesia is induced.[3]

The practice of obstetrics and gynecology poses specific ethical challenges for IC as difficult situations can arise at the time of labor and delivery, treatment of adolescents, infertility treatment, and genetic counseling.[2] At the time of labor and delivery, many key decisions are irreversible, patients' intimate relationships and personal autonomy may be at odds, and some therapies are socially controversial. In caring for adolescents, physicians must respect autonomy that is generally limited only to sexuality and reproduction. Additionally, the historical contexts of gender, race, and class biases have significant relevance in the obstetric and gynecologic care. Therefore, training in the IC process is vital for obstetrics and gynecology trainees.

There are data to suggest that training in IC is indadequate.[4–6] Lougran reviewed surgical IC documentation performed by general surgery trainees and found that complications were inconsistently detailed, risk of death was rarely documented, and the IC process was infrequently documented in the chronologic notes.[4] Currently, there are no data to evaluate IC training in obstetrics and gynecology in the United States.

In survey studies, trainees have expressed interest in increased training related to IC.[4,6] In 1 survey of medical students and residents, it was found that curricular needs vary between specialties and level of training, indicating that education in IC should be specialty specific and a process that evolves throughout training.[6]

There is no assessment in the literature of the current state of obstetrics and gynecology trainee education, experience, or comfort with the IC process in the United States.

MATERIALS AND METHODS

This is a cross-sectional survey of obstetrics and gynecology residents in the United States and Puerto Rico during the 2016 to 2017 academic year. The objective of this study was to evaluate obstetrics and gynecology residents' education, experience, and confidence related to IC. Survey notification was sent to the residency program coordinators' electronic mail listserv. Coordinators were asked to forward the survey invitation to current obstetrics and gynecology trainees. A paragraph explaining the purpose of the survey and the methods of maintaining confidentiality preceded the survey questions. The survey was administered electronically via Research Electronic Data Capture tools hosted at Hartford Hospital.[7]

The survey, which was approved by the Hartford HealthCare Institutional Review Board, was designed for this project and has not been validated. The survey questions included basic demographic information (age, gender, and postgraduate year [PGY]) and training program information (number of residents in program, training region, program type, and presence of fellows). Training region was defined per the Council on Resident Education in Obstetrics and Gynecology, an education division of the American College of Obstetrics and Gynecologists. The survey also asked if trainees had ever obtained IC for procedures performed in the office or in the operating room and at what PGY they first obtained IC. If a trainee had not obtained IC, a reason was requested. Trainees were asked to report how often they obtained consent for resident and attending cases in general gynecology, gynecologic oncology, reproductive endocrinology, and female pelvic medicine and reconstructive surgery. Trainees also were asked to report how they learned to obtain IC and if there were times that they were tasked with obtaining IC but were unsure of all of the related risks. Level of confidence in obtaining IC for gynecologic, obstetric, and office procedures was assessed specific information about conduct of the surgery also was obtained: participation of trainees, discussion of death as a risk of surgery, and alternatives to surgery. Trainees also were asked how often they mention specific risks when obtaining IC for abdominal hysterectomy, laparoscopic hysterectomy, cesarean section, and dilation and curettage/hysteroscopy. They were asked how often they document the IC process in the patient's chart and confirm that the patient understood what was discussed. The final survey questions related to educational needs, including: desire for additional training in the IC process, and type of additional training desired. A free text box was provided for additional comments.

To encourage survey participation, a drawing for 3 $100 Amazon.com gift cards was conducted after conclusion of the survey time frame. To ensure anonymity of survey responses, a link to a separate Research Electronic Data Capture survey was provided at the end of the IC survey where participants could enter first name and email address for the purpose of the drawing.

Descriptive analyses were performed using mean and standard deviation for continuous data and frequency expressed as a percentage for categorical data. The results were analyzed for statistical significance using chi-square or Fisher's exact tests for categorical variables and Student t or Mann-Whitney U tests, as appropriate, for continuous variables. All data were analyzed with SPSS version 21 (IBM, Armonk, NY), all results yielding $p < 0.05$ were considered statistically significant.

RESULTS

Two hundred eighty-one trainees completed the survey. The majority of participants were female (84.3%), from an academic training program (65.1%), and work with obstetrics and gynecology fellows (65.5%). Mean number (± standard deviation) of trainees per program was 26.6 ± 11.1 (range 6-48). Table 1 shows complete participant demographics.

Two hundred sixty-eight trainees (95.4%) reported that they had obtained IC for office procedures; the majority had first done this in PGY-1 ($n = 245$, 87.2%). Of the 11 participants who reported that they had not obtained IC for office procedures, 10 reported that they had never performed an office procedure and 1 reported that trainees are not allowed to obtain IC for office procedures. Two hundred seventy-seven trainees (98.6%) reported that they had obtained IC for operating room procedures; the majority had first done this in PGY-1 ($n = 258$, 91.8%). Two of the 4 participants who had never obtained IC for operating room procedures provided reasons; 1 reported that some trainees in their program are not allowed to obtain IC for operating room procedures, and the other reported that trainees in their PGY (PGY-1) are not allowed to obtain IC for operating room procedures. Table 2 shows responses of trainees who have obtained IC in the past, who were asked how often they obtain IC for different types of cases. Table 3 shows responses of trainees who were asked how they learned to obtain IC. Table 4 shows level of participants' confidence in obtaining IC for gynecologic, obstetric, and office procedures. Trainees who were asked: "Have there been times in your training when you had to obtain informed consent for a procedure where you were uncertain of all of the risks?" reported never ($n = 29$, 10.3%), rarely (139, 49.5%), sometimes (101, 35.9%), and often (9, 3.2%).

Trainees also were asked how often they review who will perform the surgical procedure, how trainees will be involved in the surgical procedure, whether death is discussed as a risk factor, alternative treatments, and how often they document the IC process in the patient's chart (Table 5). Trainees were asked how often they routinely mention procedure-specific risks in the IC process, see Table 6. To confirm that a patient understood the procedure, associated risks, and alternatives, 264 trainees (94%) reported asking the patient if they have questions, 92 (32.7%) asked the patient to explain the information themselves, and 3 trainees (1.1%) reported that they do not attempt to confirm patient understanding.

One hundred seventy-three trainees (61.6%) reported that they would like to have more training in IC. One hundred twenty-eight (45.6%) desired additional didactic

TABLE 1. Participant Demographics

Variable	Number (%), $n = 281$
Age (years)	
20-25	1 (0.4)
26-30	201 (71.5)
31-35	68 (24.2)
>35	10 (3.6)
Gender	
Female	237 (84.3)
Male	43 (15.3)
Postgraduate year	
1	28 (29.2)
2	65 (23.1)
3	75 (26.7)
4	58 (20.6)
Program type	
Academic	183 (65.1)
Community	30 (10.7)
Community with academic affiliation	66 (23.5)
Military	0
CREOG region	
1 (CT, ME, MA, NH, NY, RI, and VT)	74 (25.3)
2 (DE, IN, KY, MI, NJ, OH, and PA)	82 (29.2)
3 (DC, FL, GA, MD, NC, PR, SC, VA, and WV)	52 (18.5)
4 (AL, AK, IL, IA, KS, LA, MN, MS, MO, NE, OK, TN, TX, and WI)	59 (21.0)
5 (AZ, Armed Forces, CA, CO, HI, NE, NM, OR, UT, and WA)	15 (5.3)

CREOG, Council on Resident Education in Obstetrics and Gynecology.

TABLE 2. Frequency That Trainees Obtain Informed Consent Per Case Type

Case Type	Frequency (n = 277)			
	Never	**Rarely**	**Occasionally**	**Often**
Resident case	0	3 (1.1)	10 (3.6)	264 (94.0)
General gynecology (n = 276)*,†	18 (6.4)	36 (12.8)	77 (27.4)	145 (98.2)
Oncology (n = 276)*,†	94 (33.5)	65 (23.1)	63 (22.4)	54 (19.2)
Reproductive endocrinology*	155 (55.2)	79 (28.1)	29 (10.3)	14 (5.0)
Urogynecology*,†				
• All urogynecology (n = 276)	136 (48.4)	75 (26.7)	37 (13.2)	28 (10.0)
• Mesh mid-urethral sling (n = 276)	179 (63.7)	47 (16.7)	29 (10.3)	21 (7.5)
• Mesh sacrocolpopexy (n = 275)	203 (72.2)	34 (12.1)	22 (7.8)	16 (5.7)
• Vaginal mesh (n = 276)	214 (76.2)	32 (11.4)	18 (6.4)	12 (4.3)

All data are n (%).
*Attending surgeon cases.
†n listed per variable (missing responses).

TABLE 3. Trainee Report of How They Learned to Obtain Informed Consent*

Learning Method	n (%) Responding Yes
Observation of coresidents	265 (94.3)
Observation of fellows	98 (34.9)
Observation of attending	277 (80.8)
Didactic teaching in medical school	66 (23.5)
Didactic teaching in residency	61 (21.7)
Role play with simulated patients and evaluation	36 (12.8)
Observed consent with real patients and evaluation	106 (37.7)
I read on my own	84 (29.9)
I have not been taught to obtain informed consent	14 (5.0)
I don't know how to obtain informed consent	0

*Participants may have offered more than one response, thus numbers are not mutually exclusive.

TABLE 4. Level of Confidence in Obtaining Informed Consent

Case Type	Level Of Confidence				
	Not At All Confident	**Not Confident**	**Neutral**	**Somewhat Confident**	**Very Confident**
Gynecologic OR procedures (n = 280)*	0	7 (2.5)	18 (6.4)	99 (35.2)	156 (55.5)
Obstetric OR procedures (n = 279)*	0	0	9 (3.2)	51 (18.1)	219 (77.9)
Office procedures	3 (1.1)	0	14 (5.0)	69 (24.6)	194 (99.6)

OR, operating room.
All data are n (%).
*n listed per variable (missing responses).

teaching on the IC process, 128 (45.6%) desired additional didactic teaching on the ethical considerations in IC, 54 (19.2%) would like an opportunity to role play IC and receive evaluation, and 63 (22.4%) would like observation of the IC process with evaluation.

Increasing PGY was associated with having obtained IC for office procedures ($p = 0.01$); however, there was no association between PGY and having obtained IC for operating room procedures. Increasing PGY was associated with increasing confidence in IC for gynecologic procedures, obstetric procedures, and office procedures (all $p < 0.01$). Increasing PGY also was associated with an increased likelihood that possibility of death was mentioned in the IC process ($p = 0.10$). Based on PGY, there was no difference between trainees reporting that they have felt unsure of the risks when obtaining IC ($p = 0.33$). There were no differences based on PGY in frequency of reviewing who will perform the surgical procedure ($p = 0.75$), how trainees will be involved in the procedure ($p = 0.35$), review of alternative treatments ($p = 0.91$), or in documentation of the IC process in the patient's chart ($p = 0.16$).

TABLE 5. Trainee-reported Frequency of Performing Components of the Informed Consent Process

When You Obtain Informed Consent, How Often Do You:	Frequency			
	Never	Rarely	Sometimes	Often
Explain exactly who will perform the surgery (279)*	11 (3.9)	54 (19.2)	86 (30.6)	128 (45.6)
Explain how trainees will be involved in the surgery (278)*	21 (7.5)	78 (27.8)	58 (30.2)	94 (33.5)
Mention death as a risk (*n* = 277)*	29 (10.3)	79 (28.1)	92 (32.7)	77 (27.4)
Mention alternative treatments (*n* = 278)*	8 (2.8)	41 (14.6)	80 (28.5)	149 (53.0)
Document the process in the patient's visit note/progress note (*n* = 278)*	8 (2.8)	14 (5.0)	48 (17.1)	208 (74.0)

All data are *n* (%).
* *n* listed per variable.

When trainees were compared based on gender, females were more likely than males to review who will perform the surgical procedure ($p = 0.03$) and to discuss alternatives to surgery ($p = 0.03$). Otherwise, there were no gender-based differences.

When trainees were compared by program type (academic, community, and community with academic affiliation), those in an academic program were more likely to have obtained IC for office procedures ($p < 0.01$), but there was no difference in frequency of those who had obtained IC for an operating room procedure ($p = 0.27$). Trainees at academic training programs reported greater confidence in obtaining IC for office procedures ($p < 0.01$) than those in either type of community program. Otherwise, trainees in academic versus community programs did not differ.

Based on training region, trainees in Region 3 (DC, FL, GA, MD, NC, PR, SC, VA, and WV) were more likely than others to mention death as a risk factor when obtaining IC and those in Region 5 (AZ, Armed Forces, CA, CO, HI, NE, NM, OR, UT, and WA) were more likely to document the IC process in the patient's chart. Otherwise, there were no differences in trainee experience/practices based on region.

There was a significantly different distribution ($p < 0.01$) in a desire for more training, with the first 2 PGYs being higher. There was no association between PGY and type of additional training desired: didactic teaching on how to conduct IC ($p = 0.09$), didactic teaching on ethical considerations ($p = 0.17$), role play with evaluation ($p = 0.28$), and observation with evaluation ($p = 0.35$).

Procedure-specific Risks: Abdominal Hysterectomy

Increasing PGY was associated with a greater likelihood of mentioning risks of infection, injury to bowel/bladder/ureters/vasculature/nerves, bleeding, need for blood transfusion, deep venous thrombosis/pulmonary emboli (DVT/PE), myocardial infarction (MI), and death (all $p < 0.01$) when obtaining IC for abdominal hysterectomy. There was no difference in likelihood of mentioning pneumonia as a risk of abdominal hysterectomy based on PGY ($p = 0.20$).

Procedure-specific Risks: Laparoscopic Hysterectomy

Increasing PGY was associated with a greater likelihood of mentioning risk of infection, injury to bowel/bladder/ureters/vasculature/nerves, bleeding, need for blood transfusion, conversion to laparotomy, DVT/PE, MI, and death (all $p \leq 0.03$). There was no difference in likelihood of mentioning pneumonia as a risk of laparoscopic hysterectomy based on PGY ($p = 0.42$).

Procedure-specific Risks: Cesarean Section

Increasing PGY was associated with a greater likelihood of mentioning injury to vasculature/nerves as risks of cesarean section based on PGY ($p \leq 0.02$).There were no differences in likelihood of mentioning infection, injury to bowel/bladder/ureters, bleeding, need for blood transfusion, hysterectomy, DVT/PE, pneumonia, and MI as a risk of cesarean section based on PGY (all $p > 0.05$).

Procedure-specific Risks: Dilation and Curettage/Hysteroscopy

Increasing PGY was associated with a greater likelihood of mentioning infection, injury to bowel/vasculature, bleeding, and fluid overload as risks of dilation and curettage/hysteroscopy (all $p \leq 0.02$). There was no difference in likelihood of mentioning injury to bladder/ureters/nerves, need for blood transfusion, hysterectomy, DVT/PE, pneumonia, MI, and death as a risk of dilation and curettage/hysteroscopy (all $p \geq 0.07$).

Seventeen trainees provided comments in the free text section. One PGY-3 trainee commented: "...I definitely think there needs to be an improvement in didactics surrounding informed consent." A PGY-4 trainee provided this statement: "I think there should be more observation of new residents to ensure that they

are comfortable and competent in obtaining informed consents. Many residents get through residency obtaining consent and are never supervised and never witness anyone else obtaining consent so they could potentially be doing it wrong and then perpetuate that after graduation, possibly to future trainees." Another PGY-4 trainee commented: "Interns are thrown into the consent process without adequate training. . ."

DISCUSSION

Trainees report that they obtain IC often and early in their training. Almost all trainees who participated in this study reported that they have obtained IC for both office and operating room procedures and that they began doing this in the first PGY. Based on our participants, it is extremely rare for a training program to restrict when and if trainees are allowed to obtain IC. Nearly 90% of trainees reported that they had obtained IC for a procedure when they were unsure of the related risks and more than half of the trainees expressed a desire for additional training, this finding is consistent with the results of similar studies in other disciplines.[4,6] Trainees reported more confidence in IC for obstetric than gynecologic procedures, and this is likely related to the commonality of cesarean section and familiarity with the procedure from early on in training. From these observations, it is clear that additional training in IC is warranted.

Fewer than half of trainees reported that they "often" tell patients exactly who will perform the surgery and how trainees will be involved. The American College Of Obstetrics and Gynecology points out that patients should be aware that they are being cared for in a teaching setting.[8] Appropriately, the majority of trainees are documenting the IC process in the patient's chart.

Most trainees are learning to obtain IC via observation of their coresidents and attendings. The likelihood of mentioning pertinent risks of the procedure increases with trainee PGY. This association is not surprising given that those in advanced PGY have had more time to observe the consent process than those in the first or second PGY. Based on the results of this survey, it seems that most trainees gain the needed confidence by the end of training. However, education in IC is necessary at the start of residency as trainees report that they obtain IC from early in training and there is a chance that early trainees may be obtaining IC for a procedure that they do not have experience performing or a good understanding of related complications or procedure alternatives. This issue was repeatedly mentioned in the comments section of the survey where many participants noted that trainees need more formal education early in residency. This is consistent with our finding that PGY-1 and 2 trainees expressed a greater desire for additional training in IC. While it is clear that IC training needs improvement in residency programs, this training would ideally be improved during undergraduate medical education as well. The American Association of Medical Colleges lists, "obtain informed consent for tests and/or procedures" in the Core Entrustable Professional Activities for Entering Residency.[9]

The majority of trainee experience in conducting IC is with resident cases and general gynecology cases. It seems appropriate that trainees are not commonly carrying out the IC process for oncology, reproductive endocrinology, and urogynecology cases. Due to nuances of some procedures, need for intraoperative decision-making, and complexities of patient expectations and survival data, we believe that trainees should be supervised when participating in these consent discussions. It is rare that trainees are obtaining IC for urogynecology cases involving use of implanted mesh; we believe that trainees should not independently conduct IC discussion for mesh placement. As illustrated by Whiteside, individual surgeon awareness and disclosure of personal and published outcomes is relevant to avoidance of deception in IC.[10] Surgeon personal outcomes can be difficult data to obtain and it is virtually impossible to expect trainees to be able to navigate this discussion with a patient. Based on similar outcomes of various approaches to pelvic organ prolapse repair, treatment of pelvic organ prolapse is considered preference-sensitive care.[10] In this situation, the discussion of surgical plan becomes nuanced and is based on each individual patient's anatomy, symptoms, goals of care, and on the surgeon's experience and outcomes. This is not a task well-suited to trainees. Nevertheless, the education of how to appropriately obtain IC for complex, subspecialized procedures is important for trainees, even if the education is limited to observation.

Given the paucity of data regarding residency education in IC, this is an important study revealing a gap in training and a deficiency in ensuring that patients are well-informed and autonomous in their decision-making. The era of the medical education philosophy "see one, do one, teach one" is no longer adequate and is not acceptable for patient care. Obstetrics and gynecology residents clearly desire more training and education around the IC process. As with most survey studies, this project was limited by response rate. In the 2015 to 2016 academic year, the Accreditation Council for Graduate Medical Education (ACGME) reported that there were 5187 total residents in obstetrics and gynecology.[11] This survey includes 281 trainees, or 5.4% of the total population. The gender distribution of the participants is similar to the total population with 84.3% in the current study and 81.9% in all training programs and all training regions were represented, suggesting that this may be a representative sample.[11]

TABLE 6. Trainees Reporting Which Risks They Routinely Mention (at Least 80% of the Time) Based on Procedure

	Abdominal Hysterectomy	Laparoscopic Hysterectomy	Cesarean Section	Dilation and Curettage/Hysteroscopy
Infection	201 (71.5)	195 (69.4)	271 (96.4)	254 (90.4)
Intraoperative injury				
Bowel	202 (71.9)	196 (69.8)	268 (95.4)	189 (67.3)
Bladder/ureters	201 (71.5)	196 (69.8)	272 (96.8)	195 (69.4)
Vasculature	171 (60.9)	167 (59.4)	218 (77.6)	140 (49.8)
Nerves	135 (48.0)	140 (49.8)	169 (60.1)	104 (37.0)
Bleeding	205 (73.0)	196 (69.8)	274 (97.5)	258 (91.8)
Blood transfusion	198 (70.5)	183 (65.1)	269 (95.7)	197 (70.1)
DVT/pulmonary embolism	102 (36.3)	90 (32.0)	107 (38.1)	64 (22.8)
Pneumonia	26 (9.3)	26 (9.3)	27 (9.6)	18 (6.4)
Myocardial infarction	29 (10.3)	28 (10.0)	24 (8.5)	17 (6.0)
Death	97 (34.5)	91 (32.4)	115 (40.9)	53 (18.9)
Laparotomy	N/A	193 (68.7)	N/A	N/A
Hysterectomy	N/A	N/A	205 (73.0)	78 (27.8)
Fluid overload	N/A	N/A	N/A	80 (28.5)

DVT, deep venous thrombosis.
All data are *n* (%).

CONCLUSION

Based on the findings of this survey study, we have identified an important education gap and believe that early education related to the IC process is warranted and curriculum development should be the focus of future study.

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SUPPLEMENTARY INFORMATION

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.jsurg.2018.12.005.