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Development and Testing of a Curriculum for Teaching Informed Consent for Spinal Anesthesia to Anesthesiology Residents

Pedro Tanaka[1*], **Leeanne Park**[1], **Maria Tanaka**[1], **Ankeet D Udani**[2] **and Alex Macario**[1]

[1]*Department of Anesthesiology, Perioperative and Pain Medicine, Stanford University School of Medicine, Stanford, USA*

[2]*Department of Anesthesiology, Duke University School of Medicine, Durham, USA*

[*]**Corresponding author:** Pedro Tanaka, Department: Department of Anesthesiology, Perioperative and Pain Medicine, Stanford University School of Medicine, Stanford, USA, Tel: 650-724-4066; Fax: 650-724-4066; E-mail: ptanaka@stanford.edu

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Abstract

Introduction: Properly obtaining informed consent for spinal anesthesia is a skill expected of anesthesiology residents. The goals of the study were to 1) use a Delphi method to develop a curriculum for teaching informed consent for spinal anesthesia, and a checklist of required elements; 2) determine which elements of the informed consent process were most frequently missed prior to the curriculum; 3) quantify if this curriculum improved performance of correctly obtaining informed consent from a standardized patient; and 4) measure retention of learning as measured by how residents performed on actual patients.

Methods: Performance on obtaining informed consent was tested with an 11-item checklist on a standardized patient before and after completing the curriculum. Resident performance on their next three patients scheduled to have spinal anesthesia was evaluated at the bedside using the same checklist.

Results: At baseline before completing the curriculum 18 anesthesia residents (39% female) with a mean 6.29 months (SD 3.59, median 6.5, 25th-75th quartile range 4.25-9.75) of residency completed and 11.39 prior spinals (SD 13.1, median 13.14, 25th-75th quartile range 3-14) successfully performed 47% (SD 20%, median 45%, 25th-75th quartile range 36-41%) of the 11 required elements. The 3 most commonly missed elements were: "Teach back: Ask the patient to repeat key items in discussion" (0% correct), "Connect, Introduce, Communicate, Ask permission, Respond, Exit" (6%), and "Have the patient verbally agree with the consent forms (17%)." 7 residents completed the written materials and video curriculum and significantly increased their performance to successfully complete 90% of the required elements on a standardized patient, and 86% on actual patients 1-5 days later (P<0.01). 11 other residents completed the written materials and video curriculum supplemented with a 1:1 session with a faculty and significantly increased the percentage of properly completed elements to 97% on the standardized patient, and to 88% on actual patients (P<0.01).

Conclusions: The curriculum developed increased performance on how well informed consent was obtained by junior anesthesia residents on an 11 item checklist and may be used by training programs to teach and evaluate their residents.

Keywords Informed consent; Spinal anesthesia

Abbreviations

ACGME - Accreditation Council for Graduate Medical Education.

Introduction

Properly obtaining informed consent from a patient prior to an anesthetic is a skill expected of anesthesia residents. Informed consent is specifically listed in the ACGME Anesthesiology Patient Care Competency, as a milestone within Preanesthetic Evaluation, Assessment, and Preparation. For patients and physicians the consent process is a tool for building trust and enhancing decision making [1]. When obtaining informed consent, anesthesiology trainees face ethical challenges (e.g., conflict between patient and family wishes and medical judgment) and patient relationship challenges (e.g., questions about trainee competence) [2]. Other challenges may be categorized as practical and include the amount of information to provide, communication barriers, and time limitations. Although a study of primary care physicians and surgeons showed that consent discussions are often incomplete [3], how well practicing anesthesiologists obtain consent is unknown. Inadequate communication due to incomplete informed consent may increase litigation risk [4].

Studies of methods to improve residents' skills in obtaining informed consent exist. For example, 2.5 hr of training with faculty and standardized patients improved surgery residents ability to properly perform on an 8 item checklist from 6.85 to 7.40 items [5]. Direct feedback from standardized patients has also been found to be helpful to teach informed consent [6], as has an online module, a small group discussion with faculty, and standardized patient cases [7]. Training in medicine has relied on acquisition of knowledge and skills via an apprenticeship model utilizing real-world experience with actual patients. Among the limitations of this approach is variability in the types of supervision and feedback that trainees receive [8]. The optimal way to educate or assess anesthesia house staff on obtaining informed consent is unknown.

Simulation on the other hand allows for innovative ways to improve trainee skills in a controlled environment with the opportunity for repetition and accurate feedback [9]. Development of superior performance can be aided by having well-defined learning objectives, a focus on improving particular tasks via repetitive practice, and precise measurements of performance and timely informative feedback [10]. Technical procedures such as central line placement, lumbar puncture, and subarachnoid blocks may benefit from simulation training [11-13]. Less research is published on teaching nontechnical skills such as informed consent.

As a result, this study aimed to study informed consent with spinal anesthesia as the specific topic because it is a common anesthetic type. The goals of the study were to 1) use a Delphi method to develop a curriculum for teaching informed consent for spinal anesthesia, and a checklist of required elements; 2) determine which elements of the informed consent process were most frequently missed prior to the curriculum; 3) quantify if this curriculum improved performance of correctly obtaining informed consent from a standardized patient; and 4) measure retention of learning as measured by how residents performed on actual patients.

Methods

After IRB approval, anesthesiology postgraduate year two residents were recruited to participate in the study. Resident data were kept confidential and residents understood they would not be penalized for not participating in the study (Figure 1). outlines study protocol. Each resident completed a survey to collect demographic data, and answered a question on how comfortable they feel obtaining informed consent for spinal anesthesia (5-point ordinal scale).

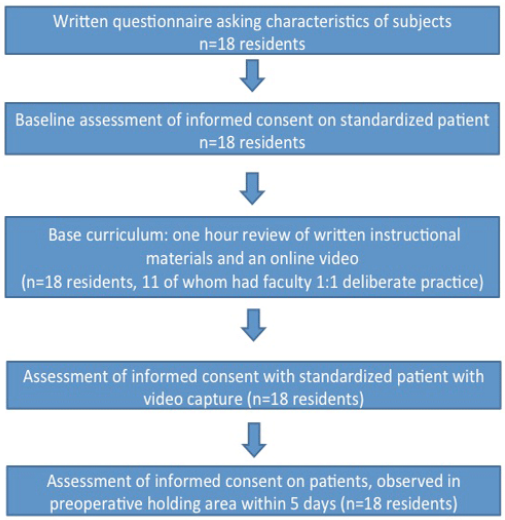

Figure 1: Study flow chart following enrollment and consent of residents.

Checklist development

A checklist of the necessary elements for obtaining informed consent for spinal anesthesia was derived via a modified Delphi approach [14] among a panel of experts of five board-certified anesthesiologists from four different teaching hospitals to determine the domains and specific items. This was supplemented by analysis of published articles. For example, a systematic review found that physicians rarely discuss alternatives, risks, and benefits when obtaining consent, and tend to overestimate patient's comprehension of the information [15]. As a result, those items were discussed for inclusion in the checklist. During the Delphi process, suggestions for adding or deleting required elements of informed consent were encouraged, and the checklist assessment tool was reviewed iteratively by the panel until consensus was achieved.

The checklist was also then pilot-tested on a group of 3 attending anesthesiologists, and reviewed again, until consensus was reached to provide face and content validity. For all assessments each checklist element was graded by two trained faculty raters and given equal weight using a dichotomous scoring system ("satisfactory" or "unsatisfactory") as recommended for performance tests [16].

Performance assessments

Performance assessment on a standardized patient before curriculum: A baseline assessment of each participant obtaining informed consent was made with a standardized patient before they were exposed to the curriculum. To ensure consistency, the standardized patient first read through the case, and trained and prepared using role-play. Appendix A contains the prompt given to the participant and the instructions for the standardized patient.

The video-recorded performances at baseline were later scored by two authors (AU, PT) using the 11-item checklist developed in the Delphi process.

Curriculum

After the baseline assessment, residents completed the curriculum consisting of one hour to review written instructional materials, including FAQs, as well as an online video a video with a standardized patient (https://m.youtube.com/watch?v=AN8CdzQj6xk) to demonstrate the desired optimal method for obtaining patient informed consent for spinal anesthesia. The curriculum specifically addressed each of the items on the checklist.

Based on an assumed baseline performance of 30% correct of the checklist items and an improvement to 80% correct after completing the curriculum, a power analysis determined that a sample of n=7 would detect this difference with alpha=0.05 and beta=0.8.

7 residents completed the written materials and video and 11 other residents completed the written materials and video curriculum supplemented with a 1:1 session with a faculty. Thereafter all residents underwent re-testing with the standardized patient. The session was video-recorded and scored using the checklist in the same fashion as the baseline assessment.

Performance assessment on actual patients for all residents

To evaluate retention and clinical application, all residents were observed at the bedside by one of the authors (AU, PT) obtaining informed consent for spinal anesthesia on the resident's next three patients scheduled to have spinal anesthesia.

Their performances were scored live, not video-recorded, using the same 11-item checklist by the two faculty raters (AU, PT).

Statistics

The Wilcoxon signed-rank test paired samples non-parametric test was used to assess before and post curriculum performance scores on the 11 item checklist.

Results

The modified Delphi method resulted in an 11-item checklist of required elements for informed consent (Table 1).

All 18 (39% female) residents recruited consented, and at baseline before completing the curriculum had a mean 6.29 months (SD 3.59, median 6.5, 25th-75th quartile range 4.25-9.75) of residency completed and 11.39 prior spinals (SD 13.1, median 13, 14, 25th-75th quartile range 3-14) (Table 2).

1	Introduce self and the discussion topic
2	Describe the indications for the procedure
3	Describe the benefits of the procedure
4	Describe the procedure itself in clear, simple language
5	Pause for questions appropriately
6	Describe the minor risks of the procedure
7	Describe the risk of serious complications. Emphasize that these are rare.
8	Describe alternatives to the procedure
9	Teach back: Ask the patient to repeat key items in discussion
10	Have the patient verbally agree with the consent form
11	Utilized connect, introduce, communicate, ask permission, respond, exit

Table 1: Eleven item checklists for informed consent for spinal anesthesia as developed from them modified Delphi process.

	Mean	**SD**	**Median**	**low to high range**	**25th-75th quartile range**
Months of anaesthesia completed	6.29	3.59	6.5	0.25-12	4.25-9.75
Age of resident	29.39	3.03	28.5	26-37	28-30
How many spinal anaesthetics have you done?	11.39	13.1	13.14	0-50	3-14
How comfortable do you feel completing a preoperative assessment and obtaining informed consent for spinal anaesthesia? (1=not comfortable; 3=somewhat comfortable; 5=very comfortable)	3.44	0.92	3	2-5	3-4

Table 2: Characteristics of residents (n=18).

Checklist element	**% of residents completing successfully**
Introduce self and the discussion topic	78%
Describe the indications for the procedure	39%
Describe the benefits of the procedure	50%
Describe the procedure itself in clear, simple language	100%

Pause for questions appropriately	56%
Describe the minor risks of the procedure	89%
Describe the risk of serious complications. Emphasize that these are rare.	56%
Describe alternatives to the procedure	33%
Teach back: Ask the patient to repeat key items in discussion	0%
Have the patient verbally agree with the consent form	17%
Utilized CI-CARE*	6%

Table 3: Prior to completing curriculum the percentage of required elements on checklist Performed properly for obtaining informed consent for spinal anesthesia as assessed on a standardized patient.

At baseline, they successfully performed 47% (SD 20%, median 45%, 25th-75th quartile range 36-41%) of the 11 required elements (Table 3). The most commonly correctly performed element was "Describe the procedure itself in clear, simple language" (100%), followed by "Describe the minor risks of the procedure" (89%)(Table 4).

	Performance assessed on standardized patient		**Performance assessed on actual patients**	
	Written and video curriculum	Written, video curriculum and deliberate practice	Written and video curriculum	Written, video curriculum and deliberate practice
Introduce self and the discussion topic	100%	100%	100%	100%
Describe the indications for the procedure	100%	91%	93%	93%
Describe the benefits of the procedure	100%	100%	93%	90%
Describe the procedure itself in clear, simple language	100%	100%	100%	100%
Pause for questions Appropriately	86%	100%	100%	90%
Describe the minor risks of the procedure	100%	100%	100%	93%
Describe the risk of serious Complications. Emphasize that these are rare.	100%	100%	93%	93%
Describe alternatives to the procedure	71%	100%	86%	83%
Teach back: Ask the patient to repeat key items in discussion	57%	100%	36%	63%
Have the patient verbally agree with the consent form	86%	100%	79%	97%
Utilized CI-CARE*	86%	73%	71%	70%

Table 4: Percentage of required elements performed properly after completing the curriculum.

The 3 most commonly missed elements were: "Teach back: Ask the patient to repeat key items in discussion" (0% correct), "Connect, Introduce, Communicate, Ask permission, Respond, Exit" (6%), and "Have the patient verbally agree with the consent forms (17%)."

The 7 residents completing the written materials and video curriculum significantly increased their performance to successfully complete 90% (SD 13%, median 91%, 25th-75th quartile range 86-100%) of the required elements on a standardized patient. They had an average of 2.0 (SD 1.4) patients for which informed consent was assessed in the preoperative holding area, and correctly performed 86% of the total of 154 (14 patients 11 elements per patient) required elements.

We were unable to study a full set of 3 patients for each of the 18 residents for logistical reasons mainly that residents moved on to other non-operating room rotations or other hospitals before completing 3 new spinals. Assessments on actual patients were performed an average of 3.22 (SD 1.2, median 3, and range 2–5 days) days after finishing the curriculum.

The 11 other residents completed the written materials and video curriculum supplemented with a 1:1 session with faculty significantly increased the percentage of properly completed elements to 97% (SD 4%, median 100%, 25th-75th quartile range 95-100%) on the standardized patient ($P<0.01$). These residents had a total of 30 patients for which informed consent was assessed in the preoperative holding area, and correctly performed 88% of the total of 330 (30 patients x 11 elements per patient) required elements.

Discussion

The modified Delphi method resulted in an 11-item checklist of required elements for obtaining consent for spinal anesthesia which can be further tested for use by residency programs in assessment of this skill. We used this procedural checklist to create a base written curriculum and an online video for teaching proper informed consent for spinal anesthesia. Prior to residents completing the base curriculum, the most commonly missed of the 11 required elements was "Teach back: Ask the patient to repeat key items in discussion" which aims to make sure patients understand what is being presented as this has been found in other studies to be a common deficiency.

The curriculum that was developed significantly increased correct performance for obtaining informed consent for spinal anesthesia as measured using standardized patients from slightly less than half to more than 90% of items as measured via an 11 item checklist. These benefits for proper performance of obtaining informed consent persisted for several days later on actual patients, revealing translation to clinical benefit. Additional research is required to determine what the minimum performance would have to be to have a "passing" score.

The main goal of the study was to develop the curriculum and to test it. We choose to have some of the residents also receive additional one-on-one faculty coaching but the study was not powered to detect if that had an independent incremental benefit and further studies may be warranted to assess this. The use of deliberate practice has been found to be an effective method for training for some skills including crisis management situations, cardiopulmonary bypass weaning, EEG interpretation, laryngoscopy, intubation and more [17]. However, this educational method is resource intensive primarily due to the cost of the expert's time. For a large program with dozens of residents the 1:1 coaching may not be feasible.

Another potential limitation of deliberate practice may be that it is not well-known or understood among anesthesiology faculty educators and programs so ongoing dissemination nationally may be helpful [18]. Innate ability and learner differences may also confound the study of deliberate practice [19].

In addition to a small number of participants, this study has several other limitations. All participants were active anesthesiology residents less than 12 months into training, with varying case numbers which is common in anesthesia training [20]. Not enough residents were enrolled and there was not sufficient variability in prior spinal anesthesia experience to assess statistically whether prior experience affected baseline performance. We chose first year clinical anesthesia residents as study participants as they were most likely to have little prior exposure to obtaining consent for spinal anesthesia. Other limitations include that this study was conducted at a single institution so it is unknown if the results would have been different if participants were members of other residency programs, the study did not test for decay of skill improvement past 5 days, and completeness of documentation of informed consent in the medical record was not measured.

Although written signed consent for anesthesia may be often bundled into the patient's surgical consent or part of a generic hospital consent form, informed consent in anesthesia is meant to be a two-way communication between the physician and the patient prior to initiation of an anesthetic. Aside from the ethical and legal responsibility, the informed consent process also may prompt active discussion of the anesthesia plan of care, associated risks, and patient concerns and expectations [21-23]. It is a key component of patient-physician communication and functions to uphold patient autonomy and promote shared decision making [24], which is associated with improved patient satisfaction and favorable outcomes [25,26]. In 2006, and again in 2011, the American Society of Anesthesiologists recommended that an anesthesia-specific informed consent to ensure that the necessary level of information has been provided to patients. Anesthesia residencies will need to have specific training and assessment for informed consent.

Anesthesiology trainees must acquire a large range of knowledge and skills. It is important to identify the most efficient way to educate anesthesiology trainees given that the formal training time is limited to 4 years. The curriculum that was developed significantly increased correct performance of properly obtaining informed consent for spinal anesthesia, and persisted at least for several day later when consenting real patients. The 11 item checklist could be further tested and used by residency programs to assess this nontechnical skill.

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