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Providing Informed Consent: A Standardized Case

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Abstract

Introduction: From the first day of residency, residents may be required to consent patients for interventions, procedures, or tests. The ability to perform an informed consent is considered one of the Association of American Medical College's Core Entrustable Professional Activities for entering residency.

This case provides learners with the opportunity to obtain informed consent for a lumbar puncture procedure and to receive immediate structured feedback on their performance. This is a formative assessment, which has been used with both senior medical students and first-year residents at our institution. **Methods:** The case involves a standardized patient with a history of leukemia who presents to the emergency department with a headache, fever, and lethargy. The learner is charged with the task of compassionately, honestly, and confidently explaining the process of a lumbar puncture in order to appropriately obtain informed consent. **Results:** This case was well received, with the vast majority of learners rating the instructions as clear and the tasks of the station as appropriate for the level of learner. Comments provided by the learners regarding the standardized patients' feedback indicate that this is a useful exercise to assist with the development of the crucial skill of obtaining informed consent.

Discussion: Overall, learners are able to perform this task and find it a meaningful exercise. We are able to measure both content and communication skills. In our cohort, learners are able to perform above the targeted passing score. This provides some evidence of competency in terms of both content and communication skills.

Keywords

Informed Consent, Counseling, Standardized Patient, Lumbar Puncture, Decision Making, Shared Decision Making

Educational Objectives

By the end of this standardized patient case, learners will be able to:

1. Obtain informed consent for a procedure and receive immediate feedback on their performance.
2. Communicate specific medical facts to a patient in an understandable way.
3. Negotiate a mutually agreeable treatment plan with a patient and confirm the patient's understanding.

Introduction

As medicine continues to advance and patients are presented with more options for the diagnosis and management of their medical conditions, the concept of providing informed consent has become a critical skill for all physicians to master. Simply signing a consent form does not constitute informed consent. The process of obtaining informed consent should be a bidirectional conversation between the patient and doctor, ideally including a discussion of the indications, risks, benefits, and alternatives of the proposed intervention.¹ The principles of patient autonomy and shared decision making are fundamental to this process. Information about the current clinical situation and the mechanics of the proposed procedure should be provided in an understandable way. Disclosure alone is not enough. Patient comprehension must be assessed throughout the discussion, and medical care should be tailored to reflect patient goals, preferences, and values.² Studies have shown that this process is performed poorly, with a minimum of

Appendices

- A. SP Content Outline.doc
- B. SP Scoring Checklist and Suggestions for Feedback .doc
- C. Door Chart Information.doc
- D. Medical Facts for Lumbar Puncture.doc
- E. Training Agenda for Lumbar Puncture.doc

All appendices are peer reviewed as integral parts of the Original Publication.

interactions meeting criteria for truly informed decision making.³ While informed consent training is common, a standardized or consistent approach to teaching informed consent is lacking in much of medical education, with only 60% of survey respondents feeling that their training in this arena was adequate.⁴ Standardized patient (SP) feedback has been shown to be a reliable tool in teaching the informed consent protocol.⁵

Obtaining informed consent requires knowledge of medical facts as well as interpersonal and professional skills. This makes the process of obtaining informed consent a crucial skill to both teach and assess during medical education. The Association of American Medical Colleges has recently published a list of Core Entrustable Professional Activities (EPAs) for entering residency.⁶ EPA 11 is to obtain informed consent for tests and/or procedures. Furthermore, the Accreditation Council for Graduate Medical Education has released its milestones, which are the knowledge, skills, attitudes, and other attributes for each of the their competencies. The ability to understand the necessary elements of informed consent and to engage patients in shared decision making to obtain informed consent for basic procedures is considered a Level 2 milestone for multiple specialties under the broader domain of *systems-based practice*.⁷ Medical students and first-year residents should thus be able to demonstrate competence on the important task of obtaining informed consent. This standardized case has been developed to assess a learner's ability to provide informed consent for a lumbar puncture procedure in the clinical setting of a patient presenting to the emergency department with a headache and fever.

This case of informed consent for lumbar puncture was designed and developed by a collaborative team consisting of faculty from the Departments of Internal Medicine, Emergency Medicine, and General Surgery, as well as staff from the Office of Standardized Patient Assessment. This case was developed to fill the gap in the medical curriculum on informed consent and was initially designed to be administered as part of the fourth-year emergency medicine rotation.⁸ SPs were trained and evaluated by SP educators (SPEs) with a combination of at-home preparation, on-site training, and audio review of transcripts. After its inception, this case was used for both fourth-year medical students and incoming interns at the University of Michigan for 4 years as a formative assessment.⁹ Learners were faced with an SP who had a personal history of leukemia presenting to the emergency department for evaluation of fever, headache, and confusion. They were informed that neurologic examination and computed tomography of the head were both normal. Additionally, learners were provided with the indications, risks, and benefits of lumbar puncture and were asked to obtain informed consent from the patient to perform this procedure.

Lumbar puncture is an appropriate procedure to use to assess the process of obtaining informed consent as it has clearly documented alternatives, risks, benefits, and potential complications.¹⁰ The procedure itself is relatively straightforward medically and would be the type of procedure a first-year resident would be expected to be able to perform. The target audience of fourth-year medical students would have already completed preclinical work in neurology, infectious disease, and hematology/oncology, as well as the internal medicine and neurology clerkships, giving them all the background knowledge and experiences necessary to direct this conversation. Incoming first-year residents, having just graduated from medical school, would also have all the prerequisite knowledge to complete this task, regardless of their intended specialty.

Methods

The SP content outline (Appendix A) provides necessary background for an SP to portray a patient in need of a lumbar puncture. The SP scoring checklist (Appendix B) ensures that all appropriate elements of informed consent are covered during the encounter. It also includes discussion points to guide the SP in providing structured feedback to the learner during the postencounter debrief. The lumbar puncture medical fact sheet (Appendix D) provides the learner with background information on the procedure, while the door chart (Appendix C) orients the learner to the clinical situation. Also included in this resource is a training agenda (Appendix E).

The appropriate elements of informed consent were obtained from the preestablished, validated checklist on informed consent described by Braddock et al.³ Ultimately, a 43-point checklist was created for scoring

the encounter (see Appendix B). The checklist included questions about the content of obtaining informed consent (questions 1-28) and communication skills (questions 29-43). For each item on the checklist, learners received 2 points if the task was done correctly, 1 point if the learner needed improvement, and 0 points if the task was not done at all. Passing scores were determined by a committee utilizing the Hofstee standard-setting method. At our institution, passing scores were 60% for content and 70% for communication.

The SPs received detailed written information on how to portray the history of present illness as well as the pertinent past medical, surgical, and social history of the patient. This occurred prior to the first on-site training. During the on-site training, a 3-hour group training session was conducted by SPEs to instruct the SPs on how to score student performance and how to provide feedback to the learner. An example video of a student obtaining informed consent from an SP was shown to the group of SPs in order for them to have the opportunity to practice scoring learner performance and to discuss scoring discrepancies within the group. Each time new SPs were trained for this case, their scoring of this video was reviewed to ensure reliability between SPs. A feedback roundtable discussion was facilitated by the SPEs, after which the SPs broke into pairs to practice giving feedback to each other, posing as learners.

SPs then independently studied the scoring checklist and points for feedback and returned for a practice interview with a fourth-year medical student. SP performance was then evaluated by an SPE with immediate feedback on role portrayal. The practice interview video was then reviewed by both SP and SPE to ensure accurate scoring of communication skills and appropriateness of feedback provided to learners.

SPEs held annual debriefing sessions with the SPs to review the students' comments. Based on these meetings, we made minor changes to the SP checklist for clarity of language; however, one of the more substantive changes occurred in SP training and clarification of scoring for learner feedback. Examples of possible acceptable student statements were provided to the SPs to help them complete these aspects of the communication checklist. These changes led to improvements in the reliability of the SP assessments.

Logistics

The sessions were performed in an SP room set to simulate an emergency department encounter. The SP was dressed in a hospital gown on the examination table, but no special examination equipment was required for the interaction.

This is a 50-minute case: 20 minutes for the interview with the SP and 30 minutes for self-evaluation and SP feedback.

The learners were provided with the medical fact sheet on lumbar puncture (Appendix D) prior to attending the session so they would be prepared to answer specific questions about the risks, benefits, and alternatives for this particular procedure. The content of the medical fact sheet was reviewed by experts in neurology.¹¹ Immediately prior to entering the room, learners were provided with a brief overview of the presenting patient (Appendix C). They were also provided with a standard institutional consent form, which was used to allow a point-by-point discussion and to obtain an SP signature for the proposed procedure.

The SP used an extensive checklist to evaluate learners on critical elements of obtaining informed consent, including appropriate content, and to evaluate for presence or absence of appropriate communication skills. The feedback session at the conclusion of the interview was guided by a list of 12 points for feedback, given to the SP alongside the scoring checklist. The points for feedback included questions about content (e.g., "What were you able to tell the patient about what the procedure entails?") as well as questions about communication (e.g., "How would you describe your tone compared to the patient's?").

This case is designed to be used as a formative assessment. The learner gains immediate feedback on his or her ability to engage a patient in the process of informed consent, as well as the opportunity to practice communicating the key components of a medical procedure to laypersons. This case is ideal for fourth-

year medical students and first-year residents, as these levels of learners should have some prior experience either observing or participating in the informed consent process.

Results

Overall, learners performed well on this task (see the Table). Performance over a 3-year period for 251 fourth-year medical students yielded a mean score of 93% for content and a mean score of 90% for communication skills. The case was also well received. First-year residents rated this case as appropriate for level of training, with 64% of new interns rating it as *just right* and none rating it as *too difficult for learning level*. The instructions for the station were rated as clear and easy to understand by the majority of trainees, with 93% rating the instructions somewhere between *just right* and *very comprehensive*. Similarly, the tasks of the station were felt to be manageable in the allotted amount of time. Ninety-seven percent of respondents rated time management between *just right* and *very manageable*. Comments for the case from first-year residents were overall very positive. Some learners would have liked more guidance about how much history to obtain before starting the informed consent process and would have liked more time to interpret the door instructions before entering the room.

Comments included the following:

- “Very helpful; perhaps give more time to read instructions/case at beginning.”
- “Useful station. I would have liked more time to read the instructions, to see all the alternatives that we were supposed to discuss since I felt pressured to go into the room quickly and start the scenario.”
- “Wasn’t sure how much history to take. Feedback was thorough and helpful. Specifics on what to say, i.e. describe procedure.”
- “Nice Station. A bit confused about how much history and physical examination to do. A bit short on time. Very helpful feedback.”
- “Wonderful standardized patient. Very helpful. Good intro to informed consent. It would have been helpful to have about 3-4 more minutes.”
- “There was some confusion about whether I had to obtain the entire history again versus focus on just obtaining consent.”

First-year residents felt that the SP provided helpful and instructional feedback. Comments on feedback were almost universally positive:

- “I got feedback regarding having patient repeat back what was going to be done as a sign of really comprehending. That’s good advice!”
- “No problems at all. Instructions are very easy to follow. Standardized patient instructor helped out with questions I had about informed consent. Excellent station.”
- “Standardized patient provided good/accurate/concise analysis.”
- “The standardized patient provided valuable feedback on how to make sure the patient understands the risks/benefits and incorporating all aspects of the patient’s health.”
- “Great feedback. I feel that I will be able to do a much better job with informed consent in the future.”

Feedback from learners indicated that door instructions were too vague and that there was not enough time to review them prior to entering the room for the encounter. Out of 445 surveyed learners, only 110 (35%) rated instructions as *very clear*. The interview time of 20 minutes was felt to be adequate for this discussion at this level of learner; however, based on evaluations we received, it would be helpful to devote more time to reading the door instructions, perhaps 10 minutes to prepare for the case outside the room in addition to 20 minutes with the SP in the room. It would also be helpful to clarify in the door instructions that it is not necessary to obtain the history from the patient as the learner can assume that this had been done prior to the current encounter.

Discussion

This case provides a unique opportunity for senior medical students and first-year residents to practice and develop the skill of obtaining informed consent, a process that is of crucial importance but that is often done poorly in clinical practice. The learners can be observed and evaluated in a consistent way, and the SP is able to provide immediate feedback. The detailed checklist of crucial elements of the informed consent discussion, as well as essential communication skills, provides an excellent format for objective evaluation. At our institution, learners performed well on this assessment, with a mean score of 93% for fourth-year medical students. This high score suggests that students have been exposed to the principles of informed consent during their medical school experience. For students with lower scores on this assessment, an opportunity is provided to intervene.

This case of informed consent for lumbar puncture is generalizable to a wide variety of learners. Since all physicians must be able to perform patient care interventions that require informed consent, the ability to do so is considered one of the Core EPAs expected of all medical school graduates making the transition to residency.⁶ Therefore, we see this as a valuable exercise to perform during specialty-specific fourth-year residency preparation courses (e.g., boot camps) or as part of graduate medical education (e.g., during intern orientation).⁹ The specific content of the SP checklist could be readily adapted to reflect indications, benefits, mechanics, risks, and alternatives for a variety of other specialty-specific procedures such as epidural placement, blood transfusion, central line placement, or excisional biopsy. As both undergraduate and graduate medical education evolve toward competency-based medical education, it will be important to be able to assess learners on specific competencies. This formative case provides an opportunity to provide specific formative feedback to learners on the important systems-based practice competency of obtaining informed consent.

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Ethical Approval

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