

Informed Consent – Exploring Instruction and Assessment Methodologies

Jim Powers, DO, Andrea Mann, DO, Brian Mann, PA-C
Campbell University School of Osteopathic Medicine, Buies Creek, NC

Introduction

Informed consent (IC) is a vital component of the doctor-patient relationship and is critical in maintaining patient autonomy and shared decision making. The ability to properly obtain informed consent is an essential skill involving a number of interpersonal, legal, ethical and emotional principles.

The importance of this skill has been recognized by both the American Osteopathic Association and the Association of American Medical Colleges as one of the Core Entrustable Professional Activities for entering residency (**Figure 1**). In terms of undergraduate medical education, there are very few published articles which suggest methods of IC instruction and assessment.

Objective

The key objective of this project is to share ideas and generate discussion regarding the use of different methods by which to teach and assess a student's ability to provide IC. Highlights of a literature search regarding IC education and assessment are presented.

Discussion

The majority of published studies evaluate and recommend the use of standardized patients (SPs) and OSCE formats to teach and assess IC. Some relevant findings in the literature include:

- OSCE format appears the most suitable to assess the multitude of combined learning objectives associated with the task of obtaining IC. ⁽⁵⁾
- The video recorded OSCE is a feasible and reliable method of assessing student communication skills and application of clinical knowledge while obtaining IC. ⁽⁵⁾
- SP feedback is an effective modality in teaching surgical residents IC protocol ⁽⁶⁾
- The utilization of SPs improved residents' self-assessment ratings of IC skills ⁽³⁾
- To acquire the necessary psychosocial skills to work effectively with patients in the IC process, trainees should be involved in simulated interactions and small group discussions, and they should receive constructive feedback on practice interviews. ⁽¹⁾

Assessment

Figure 1: EPA 11 from AAMC Core EPAs for Entering Residency

EPA 11: Obtain informed consent for tests and/or procedures	
Description of the activity	All physicians must be able to perform patient care interventions that require informed consent. From day 1, residents may be in a position to obtain informed consent for interventions, tests, or procedures they order or perform (e.g., immunizations, central lines, contrast and radiation exposures, blood transfusions). Of note, residents on day 1 should not be expected to obtain informed consent for procedures or tests for which they do not know the indications, contraindications, alternatives, risks, and benefits.
Functions	<ul style="list-style-type: none"> • Describes the indications, risks, benefits, alternatives, and potential complications of the procedure. • Communicates with the patient/family and ensures their understanding of the indications, risks, benefits, alternatives, and potential complications. • Creates a context that encourages the patient/family to ask questions. • Enlists interpretive services when necessary. • Documents the discussion and the informed consent appropriately in the health record. • Displays an appropriate balance of confidence with knowledge and skills that puts patients and families at ease. • Understands personal limitations and seeks help when needed.

Figure 2. Standardized Patient Checklist for Informed Consent

Standardized Patient Informed Consent Checklist					
Informed Consent Skills			Communication Skills		
	Yes	No		Yes	No
The student explained the nature of my illness			The student introduced him/herself and established a rapport		
The student explained the purpose of the procedure			The student verified my name and date of birth		
The student explained the what the performance of the procedure entails			The quality of the student's nonverbal communication was good		
The student discussed the benefits of the procedure			The student solicited my concerns, feelings and emotions and responded appropriately		
The student discussed the risks of the procedure			The student used easy to understand, non-medical terms and explanations		
The students discussed the alternatives to the procedure			The student demonstrated genuine empathy and concern		
Comments:			Comments:		

Figure 3: Clinical Skill Checklist Incorporating Informed Consent Assessment

Peripheral IV Placement		
	Omitted	Performed
PROFESSIONAL		
<i>Identify Self</i>		
• Introduces Self (Student Doctor, Last name)		
• Identifies title (Medical student, Campbell University)		
<i>Identify patient by two sources</i>		
• Name		
• Date of Birth		
<i>Inform patient of procedure</i>		
• Discusses Indications		
• Discusses Contraindications		
• Discusses Risks		
• Discusses Benefits		
• Discusses Alternatives		
• Asks patient if they have any questions		
• Obtains verbal consent		

Discussion

When utilizing the SP / OSCE format for informed consent, the evaluation should include both the specific components of the informed consent process (discussion of risks, benefits, alternatives, etc.) along with communication skills components. Well-designed checklists enhance the overall quality of the informed consent OSCE. An example of a simple checklist template that could be utilized is shown in **Figure 2**

As with all Core EPAs, the evaluation of student performance should not be based on single, but rather multiple assessment sessions, elements and methods. One possible method to assess student performance in obtaining IC is to incorporate the process into all clinical skills check-off or assessment activities. An example of including IC in an IV placement skills check-off is shown in **Figure 3**. This form of assessment may be especially effective because providing education in the professional, cognitive and ethical aspects of a procedure at the same time, and in the same format, as its technical skills training may be an effective means to improve awareness of and compliance with obtaining informed consent. ⁽⁴⁾

Additional opportunities for assessing student performance in providing IC could include:

- High fidelity simulation exercises and encounters
- OSCE "plus" format with team rounding and evaluation of SPs
- Direct observation of the provision of IC during clinical rotations
- Small group discussion and role playing exercises
- Standardized multiple choice or short answer testing

Conclusion

Informed consent within the doctor-patient relationship has legal, ethical, social and emotional ramifications for both patients and physicians. As with all EPAs, the ideal system of instruction for obtaining IC would provide students repeated opportunities to practice this skill with multiple, spaced formative assessments. While teaching and assessing IC through the use of SPs / OSCE experiences is supported in the literature, educators should explore additional instruction and evaluation tools to ensure student competency and entrustability.

References

1. Johnson, SM et al. Teaching the Process of Obtaining Informed Consent to Medical Students. Acad. Med. 67(1992): 598-600.
2. Roberts, LW et al. Assessing Medical Students' Competence in Obtaining Informed Consent. Am J Surg. (1999); 178:351-355.
3. Thompson, BM et al. Informed consent training improves surgery resident performance in simulated encounters with standardized patients. American Journal of Surgery (2015) 210: 578-584.
4. Steinemann, S et al. Marriage of professional and technical tasks: a strategy to improve obtaining informed consent. American Journal of Surgery (2006) 191: 696-700.
5. Kihl, C et al. Standardized and quality-assured video-recorded examination in undergraduate education: informed consent prior to surgery. Journal of Surgical Research (2014) 191: 64-73.
6. Leeper-Majors, K et al. The Effect of Standardized Patient Feedback in Teaching Surgical Residents Informed Consent: Results of a Pilot Study. Curr Surg (2003) 60:615-622.