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Assessing Medical Students' Competence in Obtaining Informed Consent

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BACKGROUND: Medical schools increasingly place emphasis on preparing students to perform routine, ethically important clinical activities with sensitivity and acumen. A method for evaluating students' skills in obtaining informed consent that was created at our institution is described.

METHODS: Formal assessment of medical students' professional attitudes, values, and ethics skills occurs in the context of three required and developmentally attuned comprehensive examinations. A videotaped station tested senior medical students' ability to obtain informed consent from a standardized patient who expresses concern about undergoing cardiac catheterization. Two checklists were completed by the patient. Videotapes were reviewed by a faculty member, and students' reactions to the assessment experience were documented.

RESULTS: Seventy-one senior students participated, and all performed well. Mean scores of 6.3 out of 7 (range 5 to 7, SD = 0.5) on the informed consent checklist and 8.7 out of 9 (range 6 to 9, SD = 0.5) on the communication skills checklist were obtained. Students endorsed the importance of the skills tested.

CONCLUSIONS: This method of examining medical students' abilities to obtain informed consent has several positive features and holds promise as an ethics competence assessment tool. *Am J Surg.* 1999;178:351-355. © 1999 by Excerpta Medica, Inc.

Helping future physicians to learn, value, and apply moral principles within the profession of medicine has long been viewed as a critical task of medical education.^{1,2} In recent years, medical school curricula have also placed increasing emphasis on preparing students to perform routine, ethically important clinical activities with

sensitivity and acumen.³⁻⁷ Such activities include obtaining informed consent or refusal for treatment, speaking with patients and families about end-of-life care, maintaining sound confidentiality and documentation practices, and establishing and preserving therapeutic boundaries within the physician-patient relationship.³⁻⁵ Medical students' knowledge and skill in ethics have thus become conceptualized as one core element of overall clinical competence, and for this reason, ethics knowledge and skill are increasingly seen as amenable to performance-based evaluation efforts in medical education.^{4,6,7} Nevertheless, formal assessment of students' clinical ethics abilities has received little attention in the medical literature especially with respect to key elements of surgical practice.^{1,3,4} Building upon earlier, more abstract approaches, this pragmatic framework has allowed for significant innovation in ethics teaching and assessment in medical school curricula.^{4,8,9} In this brief report, we describe a performance-based and contextual method for evaluating senior medical students' skills in obtaining informed consent for a catheterization procedure through a standardized patient interaction. The approach is distinct from other ethics Objective Structured Clinical Examination (OSCE) stations^{9,10} in that it focused on practical ethics skill in conjunction with specific and global communication assessments. It is also unique in its emphasis on informed consent for invasive diagnostic test.

METHODS

Curricular Context and the SPA Examination

Our institution has a history of trying new educational methods. For example, a community-oriented, problem-based curriculum ran in parallel with the traditional track from 1979 to 1994 and taught one third of students longitudinally through individual clinical supervision.¹¹ The New Curriculum, a tutorial-based curriculum, was adopted for the entire student body of roughly 300 in 1994. In this innovative curricular context, professional attitudes, values, and ethics are formally taught in a 3-year Perspectives in Medicine course. This seminar series features faculty-led, intensive, small-group discussions occurring every other week during the first two phases of medical school. Students are given responsibility for organizing their learning around seven ethics areas: professional responsibility, patients' rights, privacy and confidentiality, truth-telling, reproductive ethics, distributive justice, and research ethics. Clinical ethics teaching also occurs in supervision, teaching rounds, and didactic efforts throughout the 4 years of training.

Formal assessment of students with respect to professional attitudes, values, and ethics occurs in the context of three required, sequential, and developmentally attuned compre-

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hensive examinations (Student Progress Assessment, or SPA examinations) occurring over the 4 years of medical school.⁶ Each SPA examination is a 2 to 3 day performance test encompassing five competence areas—clinical skills, communication skills, critical reasoning and integration of knowledge, self-assessment, and professional attitudes, values, and ethics—and employing various methodologies, such as trigger videotapes, standardized patient interactions, responses to essay and modified essay questions, self-assessment exercises, and standardized multiple choice tests. Students are also assessed by faculty with respect to professional attitudes, values, and ethics in the Perspectives in Medicine seminar and in their day-to-day patient care and professional activities.

The Informed Consent Station

The informed consent station was one of six standardized patient interactions in the third SPA examination undergone by fourth-year students in the class of 1997. The station was videotaped for faculty review. The standardized patient case of Mrs. Josephine Lovato was written by a multidisciplinary team led by one of us (CV) based on a real patient's history. Mrs. Lovato was described as a 77-year-old bilingual Hispanic woman, a mother of five adult children and a homemaker whose husband had died 16 years previously. Mrs. Lovato was nicely dressed and was quiet, modest, and pleasant in demeanor. She presented as a new patient complaining of progressive intermittent chest and back pain. Mrs. Lovato was then diagnosed with coronary artery disease, hypertension, and degenerative joint disease. Her decisional capacity was assessed as fully intact. She was admitted to the internal medicine service for a cardiac catheterization scheduled for the next morning. The nurses caring for Mrs. Lovato on the inpatient unit noted that she was beginning to express doubts about the procedure and wanted to discuss "some concerns" with the doctors. Students were given the following task: "You have 25 minutes to address any concerns this patient has. Review the resident's note prior to talking with the patient. You do not need to take a history, perform a physical, or take any notes." The resident's note provided background medical and physical examination data indicating the clinical appropriateness of a cardiac catheterization and documenting that the patient had signed a consent form. The standardized patient was instructed to offer the following statement at the beginning of the interaction with the student, "I'm not sure I am ready for this thing (cardiac catheterization) that you are going to do."

Evaluative Measures

Student performance on the informed consent station was assessed through two measures. First, a 7-point informed consent checklist was completed by the standardized patient at the end of the interview. The checklist was developed by a multidisciplinary faculty and medical school consultant team with expertise in clinical ethics, medical humanities, psychometrics, quantitative and qualitative analysis, and standardized patient care in performance-based testing. It included items derived from the literature on informed consent.¹²⁻¹⁴ For example, information-oriented items included whether or not the student

had provided the patient with information about the nature of her illness and about the risks and benefits of the procedure. Consent-oriented items included whether or not the standardized patient felt comfortable asking questions about the procedure and whether or not she felt she had a choice about proceeding with the catheterization even though she had already signed the consent form. Second, as in all of the interview stations in the examination, a 12-point communication skills checklist was also completed by the standardized patient. This checklist was similarly devised and tested by the collaborative medical education/research team and placed emphasis on communication in the student clinician-patient interaction. It covered items such as whether the student had listened attentively, expressed empathy, used easily understood language, and had attempted to establish rapport. It also included three global items with a 5-point Likert scale (1 = strongly disagree, 5 = strongly agree), "I felt the student attempted to establish rapport," "Overall, I think this was an effective interview," and "I would return to this physician." The process of training standardized patients was intensive in terms of time and staff and faculty resources, and it focused on reliability and consistency in portraying the patient and checklisting the interaction.

In addition to these two measures determining students' evaluations, videotapes of the informed consent station were also reviewed by one of us (LWR) to allow for specific feedback to students regarding their performance and to faculty regarding the adequacy of the curricular preparation for this test. Students' perceptions of the overall SPA examination and its exercises were obtained through written evaluations that included both closed- and open-ended items.

Statistical Methods

Frequency data were compiled. Correlation coefficients were also calculated to compare the performance of students on the informed consent checklist with their performance on the communication skills checklist and with their overall performance on communication skills in other parts of the SPA examination. Comparisons were made on the basis of gender and ethnicity.

RESULTS

Seventy-one fourth-year students (46 women, 25 men; 63% white, 23% Hispanic, 3% Native American, and 3% Asian and "other") participated in the required examination.

Student Performance Measures

Frequency and correlation data for the standardized patient station are listed in the **Table**. Overall, students did well, with all meeting or exceeding the criteria set for passing the station. Out of a possible total score of 7 on the informed consent checklist, students' mean score was 6.3 (range 5 to 7, SD = 0.5). Out of a possible total score of 9 on the communication skills checklist, students' mean score was 8.7 (range 6 to 9, SD = 0.5). We found a small positive correlation between overall scores on these two checklists ($r = 0.28$, Pearson correlation coefficient). In addition, small to moderate positive correlations were found between informed consent checklist scores and the

TABLE

Students' Performance on Informed Consent and Communication Skills Checklists

Informed Consent Checklist*		Communication Skills Checklist*	
Checklist Item	Frequency of "Yes" Responses (n = 71) [†]	Checklist Item	Frequency of "Satisfactory" Responses (n = 71) [‡]
The student explained the nature of my illness to me.	69	Respectfully introduced him/herself to me as a medical student.	61
The student explained the risks of the procedure.	70	Demonstrated nonverbal behavior which was facilitative.	70
The student explained the benefits of the procedure.	69	Encouraged me to tell my own story.	71
The student explained alternatives to the procedure.	26	Listened attentively.	71
The student attempted to establish rapport with me.	71	Facilitated the expression of my feelings.	71
I felt comfortable asking questions regarding this procedure.	70	Expressed genuine empathy.	71
I felt like I had a choice about whether or not to have this procedure even though I already signed the consent form.	71	Avoided premature suggestions and solutions.	69
		Used easily understood language or explained technical terms.	65
		Maintained effective balance between open and closed-ended questions.	70
		Checklist Item	Mean Response (SD)[§]
		I felt the student attempted to establish rapport	3.2 (0.4)
		Overall, I felt this was an effective interview	3.0 (0.4)
		I would return to this physician [¶]	3.0 (0.4)

* As assessed by standardized patients; correlation between overall checklist scores: $r = 0.28$.

[†] Possible responses were "Yes" and "No"

[‡] Possible responses were "Satisfactory" and "Unsatisfactory"

[§] Possible responses were based on a scale of 1–5, with 1 = Strongly Disagree and 5 = Strongly Agree

^{||} Correlation between Informed Consent Checklist overall score and this item: $r = 0.38$.

[¶] Correlation between Informed Consent Checklist overall score and this item: $r = 0.45$.

specific communication skills checklist items "Overall, I felt this was an effective interview" ($r = 0.38$) and "I would return to this physician" ($r = 0.45$). There were no differences in performance on the informed consent checklist based on gender or ethnicity. Faculty review of the videotapes offered secondary confirmation that students varied in technique, sensitivity, and sophistication but that all possessed fundamental skill in obtaining informed consent in this test situation. For some students who had difficulty in their overall performance on the SPA examination, videotapes were used to help with the remediation process. In addition, information derived from this test was offered back to faculty, eg, clerkship directors, seminar leaders, clinical supervisors, to assist in their teaching efforts.

Evaluation of the Informed Consent Station and of the SPA Examination by Students

On a 5-point scale (1 = not important, 5 = very important), students ($n = 64$) were asked about the practical skills and knowledge tested in the informed consent station, giving a mean response of 3.8 (SD = 1.1). Similarly, when asked how well prepared they felt by their clerkships for the informed consent station (1 = not well prepared, 5 = very well prepared), the students' mean response was 3.0 (SD = 1.2). With respect to the overall SPA examination, when students were asked if the examination required them to integrate knowledge, skills, and abilities in

a manner consistent with what they had been asked to do in medical school (1 = strongly disagree, 5 = strongly agree), the mean response was 3.0 (SD = 1.2). On the same 5-point scale, when asked whether the level of complexity in the overall examination was appropriate, students' mean response was 3.5 (SD = 1.0). In addition, when asked whether SPA examined redundantly the materials and skills tested in other parts of the curriculum, students' mean response was 3.9 (SD = 1.1). No narrative comments, good or bad, were offered regarding the informed consent station. Students' written comments about SPA more globally reflected the stress they experienced in association with the intensely rigorous and recently implemented performance examination.

COMMENTS

Creating useful tools for assessing the ethical skills of physicians-in-training in performing clinical tasks is a key challenge within medical education.^{1,3,4,8–11,15} The development and implementation of this standardized patient station to evaluate medical students' ability to obtain informed consent for an invasive diagnostic procedure represents one of many efforts at our institution to address this challenge.⁶ We found that the 71 fourth-year students who underwent this test performed consistently well in terms of information, consent, and communication dimensions of the interaction as seen from the perspective of the stan-

dardized patients and a faculty reviewer. Interestingly, only the responsibility to explain alternatives to the procedure when obtaining informed consent ($n = 26$; 36.6%) posed problems for students. The standardized patients' willingness to return to the student for care and their impression of the overall effectiveness of the interview were positively correlated with performance on informed consent checklist criteria ($r = 0.45$ and $r = 0.38$, respectively.) Our data fit with the larger medical literature describing the intimate link between the strengths of the physician-patient relationship and the quality of informed consent processes.¹²⁻¹⁴ However, these findings also support the conclusion that the ethics skill of obtaining informed consent is not reducible to communication abilities alone.

Positive features of this approach to assessing students' abilities to perform informed consent for an invasive diagnostic procedure are several. First, it allows for direct and immediate evaluation of student behavior in performing an ethically important task by trained patients. Second, videotaping the station allows for formal review by a faculty member to confirm perceptions of standardized patients regarding student competence. It also creates a tool for student self-assessment and for the process of remediation. Third, the station is perceived as more "real" and more comprehensive in assessing ethics knowledge and skill than a paper-and-pencil test or performance in a seminar. The students appeared to receive this station well, affirming its contextual approach¹⁶; moreover, they endorsed the importance of the skill of obtaining informed consent. Fourth, this method allows for greater uniformity in ethics skill assessment than that occurring in clinical situations. Fifth, the station may be used alone or in concert with testing performed at our own and at other medical schools in providing meaningful evaluative feedback to medical students. Sixth, as noted by Bordage,¹⁷ "assessment drives learning." Positioning an ethically important task in the midst of the expected clinical and communications assessment stations affirms the value faculty place on professional ethics in medical student education. Finally, it provides data, both numeric and qualitative, for discussion by faculty who teach ethics-related material and clinical skills. Drawbacks to this approach, however, include the salient question of whether students behave similarly in actual patient-care situations, the resource-intensive nature of the examination, and the significant stresses experienced by trainees in such extensive performance-based testing. Moreover, we agree with Singer et al.¹⁰ that OSCE-like performance examinations should not be used as a single definitive measure of ethics skill—rather, it really will be interpreted in the context of several kinds of measures, as we have described elsewhere.⁶ In conclusion, this method of examining medical students' abilities to obtain informed consent from standardized patients for an invasive diagnostic procedure holds promise as a competence-based ethics assessment tool in medical education.

EDITORIAL COMMENT

"All knowledge attains its ethical value and its human significance only by the humane sense in which it is employed. Duly a good man can be a great physician."

Herman Nothnagel (1841-1905)

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In these days when "informed consent" is often used as a first line of defense against possible medical liability claims under the guise of "risk management" or "practice enhancement," it is refreshing to see that emphasis is once more being given to teaching and evaluating attitudes,