Assessing the Informed Consent Skills of Emergency Medicine Resident Physicians

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ABSTRACT

Background: Informed consent (IC) is an essential component of shared medical decision making between patients and providers in emergency medicine (EM). The basic components required for adequate consent are well described, yet little is published investigating whether EM residents demonstrate adequate IC skills.

Objective: The objectives were to assess the ability of EM residents to obtain IC for an invasive emergency procedure using a novel assessment tool and to assess reliability and validity of the tool.

Methods: This was an observational study in which participants were initially blinded to the primary objectives of the study. Each participant conducted a video-recorded history and physical examination with a standardized patient, requiring tube thoracostomy due to spontaneous pneumothorax. Two faculty EM physicians independently reviewed the videos and evaluated the participants' IC skills. First, they gave an overall impression of whether IC was obtained; they then evaluated the participants using a 30-point scoring tool based on the five elements of IC (decision-making capacity, disclosure, voluntariness, understanding, and physician recommendation). Upon all participants' case completion, we revealed the primary objectives and gave participants the option to withdraw from the study. Descriptive statistics and kappa coefficient were generated from the data collected.

Results: Twenty-two residents completed the study. None withdrew from the study after the primary objectives were revealed. Twenty residents (91%) obtained adequate IC based on both reviewers' overall impression. One disagreement occurred between reviewers ($\kappa = 0.64$). The mean IC score on a 30-point scale was 18.5 ± 0.5 .

Conclusions: In a simulated setting, most EM residents at this training program possess the knowledge and skills necessary to obtain IC prior to an invasive procedure. The assessment tool appears reliable and demonstrates construct validity.

Physicians have an ethical duty and a legal requirement to obtain informed consent (IC) from the patient before beginning an invasive procedure, but IC can be inadequate. Prior research has shown that most patients do not read the consent form before signing, have unrealistic expectations about long-term benefits of procedures, and are unaware of potential risks.^{1,2} Clinical IC studies are often small; challenging

to randomize, validate, and quantify; and may pose ethical and legal issues; and participant awareness of study goals may falsely improve performance.³ Simulation-based studies can minimize some of these issues.

Little simulation-based IC research has been published, especially regarding consent for emergency procedures.⁴⁻⁸ Carotid endarterectomy IC skills among vascular surgery physicians in Britain were assessed

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using an unpublished rating scale and overall standardized patient (SP) impressions; investigators found poorer IC scores among residents compared to attending physicians.⁹ In 2016, investigators used SPs to assess medical students' lumbar puncture skills, specifically, procedural knowledge, communication, and some IC skills. Fourth-year medical students scored 93% on average on this instrument.¹⁰ To date, no validated instruments have been published for assessing IC performance among emergency medicine (EM) physicians, and none assess all the elements of quality IC. In a review of IC specific to EM, Moskop¹¹ describes five essential elements of IC:

- Capacity of the patient to provide consent;
- Disclosure of the proposed intervention and its associated risks and benefits;
- Comprehension of this disclosure by the patient;
- Voluntariness of consent given by the patient;
- Patient's stated agreement with physician's clear recommendation.

As emergency departments' (EDs') censuses, crowding, and case complexity grow, time constraints prevent emergency physicians from having discussions allowing perfect IC. Different levels of IC may be required for different levels of risk or complexity in decision making.¹² The goal of this study was to assess EM residents' ability to obtain clinically adequate IC for an invasive procedure and to define residents' performance in all elements of IC, using a video-recorded SP encounter.

METHODS

Study Design

This cross-sectional observational study of EM residents' IC skills used assessment by a SP and EM faculty during video review of a simulated scenario involving a patient with a spontaneous pneumothorax.

Study Setting and Population

All EM resident physicians in a 3-year training program at an academic ED in an urban tertiary facility were invited to participate in a study at our simulation center, initially described as an investigation of core-content knowledge retention. Residents aware of the study's true aims were excluded. Initially, the primary objective (assessment of IC skills) was omitted from the study description. Upon study completion, the

primary objective was revealed, and participants could opt out. The project, including the lack of initial study aim disclosure, was approved by our institutional review board.

Study Protocol

The simulation facilitator, an EM faculty member, introduced the case and disclosed that participants would be video-recorded and evaluated on all six ACGME core competencies. Each participant interviewed and examined the SP, an investigator experienced in critical care nursing, and simulation. The facilitating investigator acted as technician, nurse, and/or faculty physician. If the participant did not spontaneously discuss tube thoracostomy with the patient, the simulated faculty physician recommended it. Tube thoracostomy was performed on a part-task trainer (Blue Phantom).

Key Outcome Measures

Each participant was evaluated by four investigators. The SP and simulation facilitator each completed an overall assessment of performance using a 100-mm visual analog scale (VAS). Video recordings were evaluated independently by two EM faculty members with training and expertise in medical ethics (herein called "reviewers"). The reviewers used a standardized evaluation form (Data Supplement S1, available as supporting information in the online version of record of this paper, which is available at <http://onlinelibrary.wiley.com/doi/10.1002/aet2.10037/full>). developed based on five essential elements of IC.¹¹ This evaluation form includes an overall dichotomous performance assessment and a 30-point composite score. The investigators developed it using a modified Delphi method, considering potential participant actions and resulting scores in multiple iterations of the tool. A pilot video was also scored and discussed to refine scoring. We weighted each item, representing the five elements of IC equivalently in the total composite score. For all metrics, a higher score is better.

Data Analysis

Descriptive statistics were generated from the data collected. Continuous variables were summarized by means and standard errors, as well as medians and interquartile ranges. For continuous variables, Pearson correlation coefficients are presented. For continuous outcomes, inter-rater reliability used Lin's concordance correlation coefficient and interclass correlation coefficient, while inter-rater agreement for categorical

outcomes was measured using the kappa coefficient, as well as Gwet's AC1 statistic. For measuring relationships between continuous variable scores assigned by different pairs of raters, the correlation of mean scores was reported. Statistical analyses were performed using SAS v9.1.

RESULTS

Recruitment

Of 27 eligible residents, 22 (81%) completed the study. One resident, an investigator, was excluded. One resident declined recording and was excluded. One resident completed the study but was excluded because technical difficulties with recording. Two residents declined our invitation to participate in the study. No residents withdrew. Table 1 summarizes the results of the three component scores, described below.

VAS

The mean VAS score was 80.9 (0–100 mm). The median score of 91.5 indicates a strong skew toward higher scores. The SP and simulation facilitator's mean VAS scores were not significantly different; Lin's concordance correlation coefficient was 0.67 ± 0.12 , indicating moderate-to-high degree of correlation between the two raters.

Elements of IC

The mean composite score was 18.5 ± 0.5 of 30 possible points, with median scores again skewing higher. Mean composite scores for each reviewer were 19.3/30 and 17.8/30 ($p = 0.02$). Despite this difference, correlation of scores for any individual performance remained moderate-to-high with Lin's concordance

correlation coefficient 0.55 ± 0.14 . The intraclass correlation was 0.60.

Overall Impression

Both reviewers agreed that 20 of 22 subjects (91%) obtained adequate IC whereas one of 22 did not (inter-rater agreement: kappa coefficient 0.64, Gwet's AC1 coefficient 0.95). There was disagreement among reviewers for one of the 22 subjects.

Correlations Between Scores

The mean VAS scores and mean IC composite scores for each resident showed strong correlation. The Pearson correlation ρ for the relationship was approximately 0.71 (p -value of 0.0002), with an $r^2 = 0.51$.

DISCUSSION

In a simulated setting, most EM resident physicians at our institution obtained adequate IC prior to a simulated invasive procedure as assessed by four independent investigators, with good correlation of those scores. The IC assessment tool provides a breakdown of the subjective overall IC assessment into objective assessments for each of the five IC elements. Our residents performed quite well on the elements of disclosure, clear recommendations, and voluntariness, but performed poorly on their evaluation of the patient's capacity and understanding. Only one resident asked the patient to repeat information back, and the highest-scoring residents for the understanding element earned only half the possible points. Analysis of performance on these elements allows educators to give more specific, nuanced, meaningful feedback.

The assessment tool developed here (Data Supplement S1) also shows reasonable construct validity, providing a framework for quantitative assessments in

Table 1
Summary of EM Resident IC Scores

IC Score (of Maximum Possible)	Rater	Mean	Median (IQR)	Range
Global assessment score by SP and simulation facilitator: VAS (of 100 m)	Overall	80.9 $\pm$ 3.6	91.5 (70–100)	16–100
	SP	79.6 $\pm$ 5.9	96 (67–100)	21–100
	Sim Fac	82.1 $\pm$ 4.5	91 (75–95)	16–100
Elements of IC composite score (of 30)	Overall	18.5 $\pm$ 0.5	19.5 (16.5–21)	8.5–23.5
	Reviewer 1	19.3 $\pm$ 0.7	20.75 (16.5–21.5)	9–23.5
	Reviewer 2	17.8 $\pm$ 0.6	18.25 (16.5–20)	8.5–21.5
Overall impression by expert video review:(0 = inadequate, 1 = adequate)	Overall	0.93 $\pm$ 0.04		
	Reviewer 1	0.95 $\pm$ 0.05		
	Reviewer 2	0.91 $\pm$ 0.06		

IC = informed consent; IQR = interquartile range; SP = standardized patient; VAS = visual analog scale.

future IC studies. The tool incorporates five elements of IC, with equal weight given to each element. Composite IC scores strongly correlated with VAS scores and with the reviewers' overall dichotomous assessment of IC. The tool identified inadequate IC when composite scores were below 10, and almost always identified adequate IC when the composite score was greater than 14. However, scores for one resident were not consistent with these cutoffs. This resident may have performed so poorly in one element of IC, such that despite good scores in other areas, one reviewer did not think the overall performance was sufficient. Different clinical scenarios may require different completeness of IC; thus, the cutoff on the assessment tool for adequate IC may vary with new scenarios or procedures.

LIMITATIONS

Because this was a small single-center simulation-based study, results may not be generalizable to other training or clinical environments. Our evaluation instrument was not prospectively validated, although it was developed based on published critical elements of IC in EM. Although residents were unaware that their IC skills were being assessed, they were aware that they were being observed and recorded, which may have improved overall performance.

Further investigations could involve participants from multiple centers and with different training backgrounds or IC studies done in the clinical environment. Our study did not show trends toward differentiated performance based on years of training, but was underpowered to assess such differences.

CONCLUSIONS

In a simulated setting, most emergency medicine residents from our institution possess the knowledge and skills necessary to obtain adequate informed consent prior to an invasive procedure. This study piloted the use of a novel assessment tool for informed consent in emergency medicine procedures, and the tool demonstrated construct validity and good reliability. Although this study focused on tube thoracostomy, the informed consent assessment tool is quite adaptable to use with other procedures, as its structure and score weighting is based on the components of informed consent, not the procedure.

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Supporting Information

The following supporting information is available in the online version of this paper available at <http://onlinelibrary.wiley.com/doi/10.1002/aet2.10037/full>

Data Supplement S1. Elements of informed consent composite score evaluation form.