A Novel Blended Curriculum for Communication of Informed Consent With Surgical Interns

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ABSTRACT

Background Interns often conduct procedural informed consent discussions (ICDs), identified as a core entrustable professional activity. Deficiencies in the training process for ICDs span across specialties.

Objective We provide evidence for a curriculum and assessment designed to standardize the training process and ensure ICD competency in surgical interns.

Methods In March 2019, PowerPoint educational materials were emailed to one academic institution's new surgical interns, who in June participated in an onsite 1-hour role-play "hot seat" group activity (GA) with an untrained *simulated patient*, and in October completed a single trained simulated patient (real-time raters) verification of proficiency (VOP) assessment. Curriculum evaluation was measured through intern pre-/post-confidence (5-point scale), and the VOP's Cronbach's alpha and test-retest were examined. Data were analyzed with descriptive statistics, paired *t* tests, and 2-way random effects models.

Results Of 44 new interns, 40 (91%) participated in the remote teaching and live GA and were assessed by the VOP. Pre-/post-GA confidence increased a mean difference of 1.3 (SD = 0.63, $P < .001$). The VOP's Cronbach's alpha was 0.88 and test-retest was 0.84 (95% CI 0.67–0.93, $P < .001$), with a 95% pass rate. The 2 first-time fail students required remediation. Time commitment included 1 hour maximum for individual training and implementation and 30 minutes for assessment. The use of volunteers and donated space mitigated additional costs.

Conclusions Remote asynchronous and group skills teaching for new general surgical interns improved their confidence in conducting procedural ICDs. A patient-simulation verification process appeared feasible with preliminary evidence of retest and internal consistency.

Introduction

The process of obtaining informed consent—in which the patient (or surrogate decision-maker) is made aware of the nature of the procedure, expected benefits, potential adverse effects, alternatives, and consequences of not proceeding with the treatment in question—is critical to medical practice. During the process, case- and patient-specific factors are taken into account with a goal of maintaining patient autonomy.[1] Performing informed consent discussions (ICDs) has also been described as a core entrustable professional activity (EPA) "that all medical students should be able to [do] upon entering residency, regardless of their future career specialty" by the Association of American Medical Colleges (AAMC).[2] However, deficiencies in the training process for ICDs span across specialties.[3]

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Editor's Note: The online version of this article contains the informed consent discussion educational materials, procedure-specific cognitive aids, a visual of the frequency distribution of reported confidence levels, and a breakdown of scores for all recordings.

Many graduating students report no formal training or clinical experience with performing an ICD.[4] Published ICD training programs have used a combination of case studies, informal observations, videos, narrated lectures, quizzing, and role-play with some associated with demonstration of skills through objective structured clinical examination (OSCE) style scenarios.[4–10] Extensive research in health professions education supports the use of simulation and its benefit of "lab to life" transference.[11] As a surrogate for patient interactions, standardized patients are often used, and learners voice preference for this education technique.[12–14] However, significant time, personnel, and cost investment may limit curricula that use standardized patients.[15]

We developed a curriculum and assessment process for new surgical interns to standardize the training process and ensure satisfactory communication and cultural competency for ICDs. We hypothesized that a blend of remote asynchronous and in-person skills session would be feasible, and we developed preliminary evidence to support a patient verification process for ICD skills.

Methods

Setting and Participants

In April 2019, new interns who matched into specialties forming the general surgery intern pool at a large urban academic medical center were emailed educational materials to be completed prior to starting. The materials included ICD information. In June, interns voluntarily participated in an in-person 2-day skills bootcamp that included a group facilitated practice (GFP) session on ICDs. In October a verification of proficiency (VOP) assessment was conducted.

Objectives
Develop a curriculum and assessment program with the intent to standardize the training process for informed consent discussions.

Findings
A training program that improves intern confidence and is able to identify marginal performers is feasible with minimal resources.

Limitations
This was a single institution study that did not have a comparative group.

Bottom Line
Multimodal educational interventions are feasible and possess validity evidence to support their use.

Intervention

The multimodal ICD curriculum consisted of 2 phases:

1. *Remote learning:* Written materials on ICDs were developed by the authors after a review of literature on best practices and discussion with experts in ethics. The slides were electronically distributed to the interns via a PowerPoint presentation through email (provided as online supplementary data).
2. *GFP session:* The authors created a 60-minute session with guided discussion of the remote PowerPoint materials, clinical observations and experiences, and several hypothetical ethical scenarios.[10] This included a round-robin "hot seat" activity that used elements of rapid-cycle deliberate practice with role play in which an intern volunteer or cofacilitator played the role of the patient. Individual hot seat moments were limited to 1 to 2 minutes, which allowed for frequent debriefing, questions, and opportunities to "retry" challenging areas or use different communication techniques. Two sessions were conducted with 20 interns and 1 to 2 facilitators per group.

Outcomes

Demographic information was obtained from all participants, including sex, matched specialty, prior formal ICD training, and previous clinical experience conducting an ICD. Interns completed a 15-item, Likert-type survey (scale 1–5) with validity evidence in prior studies, in areas of content and response process for use with students and residents for the purposes of studying the need for a formal ICD curriculum in the medical education system.[4] The survey assessed pre-GFP and post-GFP skill confidence and post-GFP perceived value of the materials and group session. The survey was not tested. After the VOP session in October, interns completed a single item survey that asked if the GFP ICD session in June was helpful to their current clinical practice (Yes/No).

Performance assessments were conducted as OSCEs. A simulated environment was selected for logistical purposes that allowed for efficient testing of all interns in a structured HIPAA-compliant environment and timely provision of targeted constructive feedback.

The interns were given patient- and procedure-specific cognitive aids in preparation for 2 potential scenarios: laparoscopic appendectomy (LA) for uncomplicated acute appendicitis or central venous catheter (CVC) insertion in an incapacitated patient needing central access for medication (provided as online supplementary data). These 2 scenarios were selected because they are the most common procedures that surgical interns encounter. On assessment day, the interns were randomly assigned to perform only one scenario to reduce intern and facilitator time requirements. Thirty minutes were given for the activity: 5 minutes to prepare, 20 minutes to perform, and 5 minutes to debrief with the simulated patient rater.

Trained, non–medical education team members acted as the patient and rater. Assessments occurred in 2 large conference rooms, with each divided in half. All encounters were audio-recorded (Voice Record 2019, BejBej Apps, Coquitlam, Canada). Remediation, consisting of review of self-audio performance and one-on-one role-playing activities with the education fellows, was required for performance scores less than 31 out of 50.

The VOP assessment was designed to reflect ICD best practices, including key elements and cultural competencies as recommended by the AAMC.[2] The authors modified a cognitive aid that was developed previously for patient assessment of clinician communications to use as an assessment rubric for the VOP.[16] Ten skills considered important to ICDs were assessed on a 5-point global rating scoring system

(Poor, Fair, Good, Very Good, Excellent), with a maximum potential sum score of 50 points (provided as online supplementary data).[2,10,16,17] Through faculty consensus, a cut score of 31 was chosen as a "pass" score.

Three trained raters with varied professional backgrounds (1 undergraduate student, 1 postgraduate research assistant, and 1 administrative associate from the simulation center) were volunteer recruits to act as the patients. Training occurred in a group setting and included a discussion of relevant anatomy and procedural technique and role-play of scenarios; this required approximately 1 hour for all raters to feel comfortable with the material for each scenario. One rater (R.S.) participated in both LA and CVC scenarios and reevaluated the recorded performances 6 months later to examine test-retest reliability. To examine remote assessment, 3 additional blinded trained raters (A.K., E.G., T.A) independently rated all audio recording performances that were of complete quality (24 total).

Analysis

Descriptive statistics, paired *t* test, and Pearson's correlation, where appropriate for parametric and nonparametric data, were used for all quantitative data. Psychometric analysis of the VOP (internal consistency [Cronbach's alpha], item difficulty and discrimination, test-retest, and ICC) were examined. The ICC, test-retest estimates, and 95% CI were calculated based on a mean rating (k = 3), absolute agreement, and 2-way random effects model between the on-site and audio-only raters. Significance was determined at $P = .05$. Analyses were performed using RStudio 1.2.1335 software (RStudio, Boston, MA).

This study was approved as an exempt study by the Stanford University Institutional Review Board.

Results

Demographics and Confidence

Forty of 44 eligible interns (91% response rate) participated in the GFP session and completed post-session surveys. Pre-/post-session surveys were available for 34 (77%) eligible participants, assessing demographic characteristics and confidence matched analysis (TABLE 1). Pre-/post-session confidence demonstrated a significant increase, from mean = 3 (standard SD = 1) to mean = 4 (SD = 1, $P < .001$) on the 1 to 5 Likert-type scale. (FIGURE provided as online supplementary data).

All 40 post-GFP session surveys were reviewed for attitudes toward the utility of the deliberate practice session. The majority of interns agreed that the GFP session was useful (median = 5, IQR = 1), 36 (90%) interns "somewhat agreed" or "agreed" with the statement, and the remaining 4 (10%) were neutral. Thirty-one (78%) post-VOP (4 months after GFP) surveys were completed, with 29 (94%) responses attesting to the clinical usefulness of the GFP session.

TABLE 1
Demographic Characteristics[a]

Characteristics	Participants, n (%)
Sex	
Male	18 (52.9)
Female	16 (46.1)
Specialties	
Anesthesia	2 (5.9)
General surgery	11 (32.4)
Integrated cardiothoracic surgery	2 (5.9)
Integrated plastic surgery	3 (8.8)
Integrated urology	3 (8.8)
Integrated vascular surgery	2 (5.9)
Interventional radiology	2 (5.9)
Ophthalmology	2 (5.9)
Otorhinolaryngology	4 (11.8)
Undesignated preliminary	3 (8.8)
Prior formal informed consent discussion (ICD) training	
Yes	11 (32.4)
No	23 (67.7)
Previous experience conducting an ICD	
Yes	3 (8.8)
No	31 (91.2)

[a] N = 34.

Forty (91%) of the eligible interns participated in the VOP (23 [57%] CVC and 17 [43%] LA). Performance between the 2 scenarios differed significantly: mean = 39.6 (SD = 6.2, range 30–50) and mean = 46.9 (SD = 4.3; range 33–50; $P < .001$) for CVC and LA, respectively. Two (5%) of the tested interns did not pass and required 45 minutes of remediation, which included analytic review of performance with one of the surgical education fellows. "Check for patient understanding through 'teach back'" (mean = 3.9, SD = 1.4) was marked lowest for both scenarios; "Prepared in advance about the patient's medical record including pertinent labs, imaging, cultural background, personal, and social history" (mean = 4.8, SD = 0.5) was marked highest for both.

Validity and Internal Structure of VOP Assessment

Twenty-four (60%) audio recordings were reviewed by the 3 audio-only raters. ICC for audio-only raters was 0.58 (95% CI 0.36–0.75; F(23,46) = 6.8; $P < .001$). ICC for audio raters and on-site raters was

TABLE 2
Verification of Proficiency Rubric

Tasks	Item Difficulty[a]	Item Discrimination[b]
1. Prepared in advance about the patient's medical record including pertinent labs, imaging, cultural background, and personal and social history.	4.75	0.49
2. Introduces themselves and their role in the patient's care.	4.15	0.50
3. Clearly explains the patient's current health problem as it relates to the proposed procedure.	4.7	0.64
4. Clearly describes the benefits of the proposed procedure.	4.15	0.59
5. Clearly describes the risks of the proposed procedure.	4.1	0.74
6. Clearly describes alternatives to the proposed procedure. Also, explaining that there is the option to not undergo procedure.	4.08	0.79
7. Describes what to expect following the procedure (eg, amount and duration of pain, length of recuperation, limitations on activities of daily living, quality of life).	4.05	0.78
8. Elicits questions and concerns.	4.35	0.78
9. Check for patient understanding through "teach back."	3.87	0.84
10. Review the written consent form with the patient.	4.74	0.46

[a] Item difficulty is a measure of individual test question difficulty as calculated by the average score obtained by examinees.
[b] Item discrimination is the capacity of the item to distinguish low- or high-performing examinees. A higher number has a greater ability to distinguish examinees.

0.54 (95% CI 0.28–0.73; $F(23,69) = 45.7$; $P < .001$). The test-retest coefficient was 0.84 (95% CI 0.67–0.93). Mean scores from audio-only raters were 34.8 ($SD = 5.2$), significantly lower than on-site scores. The correlation between each score for the 2 groups was 0.78 (95% CI 0.60–0.88, $P < .001$). See online supplementary data for a breakdown of scores for all recordings. See TABLE 2 for all item discrimination and TABLE 3 for internal consistency (Cronbach's α) for on-site and audio-only assessment.

Overall Feasibility

Individual learner driven review of content was estimated to take approximately 30 minutes to 1 hour. GFP required no additional props. Training to effectively facilitate a session required 30 minutes, and each session required less than 10 minutes for preparation. Approximately 1 hour per scenario was used to train the simulated patient. As the raters were members of the core education team, no additional cost was incurred for the training process. The 2 large conference rooms were within our dedicated simulation space and did not incur additional costs. Ten hours (including time to analyze results) split over 2 days were required to test 40 interns. The recording application was a free program.

A debrief was held and all educators involved with the curriculum expressed that this program was manageable and did not place undue burden on the team given the number of interns who underwent training and assessment.

TABLE 3
Internal Consistency (Cronbach's α) of 2 Scenarios Using 10 Items on the Verification of Proficiency Rubric

Case Scenario	On-Site (0.88)	Audio-Only (0.72)
Central venous catheter insertion	0.80	0.74
Laparoscopic appendectomy	0.88	0.64

Discussion

This study identified deficits in the experience and self-confidence of entering surgical interns' ability to properly conduct an ICD. With training, the confidence of the interns increased, and they found value in the overall process. By using remote learning, large group sessions, and simulated patients, a relatively small team was able to successfully implement this rigorously developed curriculum and assessment without undue burden.

This study of a low-cost combined distance and on-site ICD skills training approach, with a novel verification process for early surgical trainees, builds on prior work using simulation or role-play in ICD training. Some studies focus more on communication skills such as "compassionate behavior.[8,18–22] Similar to our results, most simulation programs find that training with immediate feedback may sensitize the learner to desired behaviors and also identify areas for curriculum improvement within residency programs.[8,19,20–22]

Assessment using *standardized* patients have been reportedly used for assessment of residents; however, this verification of proficiency appears to be the first

successfully conducted with *simulated* patients and, as reported, was a more cost-effective alternative.[4,7] While the concept of this approach is not new, it does provide a feasible model with content, response process, internal structure, and consequential validity evidence.

As a single institution pilot study, generalizability may be limited. There was also a 4-month interval between the training session and verification of proficiency, thus, without a control group, satisfactory skills performance may have been related to learning during internship rather than the educational intervention. As there was no comparison group, it is unclear what the exact impact of the educational intervention was, compared to clinical acquisition. At this time, we have focused on multiple intern surgical specialties; however, many of the skills emphasized within this program are likely useable for health care providers of all areas and experience levels.

Future endeavors may examine performance with interns receiving remote PowerPoint presentations alone, compared to those who only participated in group role-play, compared to those who received no specific training. It would also be beneficial for interns to undergo assessment of multiple procedures for a more holistic evaluation of proficiency.

Conclusions

A combination of remote asynchronous and group skills teaching for new general surgery interns improved their confidence in conducting procedural ICDs, with little resource and time requirement. A patient-simulation verification process appeared feasible with preliminary evidence of retest and internal consistency.

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