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Trainee Decision Making Concordance in the Pediatric Emergency Department: A Surrogate Marker of Learning?

A. Study Purpose and Rationale

Medical students and residents rotating in clinical settings need to be assessed on their abilities. This assessment is often based on the Accreditation Council for Graduate Medical Education (ACGME) core competencies: medical knowledge, patient care, professionalism, communication and interpersonal skills, practice-based learning and improvement, and systems based practice.(1) However, developing valid and reliable measures of these diverse competencies continues to be a challenge. Existing forms of assessment for medical students include written examinations (open-ended vs. multiple choice), assessment by a supervising physician, direct observation or video review, and clinical simulation.(2) These assessment tools are generally either formative, which help guide learning during the rotation by giving timely feedback and encouraging reflection and reinforcement, or summative, which make an overall evaluation of performance or competence at the end of a stage of learning (i.e. clinical rotations, board exams). There is no one assessment that measures all of the competencies; and even for the individual competencies, there continues to be discussion and research to determine the ideal measure.(25)

Evaluation of clinical reasoning and problem solving skills is often done by multiple choice questions (MCQ) and/or assessment by a supervising physician.(3) Although MCQ have been shown to be reliable and are not influenced by subjective inputs(6), there remains some question whether performance on these in vitro scenarios reflects performance in the actual patient care setting.(2) Assessment by a supervising physician can be done in the clinical setting, but the evaluation may be affected by bias and variable expectations of evaluators, and specific patient encounter variability. The retrospective nature of these assessments (i.e., typically a summative assessment done at the end of a rotation), may further bias the evaluation. Each trainee must have numerous assessments to be combined for a reliable evaluation to overcome some of these biases(3), and this is often difficult to do in the busy emergency room setting.

Experienced clinicians organize their knowledge into "illness scripts" that are retrievable when relevant clinical presentations are encountered.(7) These scripts expand from the classic presentation to include variations thorough the experience of many patient encounters. Experts may vary in the exact scripts based on their individual experience, but the key elements of these scripts are similar. Thus, two experienced clinicians will usually reach the same decision on key aspects of patient care despite variability of individual encounters, though some degree of practice variability still exists.

Learners may have the knowledge about different diseases, but not the experience to know how to access that knowledge or to apply it to the patient they are seeing. As their clinical experience grows, learners are able to develop their own illness scripts, which they then use to assess the information they are presented in a patient interaction: identifying key features, comparing and

contrasting hypothesis, and eventually prioritizing diagnoses.(7) It is our hypothesis that the level of concordance of learners' decisions with those of expert clinicians is a valid indicator (measure) of the learners' clinical reasoning ability; or more precisely, of their acquisition and organization of information into accessible and applicable knowledge.

We propose a new method for assessment of clinical reasoning during actual trainee-patient interactions. This assessment method directly compares learners' clinical decisions to those of experienced clinicians for the same patients. Examples of clinical decisions can be as broad as whether or not to admit a patient, or as specific as whether to draw a blood culture in a patient whose temperature is 102.6F. These decisions are the essence of being a clinician in an Emergency Department.(8) The ED is known to be a decision dense environment made even more difficult by relatively poor access to information and limited time to process what information is given.(8) The ability of the learner to make these decisions is influenced by their ability to identify and their knowledge about the disease process, and how easily this information is accessible.

In addition to using this form as a tool for assessment, there is also potential to use the form as a teaching intervention. Models for teaching, including the microskills(9) and the SNAPPS(10) models, encourage the learner to present a case concisely, and then commit to a decision (ie a diagnosis or care plan). Neher et el proposed that by requiring the learner to commit to a diagnosis or care plan prior to intervention by the attending, the learner experiences an increased responsibility and investment in the management for the patient.(9) By committing to a decision option, the learner is less susceptible to confirmation bias and better able to contrast his or her own thinking to that of the expert. We hypothesize that by using our form to ensure commitment of the learners to their diagnosis and plan, they will have an improved overall learning experience, and they will therefore have a better progression of concordance with attending in decision making than students in the traditional precepting model.

Hypotheses

Hypothesis #1
As trainees see cases in a clinical setting, they learn to function as physicians by comparing and contrasting their diagnostic and therapeutic formulations with those of experts. We hypothesize that with more experience, there is an increase in concordance with attending decisions in the pediatric emergency department.

Specific Aim #1
To compare concordance of attending decisions to those of medical students and pediatric residents in the pediatric emergency department.

Relevance
If we find an increase in concordance with more experience in the emergency department, this can be used as an assessment tool for evaluation of performance.

Hypothesis #2

We hypothesize that this learning will be manifested by incremental improvements in the observed concordance between the learners' and the experts' decisions.

Specific aim #2
To describe the change in trainee clinical decision concordance with attending decisions through the course of a rotation in the pediatric emergency room.

Relevance
If we find that concordance of trainee to attending decision detectably improves with case experience, this will further support that this assessment is a valid measure of clinical reasoning and acquisition and organization of knowledge.

Hypothesis #3
Students and residents that are more concordant with attendings on differential diagnosis and decision making also do better on tradition measures of performance (ie. attending assessment, shelf exam)

Specific Aim #3
To compare learners concordance with attendings to assessments of performance on evaluation measures already in place for the rotation.

Relevance
If we find the concordance of diagnoses and decision making correlates with the measures of performance, this will support the use of this in situ clinical evaluation measure.

Hypothesis # 4
The trainee and attending forms can be used as a teaching intervention.

Specific aim # 4
To assess medical students' and faculty members' thoughts on how our concordance study forms affected the learning encounter.

Relevance
If we find that trainees and faculty find the forms to be beneficial for the learning encounter, we can increase the quality of teaching in the Pediatric Emergency Department.

B. Study Design and Statistical Analysis

STUDY DESIGN
This is a prospective observational cohort study of medical students and residents and their concordance in diagnosis and decision making with attendings as they develop experience in the pediatric emergency department. After evaluation and examination of each patient, trainees will complete the Trainee form (Appendix A) regarding their diagnostic and management decisions. The attending will hear the presentation, precept as usual, evaluate the patient, and then independently complete the Attending form (Appendix B) on the back of the Trainee form, compare their answers to the trainee answers and record discordance, and place it in the locked

box. Each trainee will complete this form with all of their patients throughout their rotation, as will the attending to whom they present, each time.

At the end of the data collection, we will compare the concordance between trainee and attending diagnostic and management decisions for individual interactions, as well as any change in trainee-attending concordance over the course of the rotations. We will also compare trainee-attending concordance with trainee performance on end-of-rotation testing and evaluations in order to further test construct validity. We will then compile all the same level (i.e. CC3, PGY1-3) trainee interactions for the rotation and compare concordance with attendings between the different levels of experience (i.e. CC3 vs. PGY3).

Qualitative Component:
The study will include a qualitative component which will consist of at least three separate focus groups with medical students (two) and faculty (one) to evaluate the educational value of the concordance forms in the precepting encounter. We will use the concept of "think back questions"(14) to guide an adaptable conversation about what it was like to use the forms.

DATA ANALYSIS
Our main outcome variable will be the concordance (including a 95% CI) of the learners' decisions at different levels of training against the gold standard of the attendings. In our second specific aim, our main outcome variable will be the concordance (including 95% CI) of the learners' decisions over the course of the rotation against the gold standard of the attendings. Our main comparison will be whether the concordance improves in the second half of the rotation with the first. Using ANOVA, we will investigate the correlation of concordance with covariates including scores on shelf examinations and grade for the rotation.

Qualitative Component:
We will look for the frequency and extensiveness of words, phrases, and themes cited by the students and faculty in the focus groups.

SAMPLE SIZE
In our preliminary data, medical students were least likely to be concordant with the attending on which question they identified as the most relevant to the encounter. We will need to collect 24 forms in order to power the study to detect a difference between this question and each individual question to be certain we were not committing a type II error due to lack of power. (Calculation based on first block of medical student data. There was an average of 8.9% discordance on questions a-g, and 48.5% discordance for which question was the most relevant to the encounter.) We know that medical students on average see about 25 cases during their rotation, which means in order to power the study to detect a difference between questions for an individual student, he/she would need to complete a form for all of the patients that they see. We think this is unlikely.

Qualitative Component:
The focus groups will occur at the end of each cohort's 6 week clerkship at the end of a regularly scheduled clerkship session. This will yield groups of approximately 8-12 students which are considered an ideal size for focus groups. We will conduct a single focus group for the attending

physicians in the pediatric emergency department carried out during a regular divisional meeting. We will conduct the student focus groups until we reach data saturation. This will require a minimum of two sessions, but we will continue to conduct focus groups with each new cohort if new themes are introduced

DATA TO BE GATHERED
Prior to starting the rotation, participants will be verbally consented to use the data collected on the form and obtain de-identified end of rotation scores from the pediatrics shelf and clinical grades.

After seeing the patient but before presenting to the attending, they will complete and turn in the Trainee form (Appendix A) that includes:
Unique participant identifier
Date and time of decision making
Patient age
Chief complaint (in check box categories)
Triage level
Most likely and most concerning diagnoses
Several diagnostic and therapeutic decision choices
Circling the most relevant decision choice

Attending will fill out Attending form (Appendix B) after seeing the patient that includes:
Attending initials
Chief complaint (in check box categories)
Most likely and most concerning diagnoses
The same diagnostic and therapeutic decision choices
Circling the most relevant decision choice
2 questions asking whether the form identified any topics of discordance

C. Study Procedure

Participants will be verbally consented prior to their first day on the rotation. Those that consent will have their forms used as part of our database to study the concordance with attendings on the forms. These forms will be de-identified to trainee by their use of a 4 digit number chosen by the trainee. The trainee will hand the attending the Attending Form with a number on the form to pair it with the completed trainee form. The attending will then precept as normal, and see the patient with the student. After seeing the patient, the attending will then complete the Attending form, identify any discordance between their form and the trainee's form, and place it in the locked box.

Qualitative Study:
The focus groups will occur at the end of each cohort's 6 week clerkship at the end of a regularly scheduled clerkship session. This will yield groups of approximately 8-12 students which are considered an ideal size for focus groups.(15) We will conduct a single focus group for the attending physicians in the pediatric emergency department carried out during a regular divisional meeting. We anticipate approximately 20-30 minute sessions.

After the clerkship director leaves the regularly scheduled clerkship sessions, the focus group moderator will orient the students to the focus group session. Students who chose not to participate will be allowed to leave the room. Students who chose to participate will be complete a written consent form to participate in the focus groups and have their discussion audio recorded. Subjects will also be given the option to have their comments discarded and not included in the analysis at the end of the focus group. The interviews will be transcribed with no identification of research subjects.

We will conduct the student focus groups until we reach data saturation. This will require a minimum of two sessions, but we will continue to conduct focus groups with each new cohort if new themes are introduced. We will also ensure that the themes in our data are not limited to the positive, as this is a common mistake of focus groups.(16)

D. Study Drugs
Not applicable

E. Medical Device
Not applicable

F. Study Questionnaires
Trainee Form (Appendix A)
Attending Form (Appendix B)

G. Study Subjects

All medical students and residents rotating in the pediatric emergency department.

Inclusion Criteria - Medical students and residents in their outpatient pediatric or pediatric emergency rotation in the pediatric emergency room at Columbia University/NYP Children's Hospital.

Exclusion Criteria - None

SOURCE OF MATERIAL
The participant and attending will document diagnosis and decision information on standardized data forms, as well as patient age and chief complaint. Forms will be matched together by using a double-sided form. We will obtain end of the rotation evaluation scores, de-identify them with same 4 digit number, and compare evaluation scores with decision making concordance.

H. Recruitment of Subjects

We will recruit the medical students and residents on their first day of their pediatric rotation and clarify that these forms will not influence their grade and request their participation in this study. We will obtain informed consent from the students and residents prior to their involvement in the

study. We will recruit and consent attending physicians individually and explain the study forms and procedures to them to make sure uniform procedures.

INFORMED CONSENT
We request a waiver of informed consent for the patients seen by the study participants as:
1. This is a primarily observational study that poses no medical risks to patients. Care of the patient will not be altered in any way. The patients will not be exposed to any medical intervention and no PHI will be collected on the forms. The data collection tool will not be part of the medical record, and will be stored in locked cabinets in the investigators' offices. Substantial means will be used to prevent loss of patient confidentiality.
2. Our research could not be practicably carried out without the waiver. The enrollment period for each trainee is at times only 2 weeks, and it would be very difficult to obtain the sample size in our power calculations within this time period if patient consent was required. Without the waiver, patient enrollment would in all likelihood be severely biased and render the study scientifically invalid. The literature strongly supports that in non-interventional studies, such as that proposed, the refusal rate will be high when written informed consent is required, resulting in a biased patient population. The following is literature that support such a premise:
a. Mitchell et al performed a study to determine population characteristics, outcomes, and reasons for unsuccessful enrollment among potential study subjects approached for written, informed consent in a minimal risk emergency department (ED) study. The proportions of African Americans, uninsured, and Medicaid patients were significantly higher among nonparticipants. Their data implicated the written, informed consent process as a significant source of bias on estimated disease prevalence [11].
b. In a New England Journal of Medicine article, Tu et al. reported on a prospective study of the Registry of the Canadian Stroke Network. The authors made great efforts to obtain informed consent, but only 39.3 percent of patients in phase 1 of the study and 50.6 percent in phase 2 provided consent for their inclusion. The authors report that obtaining written informed consent led to selection bias; patients who were more seriously ill or impaired were not enrolled [12].
c. In a non-interventional cancer registry in Germany that had been in place for 50 years, the introduction of informed consent for inclusion in the registry led to a marked deterioration in enrollment and data collection. This enrollment problem led, even with involvement of the government to alleviate the difficulties, to a failure of the mission of the registry [13].

I. Confidentiality of Study Data
See section L. Potential Risks.

J. Potential Conflict of Interest
None to disclose.

K. Location of the Study
CHONY ED

L. Potential Risks
It will be necessary to enroll medical students and residents in this study as the study aims are to determine if concordance of decision making changes during their experience. It will also be necessary to record and access some patient information during data collection to compare the

student's decisions to the attending's actual management. The risks of this study are small. There is evidence in the medical education literature that having the students commit to their decision is beneficial however, we do not know if the form will succeed in accomplishing this. We think it is highly unlikely that the form would impair the students learning. One potential minor risk associated with participation in this study is the loss of confidentiality, as subjects' names will be linked to ID numbers. Every effort will be made to protect confidentiality, as discussed directly below. We believe the focus groups will have minimal risk to the study participants. They may feel anxious by participating in the focus group. They may appreciate having their feedback heard.

PROTECTION AGAINST RISKS
Every effort will be made to protect the confidentiality of the students and residents who participate. Each participant will select a unique identifier (4 digit number of their choice) that will be used in the data collection tool and in the electronic database. The key to match the unique identifier to the student or resident will be stored in a locked cabinet in the study investigator's office and will be destroyed at the conclusion of all research analyses. The focus group transcription will include no identification of research subjects. The medical student focus groups will be moderated by a pediatric resident who does not evaluate or influence the grade received by the medical students. The clerkship director and emergency medicine attending will not attend the focus groups nor hear the audio recordings. The pediatric emergency medicine attending focus group will be moderated by their peer. Data will be entered electronically by the study investigators onto a password-protected computer database. Only authorized persons will be granted access to the data, only authorized persons may enter and view study data, passwords and system IDs will not be shared, physical security of the workstations/files will be maintained, and staff will be trained on the data entry system and importance of security procedures.

M. Potential Benefits
This study will not directly benefit patients cared for during this study. We believe that the information gained from this study could help patients in the future by better identifying medical students and resident knowledge gaps and errors in clinical reasoning. This therefore provides them an enriched learning experience and ultimately produces better trained physician.

N. Alternative Therapies
Not applicable.

0. Compensation to Subjects
None.

P. Costs to Subjects
None.

Q. Minors as Research Subjects
Not applicable.

R. Radiation or Radioactive Substances
None.

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