Are Incoming Pediatric Interns Ready to Obtain the Essential Components of an Informed Consent for Lumbar Puncture?

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Abstract

Objective: In 2013, the Association of American Medical Colleges created the "Core Entrustable Professional Activities (EPAs) for Entering Residency" to more clearly define the set of activities that entering residents should be able to perform on day 1 of residency without direct supervision. EPA #11 is obtaining informed consent for tests and/or procedures. This EPA acknowledges that an entrustable learner should be able to document a complete consent among other components. The aim of this study is to explore whether incoming pediatric interns demonstrated the behaviors of an "entrustable learner" in the domain of documenting informed consent for a common pediatric procedure.

Methods: All incoming interns in our program (2007−2017) completed a 6-station Objective Structured Clinical Examination during residency orientation. One of the scenarios involves obtaining parental consent for a lumbar puncture (LP). The researchers determined and agreed what components would be important for a complete and accurately documented consent. A retrospective review of the resident's written informed consents occurred looking for accuracy of documented components.

Results: Of the 258 consents reviewed, 8 were complete and accurate. Incoming interns appear to be skilled when completing the basics of the informed consent form such as documenting names, obtaining signatures, and correctly identifying the procedure. However, detailing all the risks of the LP were areas for which they did not demonstrate proficiency.

Conclusions: Documenting informed consent is not adequately demonstrated by our learners prior to the beginning of internship. We would recommend specific training before entrusting pediatric interns to obtain LP consent independently.

Keywords: entrustable, competency; informed consent; graduate medical education

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What's New

A retrospective study of pediatric interns in a large urban program highlights the importance of training in informed consent.

A LUMBAR PUNCTURE (LP) is cited as one of the most common procedures consented for in general pediatrics.[1] Incomplete consents may compromise patient autonomy, increase the likelihood of patient safety errors, and increase malpractice claims.[2-5] Ideal informed consent requires a discussion between the patient or guardian and the provider using shared decision-making throughout the process.[6] The completed consent form serves to document that both parties agree on treatment plans and are aware of potential risks.

In 2013, the Association of American Medical Colleges (AAMC) created the "Core Entrustable Professional Activities (EPAs) for Entering Residency" as a way to more clearly define the set of activities that entering residents should be expected (entrusted) to perform on day 1 of residency without direct supervision.[7] One of the EPAs is obtaining informed consent for tests and/or procedures.[6] This EPA acknowledges that an entrustable learner should be able to document a complete, "comprehensive" and accurate informed consent. The documentation should avoid "prohibited abbreviations," "rarely has errors of omission," and has a "time, date, and signature." No study before or after the core EPAs were released in 2013 has explored the accuracy of informed consent documentation for incoming pediatric interns.

The aim of this study was to explore whether incoming pediatric interns demonstrated the behaviors of an AAMC defined "entrustable learner" in the domain of documenting informed consent for a common pediatric procedure. Using these results can inform future curriculum development in this area.

Methods

We conducted a retrospective cohort study of incoming pediatric interns' ability to document informed consent in

an Objective Structured Clinical Examination (OSCE). It was given exempt status by the University of Texas Health Science Center at Houston Institutional Review Board (HSC-MS-15-0481).

STUDY SETTING AND SUBJECTS

All incoming pediatric interns (n = 258) completed a series of 6 stations in an OSCE during orientation before starting clinical rotations in 2007 to 2017. One of the scenarios involves the intern obtaining parental consent for an LP. The consent forms had been in storage in one of the author's (M.S.B.) office before review for this study.

EVALUATION TOOL

In the OSCE, the pediatric interns have one station to obtain informed consent from a standardized parent (SP) whose child has suspected meningitis. For the purposes of the OSCE, the child is not present. They are told that a preference for cerebral spinal fluid is desired before starting antibiotics. The resident is expected to accurately complete a generic procedures consent form using the actual blank paper form from our primary teaching hospital. This form does not provide preprinted information for LP, does not require the provider to document the benefits or alternatives of the procedure, and did not substantially change during the 10-year study period. The residents had 15 minutes to spend with the SP to complete the entire process of informed consent. They next received feedback from the SP for 5 minutes focused on their communication skills and finally completed a 10-minute postencounter exercise that allowed them to review the informed consent documentation before moving to the next OSCE station.

EVALUATION TOOL DEVELOPMENT

The researchers determined and agreed what components would be important for a complete and accurate consent. The necessary items were based on a literature review and consensus panel made up of 3 pediatric hospitalists, 2 intensivists, and 4 general practitioners polled at multiple regional and national medical education conferences in 2016. A retrospective review of the resident's informed consent (based off encounter with SP) occurred looking for accuracy of documented components based on the consensus criteria. There were 2 reviewers per document, and an interrater reliability analysis using the kappa statistic was performed to determine consistency among raters. High inter-rater reliability was achieved with a kappa of 0.89.

STATISTICAL ANALYSIS

The consents were compiled and tallied for each discrete question. Frequency tables were generated. We performed all statistical analyses using STATA software, version 11.0 (Stata Corp, College Station, Tex).

RESULTS

During the study period (2007−2017), there were approximately 258 pediatric interns who participated in the scenario. In total, 86 medical schools were represented in the sample (Table 1). Of the 258 consents reviewed, 8 (3%) were complete and accurate based on consensus criteria. Items likely to be accurately completed were "name of procedure" (83%); "date of consent" (75%); and obtaining the SP's signature (88%). The items most likely to be missing from the consent document were the risks associated with a LP. The risk of "injury to nerves" was documented by only 26 % of incoming interns. Risk of "pain" was documented by 35% of incoming interns (Table 2).

Four consents were accurate and complete before the onset of the EPAs in years 2007, 2009, and 2012 and 4 consents were accurate and complete after 2013 when the EPAs were implemented. These occurred in year 2013, 2014, and 2015.

An additional 32 interns were 1 component shy of a complete and accurate consent (Table 3). The most common reason for an incomplete consent was an error of omission for failing to write one of the potential risks associated with the procedure (29 of these 32 consents). Analysis looking at differences in sex or type of medical degree (MD vs DO vs MBBS) did not reach clinical significance.

DISCUSSION

Informed consent can be viewed on a developmental spectrum.[8] To meet criteria of an entrusted learner for the EPA looking at informed consent, the resident should be engaged in a continuous dialogue with the patient/parent with true understanding and agreement measured by the patient/parent ability to teach back key elements of risks, benefits, and options.[6] Our study focused on the items documented on the completed consent. In our study, documenting risk involved in the procedure proved to be the biggest deficiency, especially as the negative perception of the risk increased. It can be inferred that the intern physicians may not think of bleeding, pain, or injury to nerves/surrounding structures as a "real" risk, or they may not be comfortable verbalizing these potential risks either due to fear of rejection of the procedure by the parents or some other concern. Our findings are consistent with that of Nickels et al, [1] who reported that resident respondents felt more comfortable discussing the benefits of the procedure than the risks. The authors of this study worry about

Table 1. Demographics and Training Characteristics

Characteristic	Variable	Value
Sex	Female	197 (76%)
	Male	61 (24%)
Degree type	MD	214 (83%)
	DO	25 (10%)
	MBBS	19 (7%)
Origin of degree	US	239 (93%)
	International	19 (7%)
Medical school geography	McGovern Medical School	57 (22%)
	Other Texas Medical School	83 (32%)
	Other US State Medical School	99 (38%)
	International Medical School	19 (7%)

Table 2. Results of Checklist for Completeness

Checklist for Completeness	Percent Correctly Completed (n = 258)
Necessary components for a complete consent	
Is the name of the patient complete?	79% (205)
Did they correctly name the medical condition?	68% (176)
Did they correctly identify the procedure?	83% (215)
Did they completely DATE the consent?	75% (194)
Did they completely fill out the TIME the consent was obtained?	63% (163)
Did the standardized patient/parent SIGN the consent?	88% (223)
Did they write the risk of PAIN?	35% (91)
Did they write the risk of INFECTION?	44% (114)
Did they write the risk of INJURY to NERVES and SURROUNDING STRUCTURES?	26% (67)
Additional components of the generalized consent (but NOT included in checklist for completeness)	
Did they write the risk of DEATH?	4% (10)
Did they consent for BLOOD PRODUCTS?	47% (122)
Did they consent for having an IMAGE taken of the procedure?	49% (127)

Table 3. Common Errors of Omission That Made Documentation Incomplete (Definition: Missed 1 Item on the Checklist of Completeness)

Component of Checklist for Completeness	Number of Consents with This Missing Component (n = 32)
Risk of BLEEDING documented	2
Risk of PAIN documented	11
Risk of INFECTION documented	6
Risk of DAMAGE TO NERVES OR SURROUNDING TISSUE documented	10
Document the TIME consent was received	2
Obtain signature of (standardized) parent	1

the potential impact of framing the discussion more heavily toward the benefits and how it may affect the accuracy of the informed-consent process.[1] Another explanation for this finding may be that learners just have a lack of knowledge of all the risks involved. Interestingly, we found 10 interns documented "death" as a potential risk. Death, as well as blood products and imaging, were extraneous risks documented by a small minority of residents and not deemed necessary risks by the study team. These risks were not included as part of the study team's checklist for accuracy. Standards for consent vary on what needs to be disclosed and documented to minimize the risk of lawsuits, and, more importantly, increase patient's full understanding of the procedure.

There is high variability in pediatric trainees' exposure to informed consent curriculum, and many trainees report that observing peers was their main introduction to informed consent.[1,9] In a study by Gaeta et al, [10] 56% of the emergency medicine residents had never received formal training on obtaining informed consent and felt uncomfortable obtaining consent for a procedure. Our study demonstrated that many incoming pediatric residents could not successfully document a complete consent and could potentially have difficulty educating their peers in this important skill. Throughout the study period, we did not see any improvements in the documentation of the informed consent. Analysis of the data during the time period before and after the introduction of the EPA suggests interns are either not getting trained or not retaining the information before starting residency. At our institution, there is no formal education on the process of obtaining informed consent and none has been added since the EPAs were released in 2013. Because 86 medical schools were represented in our study, we further extrapolate that there is a need for medical education across all represented schools in terms of teaching how to obtain a well-documented informed consent. Training needs to extend into residency, as few residents report that they received formal training in this area.[1] In a study by Patel et al, [11] most of the consents obtained in a tertiary care pediatric emergency department were by residents (73.6%) and the researchers found clinicians on all levels of training failed to document the essential components of informed consent. Longitudinal curriculum in this area may be considered to touch all level of learners and we recommend specific training before entrusting pediatric interns to obtain consent independently. We have since added short didactic teaching following the incoming OSCE on informed consent but have not studied its efficacy.

This study affirms that informed consent is a skill that should be taught and reviewed in medical education, especially throughout the clinical years. It is unclear what this training should look like and where during the medical education it is best incorporated in the curriculum. It is known that pediatric residents improve their knowledge and attitudes about informed consent with a 1-hour intervention.[12] However, training in this area seems to be

highly variable, from no training to a combination of lectures, role playing, and anything in between.[9] Cook et al[13] surveyed pediatric program directors regarding professionalism and ethics curriculum concluded that there is an underuse of curriculum available to improve professionalism training, including informed consent. The AAMC recommends that a comprehensive entrustment decision about residency readiness come from the use of multiple methods of teaching and assessment tools.[14] Simulation, reflective exercises, and standardized experiences may be used to determine learner competence and, ultimately, belief that authentic clinical experiences are key to determining performance capabilities.[14]

Given that a LP is a common pediatric procedure, quality and safety improvements may be seen if hospitals move away from generic "fill-in-the-blank" informed consent form that requires the physician to handwrite the risks and complications of the procedure.[2] Having a generic form may worsen the issue of not obtaining complete documentation because if the physician does not think about a risk (minor or major), it will not appear on the form.[8,15,16] Moreover, as most hospitals use an electronic medical record, standardized informed consent documentation could become more easily adapted to diminish omission errors by embedding the correct date, time, and patient's name on the form. As Patel et al mention, it may be beneficial to have procedure-specific consent forms that have written explanations about a procedure. This may increase the quality of the informed consent process for the patient and/or family and will certainly improve the completeness of documentation.[17]

Weaknesses

One of the weaknesses of our study is that our data are from one training program; however, incoming residents represented 86 medical schools over a 10-year period. Our study also only focused on information that was documented on the paper informed consent, so the impact of the discussion between the resident and the SP/actor on the final consent document is unknown, as is the ability of the SP to teach back key elements of risks, benefits, and options.[18] However, errors of omission in the discussion may be inferred from the incomplete documentation. It is also unknown what may have occurred for those consents that are completely blank. We did not query the interns on their level of comfort with informed consent before the OSCE or their familiarity with the LP procedure. Obtaining qualitative data would be an appropriate next step to explore the communication themes between provider and patient and a national study would increase generalizability of the findings.

Conclusions

This study identifies an educational gap in the ability of most incoming pediatric interns at one institution to perform a component of EPA #11, specifically documenting informed consent for a LP. Most of these interns were not adequately prepared to be entrusted with obtaining informed consent on a common pediatric procedure, especially in documenting risks of the procedure. We urge more focused education on informed consent in medical school curricula and recommend assessment before considering an incoming intern ready to obtain informed consent. Future studies would be useful in confirming the effectiveness of the proposed expanded curriculum as well as looking at real-life scenarios beyond OSCE to help improve the quality and safety of patient care and to examine the use of shared decision-making by interns during informed consent for procedures. The American Academy of Pediatrics and the Association of Pediatric Program Directors are encouraged to provide a practice guideline on consent for common pediatric procedures such as the LP.

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