

Ethics Rounds: Ethical Concerns When Minors Act As Standardised Patients

Erwin Jiayuan Khoo, MRCPCH, MBBS,^a Robert D. Schremmer, MD,^b Douglas S. Diekema, MD, MPH,^c John D. Lantos, MD^b

When minors are asked to assist medical educators by acting as standardized patients (SPs), there is a potential for the minors to be exploited. Minors deserve protection from exploitation. Such protection has been written into regulations governing medical research and into child labor laws. But there are no similar guidelines for minors' work in medical education. This article addresses the question of whether there should be rules. Should minors be required to give their informed consent or assent? Are there certain practices that could cause harm for the children who become SPs? We present a controversial case and ask a number of experts to consider the ethical issues that arise when minors are asked to act as SPs in medical education.

abstract

Medical educators often use simulations and standardized patients (SPs) to improve students' clinical skills. In pediatrics, children or adolescents may be asked to become SPs. This practice can raise a number of unique ethical issues. Can minors consent to be teaching tools in medical education? Are there certain practices that could cause harm for the children who decide, or whose parents decide, to go this route? In this Ethics Rounds, we present a controversial case and ask a number of experts to consider the ethical issues that arise when minors are asked to act as SPs in medical education.

THE CASE

M.S. is a 6-year-old with hemoglobin E/ β thalassemia who lives on a farm who lives on a farm in Indonesia. He was diagnosed at 2 years of age. For his clinical care, he requires frequent transfusions of packed red blood cells. He was started on iron chelators at the age of 5 years. The patient has many of the clinical features of β thalassemia. He is small, pale, has prominent facial bones, and has hepatosplenomegaly.

There are multiple subcutaneous injection scars over his abdomen due to the use of the iron chelators.

M.S.'s father and mother are self-employed farmers. Both have the thalassemia trait. M.S. has 2 younger brothers who are well. The family has an income of less than 200 Indonesian Rupees (US \$3) per day. They have struggled to make ends meet over the years.

M.S. is followed up in a university hospital. During one of his visits to the clinic there, the hematologist asked M.S.'s mother if she would allow him to be hired as an SP for an undergraduate clinical examination. If she agreed, M.S. would then be one of many patients upon whom medical students would be asked to perform an objective structured clinical examination (OSCE). This examination involves history taking and physical examination by students (examinees) in which they take turns being assessed by examiners. Examinees rotate from station to station with different objectives of competence being assessed. Patients are typically hired because of their

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“interesting” or classic signs of their disease, in which findings cannot be simulated. On the day of OSCE, M.S. would be examined by 24 medical students separately over a period of 12 minutes per student for a total duration of 5 to 6 hours continuously. These examinations will be repeated with a different set of examinees the next day. The students' performance on these examinations will be used to assess the students' clinical competence in pediatrics. For being a SP for 2 days, M.S.'s parents will receive a sum of 600 Indonesian Rupees (US \$9).

Question: Is it permissible for doctors and educators to request of parents that their child be used to evaluate students' clinical competence? Are there limits to the sorts of situations in which this undertaking should be permitted?

Erwin Khoo Jiayuan, MRCPCH, MBBS, Comments

The involvement of minors as a tool in medical teaching has been a widely overlooked, valued component of medical education. Minors have been used in many professional examinations, including those of the American Board of Medical Specialties, the Medical Council of Canada national licensing examination, and many Royal Colleges around the world.¹ Using SPs in OSCE has become an effective method for evaluating clinical competence in medical education. Even large numbers of child SPs have been made feasible despite the challenging logistics and potential disaster when involving children in such high-stakes clinical examinations.²

Sir William Osler said, “to study the phenomenon of disease without books is to sail an uncharted sea, while to study books without patients is not to go to sea at all.”³ There is no doubt using actual patients is a necessity in medical education for the assessment of students'

learning outcomes.⁴ Patient contact provides learners the opportunity to apply their knowledge in real teaching settings and to develop clinical reasoning and enhance cultural diversity. They nurture professionalism and good ethical behavior by fostering empathy. Involvement of child SPs in education improves training and overall societal health care.

The ethical principles of “nonmaleficence versus beneficence” have been invoked to justify the use of minors in medical education. Being an SP increases one's own knowledge and gives the opportunity to share concerns with a professional, while also gaining enjoyment from these encounters. These experiences also lead to potential psychological and emotional benefits. However, patients involved in education benefit the least when involving younger children using the traditional benefit/burden calculus. A neonate or toddler lacks autonomy and so could be easily coerced or compelled by their parents (or an educational institution) into participating in such educational activities. With no observed direct benefit to these subjects, they are considered noble and self-sacrificing to the production of quality doctors prioritizing the best interest of the community.

The risk of harming a child could be akin to the debatable “July phenomenon” (ie, the increased patient morbidity and mortality related to the influx of new medical trainees).⁵ We should also consider the risk of infection or risk of being hurt and being traumatized while trainees were so engrossed in eliciting a sign that they forgot about the child's discomfort and parent's anxiety, as well as the potential exhaustion and risk of confusion and embarrassment when cases are presented differently from what the child is actually experiencing.

There are 2 ethical approaches here. Using minors as SPs for the benefit

of the institution and society could be compared to using children in research, and be regulated in a similarly stratified manner based on the child's age.⁶ The younger the child is, the greater the risk-to-benefit ratios. The broader societal benefits must be balanced with the rights of the child while retaining the principle of nonmaleficence. When the risk-to-benefit ratio is deemed significant, as in participation of toddlers and newborns, both parents should consent. The “rule of 7” would be a subtle approach to capacity of a minor. Minors aged <7 years, minors aged 7 to 13 years, and minors aged ≥14 years are an important watermark to minors having the capacity and maturity to differentiate decision-making and understanding consent.⁷ The next consideration would be employment of children within the limits of the country's law. As with simulation as employment in the entertainment industry, appropriate regulations should be in place. The age of the child, the role he or she plays, and the duration of engagement are crucial considerations when regulating such law.

In both ways, parents must be provided with adequate information to enable provision of informed consent before their child's participation. The concern here is, could minors be exploited where poverty creates personal financial interest? How can children refuse when their parents are asking them to volunteer? If the child refuses, guilt and interfamilial conflict may result. These concerns are similar to concerns that arise in research. Remember that asking for parental consent during a clinic visit can increase pressure on the parent to consent. This persuasion, if not wittingly, then perhaps by virtue of body language or institutional authority seems unethical. Sometimes, children may seem to signal dissent, and these objections

are, of course, overridden by parental instructions. In all these cases, the worry is that the child's consent, or assent, may not be real when it comes to younger children. We then think of possible reasons for a child's dissent, and we start to worry about educators taking advantage of children.

In the present case, the question is not whether it is permissible for doctors to request of parents that their child be used as an educational tool. Instead, the key question is how rightfully recommendations are implemented for children to volunteer in medical education. Involvement of minors as SPs remains an educational challenge needing logistic effort, a child advocacy team, and awareness of the minor's best interest and of any risk of maleficence. For educators, discussions among ethicists or a child advocacy team when minors are too young to express assent are an important first step. As with an institutional review board, such steps ensure that involvement of minors as an education tool is conducted in accordance with institutional and ethical guidelines. Educators should be sensitive to the child's dissent and be aware of age-appropriate assent. Consent must be sought by an independent team away from clinical responsibility. Parents should be briefed about the details of the OSCE and what is expected during the process.⁸ Their rights to refuse participation should be informed and that refusal would not negate their child's health care follow-up. While monitoring of appropriateness and overuse of similar patients, educators should identify alternative simulation tools to achieve students' clinical competence. There should be a disclosure of the remuneration system, and its nature should not be coercive.

The well-being and comfort of minors should be paramount while allowing for the option to withdraw

at any time. Respect for children is fundamental in cases such as that discussed here. A minor's assent is required, and dissent should be respected. I would also suggest the involvement of the family in any educational discussion and provide the opportunity for feedback (ie, the "patient's voice").

Robert D. Schremmer, MD, Comments

An SP is an actor who is trained to portray a patient with a specific condition in a realistic and consistent manner.⁹ SPs are frequently used in health care education in a number of different settings, including OSCEs and other instances of formative and summative feedback. Studies have shown that SPs, as with real patients, are highly valued by students and that SP encounters can be as effective as live patient encounters for learning skills such as interviewing, physical examination, and communication.¹⁰ The advantages of using SPs in simulation may include repeated, consistent depiction of a particular patient for a number of different learners; accurate portrayal of history, physical examination, behavioral features, emotions, and personality characteristics of a variety of different patient types; enhancement of a safe learning environment in which the learner can practice without fear of embarrassment or harm to a live patient; and provision of feedback to the learner from a patient's perspective. Disadvantages include high-resource utilization for training and use of SPs, difficulty for a healthy actor to represent a disease process with characteristic physical examination findings, inconsistent availability of actors, unrealistic time commitment for an SP to be involved in a training or testing program with dozens of learners, and lack of actors who can portray age extremes. Unfortunately, there are few data comparing outcomes of students who learn by examining

SPs compared with students who use other pedagogic techniques.

Using a child in the role of an SP adds further practical challenges. A younger child may not be able to maintain consistency with historical information. He or she may not have the patience to be examined repeatedly and may get bored with the process. A minor cannot consent to being used as an SP, and thus a parent or guardian must provide consent.

Although not often used as true SPs, children are commonly used as patient models for practice or testing of learned skills. This practice is especially common in pediatric point-of-care ultrasound workshops. Children with both normal anatomy and abnormal ultrasound findings (ie, a peritoneal dialysis patient who mimics a positive focused assessment with sonography in trauma) are asked to lie still while workshop participants scan them repeatedly. The practical portions of these workshops that require child models are usually less than one-half of a day because the rest is spent on didactic content and scanning task trainers.

In the vignette presented, M.S. is asked to be a physical examination model during medical student OSCEs on 2 consecutive 5- to 6-hour days. His mother or father would likely also need to accompany him because he would not be able to provide an accurate history for the students and because his parents would rightly be hesitant to allow their 6-year-old child to be alone in a room with a parade of strangers.

Such a situation raises a number of concerns. The duration of participation and number of examinations proposed are daunting for a 6-year-old. The process may be emotionally stressful. His parents will receive compensation, but there is no mention of a direct incentive for the child, not even lunch during his long days.

Do the benefits for students or for M.S.'s parents outweigh the burdens? One way to sidestep this question would be to imagine other ways of providing similar educational experiences. Technology may render the need for minors as SPs moot. Virtual humans and other forms of artificial intelligence have become much more lifelike due to the advances of the computer chip and networking.¹¹ Health profession educators now use virtual patients in training.^{12,13} Pediatric virtual patients have been developed and have been in use in some locations for >10 years.¹⁴ This modality will likely soon be standard practice. Developing and using virtual patients is expensive, however, and M.S. lives in a resource-limited area; thus, the availability of computing power and networking is not guaranteed. The use of a virtual patient simulator has been reported in at least 1 resource-limited setting, however.¹⁵

The use of either virtual patients or SPs can improve medical education. Minors can work as SPs with appropriate safeguards in place. If parents judge that a child has the ability to perform the duties asked of him or her, and they consent to the child's participation, then it is permissible for the child to act as a SP. There should be limits to the duration and number of examinations, however. The child should not be required to undergo any painful or overly embarrassing procedures. But with such safeguards in place, and with careful monitoring for fatigue or other adverse effects, it is ethically permissible to hire children as SPs.

Douglas S. Diekema, MD, MPH, Comments

The situation presented by this case raises ethical issues analogous to those arising in the research context. Like research, the primary purpose of the activity is not to benefit the patient but to contribute to the

greater social good, in this case by educating a future generation of physicians. Several well-established ethical principles exist for deciding when and under what conditions enrolling a child in research is appropriate, and I would suggest that deciding whether to allow children to serve as SPs should be subject to the same principles and constraints that we apply to the research context.

Potential risks and benefits are essential elements in determining whether children can participate in research. In most circumstances, children are not permitted to participate in a research project that exceeds minimal risk unless it offers the child sufficient prospect of direct benefit to justify any potential risks involved. A similar rule should apply to children being considered for the role of an SP.

M.S. will be subjected to 48 physical examinations repeated over the course of two 6-hour days. The boredom and unpleasantness of that exercise seem excessive for even the most patient and compliant 6-year-old child. This situation is exacerbated by the relatively passive nature of the role. Even more importantly, M.S. has been specifically selected for his unique visible physical features, features that very possibly alienate him from peers and subject him to teasing. Participation as an SP will highlight the features that make M.S. different from other children and potentially enhance their stigmatizing effect. Although some 6-year-olds might take this all in stride, I suspect most would not. I would be reluctant to characterize that risk as minimal but concede that it might be considered a minor increase over minimal risk in a carefully controlled environment attentive to the boy's needs.

Does participation provide sufficient direct benefit to M.S. that these potential harms are neutralized? Financial compensation provided to the family is generally not considered

to be a direct benefit to the child. Adults would likely argue that the most significant benefit of serving as an SP (beyond the money) resides in the feeling of having contributed to society by enhancing the education of future physicians. An older child might feel similarly, but I would argue that most 6-year-olds are not developmentally capable of reliably enjoying that sense of having contributed to the community. They are much more likely to feel as if they have fulfilled an obligation placed upon them by their parents.

Even if allowing a 6-year-old with potentially stigmatizing physical findings to serve as an SP was deemed to be minimal risk or to offer a reasonable prospect of direct benefit to that particular child, several other ethical obligations exist. First, having young children serve as SPs should occur only when adults or older children are not available to serve that role. If an adult or adolescent with thalassemia and similar physical findings can be recruited, that would be preferable to using a young child.

Second, if the child is allowed to serve as an SP, the welfare of the child must remain paramount and every effort made to minimize potential harm to the child. Frequent breaks should be scheduled. The child should be engaged as much as possible as an active rather than passive participant. Should the child display distress or discomfort at any point, the examination should stop and the needs of the child addressed, including offering the opportunity for a break or for cessation of the activity.

Third, compensation of the parents incentivizes them to consider factors other than their child's welfare and may hamper their ability to judge the potentially negative impact of this activity on their child. This scenario is most important when the activity may exceed minimal risk. Although the compensation in the

present case seems fair for 2 full days of activity (similar to the parents' usual income), some consideration should be given to incorporating an independent advocate; the advocate's role would be to assure that the child's welfare is optimized during the process.

Finally, there should be an absolute requirement for assent; that is, the active affirmative agreement of the child to participate. Assent serves to remind parents, educators, and students that children are persons with interests and not solely a means to an end. The child should be permitted to revoke assent at any time he or she becomes dissatisfied, and dissent should be respected regardless of whether parental permission has been granted.

John D. Lantos, MD, Comments

SPs are cool. Compared with classroom situations, they allow teaching and learning that more clearly mirrors the situation of an actual doctor talking to and examining an actual patient. To the extent that they improve doctors' skills, SPs are good for actual patients, who benefit by having trainees who are more skilled and less anxious. When the actors who play SPs are adults, they know what they are getting into and do so voluntarily. When the actors are children, the potential for exploitation exists. Interestingly, this situation may mirror the potential for exploitation among child actors in film and television.

Child actors are granted an exemption from child labor laws because it is understood that the work that they do (ie, playing the part of a child) cannot be done by an adult. In the United States, each state regulates child actors, under guidance from the federal government. In California, minors

can only work in theater if the State Labor Commissioner issues a permit. They are not allowed to work >5 consecutive days. They are excused from up to 5 school absences per year, and school districts are to allow pupils to complete all assignments and tests missed during their absence. Courts may require a portion of earnings be set aside for the minor in a trust. Other states have different rules, but all have some rules.¹⁶

Children who are used as SPs deserve similar protection. Although the analogy to participation in research is interesting, the analogy to participating in the workforce might also offer valuable guidance as to how this practice should be regulated.

ABBREVIATIONS

OSCE: objective structured clinical examination
SP: standardized patient

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