



Professional Responsibility and Early Childhood Vaccination

Frank A. Chervenak, MD¹, Laurence B. McCullough, PhD², and Robert L. Brent, MD, PhD, DSc (Hon)³

The recent outbreaks of measles and other childhood infectious diseases in the US and other countries¹⁻³ have garnered considerable public attention and prompted controversy about early childhood vaccination.^{4,5} A newcomer to this controversy would be forgiven for thinking that there is a scientific and ethical basis for controversy about the professional responsibilities of physicians regarding early childhood vaccination. For example, there are reports of physicians stating publicly that they have not authorized vaccination of their own children.⁶ At least 1 physician who holds federal elected office and is an announced Republican Party candidate for the nomination to become president of the US, Senator Rand Paul of Kentucky, has stated that parents' refusals of vaccination should be respected by physicians and the government.⁴ Andrew Wakefield, a former physician who has been eliminated from the General Register in the United Kingdom, fabricated data supporting a connection of the measles vaccine to autism, in a paper that was formally withdrawn.^{4,7,8}

The safety and effectiveness of early childhood vaccination are well established.⁹⁻¹³ In response to the recent measles outbreak, the American Academy of Pediatrics has recently released a statement urging parents to have their children vaccinated.¹⁴ In this article, using the professional responsibility model of pediatric ethics, we address the ethics of early childhood vaccination, including counseling parents, the physician's public role, and implications for policy makers.

We begin by introducing the professional responsibility model of pediatric ethics. We then identify its implications for physicians in counseling parents, for the public statements by physicians, for the public statements of policy makers, and for health policy. We will show that there is no scientific or ethical basis for ethical controversy about these matters.

The Professional Responsibility Model of Pediatric Ethics

Based on the landmark work in the history of medical ethics by the Scottish physician-ethicist John Gregory (1724-1773) and the English physician-ethicist Thomas Percival (1740-1804),¹⁵⁻¹⁷ the professional responsibility model of pediatric ethics establishes that the physician's ethical obligation is to protect and promote the health-related interests of the child who is a patient. Professional obligations to neonatal and young pediatric patients are beneficence-based. Beneficence is an ethical principle that obligates the physician to seek the greater balance of clinical goods over clinical harms in the processes and outcomes of patient care. Beneficence-based clinical judgment is rigorously evidence-based.

The professional responsibility of the physician to a child who is a patient originates in the best interests of the child

standard, a beneficence-based core component of pediatric ethics.¹⁸ This standard can function as an ideal or as a norm.¹⁹ As an ideal, it sets a goal toward which pediatricians and parents should strive, knowing that in some cases they may fall short. In its 1995 statement on parental permission, the American Academy of Pediatrics invokes the standard as a norm that creates ethical obligations of both pediatricians and parents when there is effective treatment that protects the health of children.¹⁸ Vaccination of all children without medical contraindications is such treatment, according to the international experts on vaccination, epidemiology, and infectious disease who produced the Institute of Medicine statement⁹ and the American Academy of Pediatrics.¹⁰ Falling short of the goal of vaccinating all children without medical contraindication is acceptable when the best interests of the child standard is an ideal but is not when the standard is a norm. The best interests of the child standard as an ideal does not effectively protect the health of children and is, therefore, an inappropriate basis for the ethics of early childhood vaccination.

Understood as a norm, the best interests of the child standard requires physicians to protect and promote the health-related interests of pediatric patients. The clinical ethical judgment about what should count as the best interests of the pediatric patient focuses on the patient; the patient's parents' interests are not included because they are not the pediatrician's patient. Like all patients, the best interests of the child should be understood biopsychosocially, a concept introduced by George Engel.²⁰ Such an approach prevents biomedical reductionism and consequently, excessively narrow, and therefore, clinically inadequate diagnostic and therapeutic reasoning.

The physician has ethical obligations to the parents of the newborn but not because they are the physician's patients; the child is. The physician has autonomy-based obligations to the parents in their role as surrogate decision makers for their child, who is the patient. The physician empowers parents to discharge their responsibilities in this role by supporting the exercise of their autonomy with evidence-based information and recommendations. However, parental autonomy is justifiably constrained by the parents' beneficence-based obligations to their child who is the patient.¹⁸ The restraint on parental autonomy that originates

From the ¹Department of Obstetrics and Gynecology, Weill Medical College of Cornell University, New York, NY; ²Center for Medical Ethics and Health Policy, Baylor College of Medicine, Houston, TX; and ³Department of Pediatrics, Sidney Kimmel College of Medicine of Thomas Jefferson University, Philadelphia, PA
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in the best interests of the child standard as a norm is a distinctive feature of pediatric ethics. It follows that parents should not be empowered by physicians to make decisions that harm their child's health-related interests.

The pediatrician has the professional responsibility to make clinical judgments about which forms of clinical management protect and promote the health-related interests of the child. Such judgments appeal to both evidence about outcomes and the clinical values of prevention of mortality and morbidity, as well as prevention of pain, distress, and suffering that are not necessary in order to prevent mortality and morbidity. This beneficence-based clinical judgment permits taking clinical risks in patient care when such risks are offset by significant clinical benefit. This condition is satisfied in the case of early childhood vaccination. This evidence-based clinical judgment about the overwhelming net clinical benefit of early childhood vaccination should guide the pediatrician in counseling parents.⁹

The parents' beneficence-based obligations are a function of, and, therefore, directly parallel to, the beneficence-based obligations of physicians. Parental authority to make decisions on their child's clinical care is a direct function of parents' fulfilling their beneficence-based obligation to authorize clinically beneficial management. In particular, parents have a beneficence-based obligation to authorize effective treatment for the clinical management and prevention of life-threatening and other clinically serious conditions in their child when the risks of doing so are reasonable. This condition is fully satisfied in the case of early childhood vaccination.

In pediatric ethics, both parents share decision-making authority over their child. Together, they act as their child's surrogate decision makers, unless otherwise determined by organizational policy that allows for authorization by one parent or by law (eg, loss of medical custody). Inasmuch as the neonate does not yet have beliefs and preferences, the substituted judgment standard does not apply. This standard requires surrogate decision makers, as reliably as they can, to make decisions reflective of what the patient would have decided. The best interests standard of surrogate decision making does apply. This standard requires the surrogate decision makers, as reliably as they can, to make decisions that protect and promote the health-related interests of the patient. This explains further why parental autonomy is exercised under the constraint of the best interests of the child standard. This is known as informed permission^{10,17,18} rather than informed consent. The best interests standard of surrogate parental decision making requires parents to give permission for early childhood vaccination that is not medically contraindicated. Parental refusal, therefore, does not have an ethical basis.

Implications for Physicians in Counseling Parents

Evidence-based counseling of parents about early childhood vaccination is an essential component of the informed

permission process.^{9,10} The informed permission process shares with the informed consent process the physician's professional obligation to empower the decision maker with evidence-based information and recommendations. With respect to early childhood vaccination, this means that the physician should explain the nature and purpose of the vaccine and evidence about its effectiveness and minimal risk.⁹ In doing so, the physician should explain the importance of relying on expert scientific and clinical opinion because it is evidence-based and shaped by the commitment in the professional responsibility model to the best interests of the child. In the counseling process, the physician should explain to parents the key components of expert scientific and clinical opinion about childhood vaccination, guided by the 2015 Institute of Medicine report.⁹ Parents should be informed that many websites on early childhood vaccination are not based on expert opinion. The physician should recommend that parents visit the American Academy of Pediatrics website¹⁰ or read the Institute of Medicine report.⁹

Parents should also be informed that the introduction of early childhood vaccination (**Table**) is one of the most important advances in the 20th century on improving the health of infants and children.⁹ Infant and child deaths from complications of preventable, major infectious diseases have decreased dramatically. Based on the evidence, experts indicate that the risk of vaccines is negligible compared with the risk of being infected by one of the childhood infections. The evidence is clear that early childhood vaccinations are effective and have negligible risk. By "negligible risk" we mean that the risks of adverse outcomes are extremely rare and that the risk of infection without vaccination is much higher. Vaccinations, therefore, should be expected to result in net clinical benefit for every child. Any belief to the contrary lacks an evidence base. We, therefore, disagree with Gostin that parental refusal "can have a rational basis."⁴ Parents, therefore, should not be empowered by physicians to refuse early childhood vaccination when it is not medically contraindicated.

The primary purpose of early childhood vaccination is to protect that child from infectious diseases that cause mortality and major morbidity, such as chronic pulmonary disease, and physical and intellectual disabilities, such as those can

Table. Early childhood vaccinations for major infectious diseases

1. Hepatitis B vaccine
2. Inactivated polio vaccine
3. Diphtheria, tetanus, polio (live modified virus)
4. Pneumococcal vaccines
5. Rotavirus vaccine
6. Hepatitis A vaccine
7. Influenza vaccine
8. Measles, mumps, Rubella vaccine
9. Varicella vaccine
10. Meningococcal vaccine

result from encephalopathy. The physician should explain the paramount clinical importance of vaccination for the future life and health of their child and, therefore, strongly recommend vaccination.

When clinically applicable, the physician should also explain the concept of herd immunity and the necessity of achieving herd immunity and that this goal can be safely achieved for the child who is to be vaccinated. The physician should explain the importance of achieving herd immunity for other children who cannot be vaccinated because of medical contraindications. In the absence of herd immunity, the health and life of these other children could be placed in preventable danger. Even though these children are not the children of the parents being counseled, these parents, like all parents and members of a community, have a beneficence-based obligation to prevent harm to vulnerable children that can be safely prevented. The physician has a parallel professional responsibility to these other children, based on the best interests of the child standard of pediatric ethics.

Simply respecting refusal of vaccination in such circumstances is inconsistent with professional integrity. To implement this clinical ethical judgment, the physician should explain that the clear, well-established clinical benefit to the patient and to other children justifies a strong recommendation for vaccination.⁹ Such a recommendation does not interfere with parental autonomy but empowers parents to fulfill their ethical obligations to their own child and other children and, therefore, understand why they are ethically obligated to give permission for vaccination. This is not shared decision making, as it is often understood: nondirective counseling in which the physician offers but does not recommend clinical management. The professional responsibility model of pediatric ethics explicitly rules out such shared decision making about childhood vaccination.

Should the parents continue to refuse the strong recommendation of vaccination, the physician should discharge the legal and ethical obligations of informed refusal. The legal obligation is discharged by informing parents of the risks that they are taking for their child and that these risks can be prevented by vaccination. This disclosure must be documented in detail in the patient's record. The ethical obligation goes further and requires that the physician explore with the parents the bases of their reasoning. The goal should be respectful persuasion, by appealing to the shared commitment to the protection of the child's health and life.¹⁷ The physician should point out how this commitment supports childhood vaccination and ask the parents to reconsider. Taking time during subsequent office visits to continue this exploration of the parents' beliefs and repeated efforts at respectful persuasion is necessary, as a means to demonstrate respect for the parents.

Many parents may not appreciate the history of childhood diseases before modern vaccination. They may, therefore, benefit from learning this history, so that they appreciate that children and their parents no longer fear polio, which affected tens of thousands of children,²¹ pregnant women

do not fear exposure to children who might have measles, and parents do not need to worry that their son might become infertile following mumps infection.

If respectful persuasion fails, it is not respectful of the parents or professionally responsible to remain silent and, thus, implicitly acquiesce to clinical management that is not consistent with the best interests of the child standard as a norm. A more directive approach is required, an approach with which many pediatricians may be uncomfortable but which approach the best interests of the child standard demands. When respectful persuasion has failed, to focus the parents' attention on the gravity of their persistent refusal of vaccination for their child's health, the physician has the professional responsibility to point out to parents, when it is the case, that their beliefs about vaccination are misinformed or false. Blunt talk is unavoidable because there is no indirect or muted way to communicate this reality. Empowering parents to participate in evidence-based shared decision making, therefore, requires this frank disclosure, followed by education to correct such false beliefs. Silence in response to the expression of misinformed or false beliefs⁹ is both disrespectful of the parents and professionally irresponsible preventive medicine.

The physician should also reiterate the ethical obligation of parents to protect other vulnerable children, by preventing their child from innocently becoming a vector for infection. If necessary, the physician should also explain that the parents are inappropriately becoming what the Bioethics Committee of the American Academy of Pediatrics refers to as free riders¹² (gaining benefit of herd immunity without assuming any burden to their child) on the willingness of other parents to accept their responsibility to vaccinate their children. Parents might attempt to justify being free riders by claiming that vaccination does not guarantee immunity. This is true but irrelevant because it holds vaccination to an unrealistic standard of success and exposes the child to a risk that the parents are ethically obligated to prevent.

If, despite education, informed refusal, respectful persuasion, and unvarnished communication do not result in the parents authorizing vaccination, the best interests of the child standard as a norm should guide professional responsibility. Terminating the physician-patient relationship has initial appeal, but is an ethically inappropriate expression of understandable self-interest in no longer having to deal with difficult, time-consuming parents. Terminating the professional relationship would be ethically impermissible abandonment.^{17,22} At the same time, the best interests of the child standard creates the professional responsibility to protect other nonimmunized patients in one's practice. Office visits for patients of these parents should be scheduled to avoid the patient from becoming a vector of infection to other patients. To fulfill this professional responsibility, the response to requests for unscheduled office visits should be scheduling them for the end of the day. If that is not feasible, they should be referred to the emergency department, which has the capacity to provide appropriate infection control measures. The physician should notify the emergency

department of this referral and the fact that the child is not immunized. All of this should be explained to parents as the policy of one's practice, so that they are not surprised by limitations on access to their child's pediatrician based on professional responsibility to protect the health and life of other children in his or her practice and in the community.

If parents remain unpersuaded, their informed refusal becomes child neglect, because they are refusing to authorize evidence-based, effective, and safe preventive care required by the best interests of the child standard as a norm. There is a strict legal obligation to report child neglect to the local child health protective services agency. We propose that the purpose of doing so should be to engage this state agency in further efforts to persuade the parents. Highly intrusive measures, such as removing the child from the home, are not ethically justified, inasmuch as public policy that prohibits school attendance without vaccination would be a far less intrusive and perhaps more effective measure. The police powers of the state include enforcement of the ethical obligation of parents related to the protection of the health of children. State laws that prohibit attendance at pre-school and school, public and private alike, are, therefore, ethically justified by the best interests of the child standard as a minimally intrusive enforcement measure.

Implications for the Physician's Public Statements

The professional responsibility model of pediatric ethics has implications that go beyond clinical practice to cover the physician's public role in making statements about health matters. The model prohibits physicians who are not qualified experts in childhood vaccination to make any public pronouncements about early childhood vaccination and children's health, unless they first become fully informed about the science of vaccination and its clear, established minimal risk and efficacy.^{9,10} That a physician has the opportunity to speak publicly about health does not make that physician an expert on any medical subject. The professional responsibility model, therefore, prohibits physicians from stating publicly that they have refused to authorize vaccination of their own children who lack contraindications because such statements lack an evidence base and, therefore, lack professional integrity. Such statements are medical statements, not personal statements, and are, thus, governed by the professional responsibility model. Physicians, therefore, have the professional responsibility never to make any public statement on health matters that lacks an evidence case because doing so is promulgating junk science and, therefore, reflects professional incompetence. This includes physicians who hold or are seeking public office, in which respect they are held to professional standards that do not apply to elected officials or candidates who are not physicians. One physician holding public office, Senator Paul, has made statements about not having his children vaccinated.⁴ Dr. Benjamin Carson, who is a candidate for the presidential nomination of the Republican Party, stated at the September 16, 2015,

primary debate that "it is true that we are probably giving way too many [childhood vaccinations] in too short a period of time."²³ Dr. Paul agreed: "I ought to be able to spread my vaccines out a bit, at the very least."²³ These statements imply the erroneous view that not vaccinating children who do not have a medical contraindication and that spreading vaccinations out rather than following established schedules are consistent with the professional responsibility of physicians to make clinical judgments about the healthcare of children on the basis of evidence and the best interests of child standard understood as a norm. The Daubert case established that professional medical expert testimony must meet accepted standards of scientific reasoning in clinical practice and research.²⁴ The professional responsibility model of pediatric ethics imposes the same standards on all public statements of physicians about early childhood vaccination of their own children or of their patients. These ethical implications hold, the First Amendment right to free speech of citizens notwithstanding. Being a healthcare professional creates ethical obligations that justifiably constrain physicians' exercise of their Constitutional rights because physicians are not professionally free to promulgate junk science.

Implications for Statements of Policy Makers

The professional responsibility model also has implications for policy makers. Policy makers, including elected officials,²⁵ independently of whether they are physicians, are also ethically bound by the best interests of the child standard as a norm. They, therefore, bear the responsibility to enact and implement public health policy that protects and promotes the health-related interests of children. To prevent health policy from being made in the absence of an evidence base or, worse, incompatible with evidence-based reasoning, or, worst of all, based on unreasoning fear, elected officials and policy administrators should consult qualified experts and make public statements and propose health policy only when they are supported by the best available scientific and medical evidence.^{9,10,18}

Implications for Health Policy

The professional responsibility model of pediatric ethics requires early childhood vaccination policy that allows only for exemptions based on medical contraindications. Mississippi and West Virginia policy meets this ethical standard.²⁶ California has recently eliminated exemptions based on religious or other personal beliefs.²⁷

Conclusions

There is no ethical controversy about professional responsibility and early childhood vaccination. The professional responsibility model of pediatric ethics requires physicians to be vigorously directive in the informed permission and informed refusal processes about parental permission for childhood vaccination. The professional responsibility

model of pediatric ethics also imposes the discipline of scientific reasoning on all public statements by physicians, elected officials, and policy administrators about childhood vaccination, and on health policy regarding childhood vaccination. ■

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