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Adolescent Consent to COVID-19 Vaccination: The Need for Law Reform

Robert S. Olick, JD, PhD[1,2]; Y. Tony Yang, ScD, LLM, MPH[3]; and Jana Shaw, MD, MPH[4]

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With the US Food and Drug Administration's (FDA's) emergency use authorization of the Pfizer-BioNTech COVID-19 vaccine for adolescents aged 12-15 years on May 10, 2021, COVID-19 vaccination is now available to all adolescents aged 12-17 years.[1] Moderna has also applied for emergency use authorization approval for this age group.[1] The Centers for Disease Control and Prevention strongly recommends vaccination of the adolescent population, which comprises approximately 25 million people in the United States.[2] Comprehensive protection is critical to adolescent and population health and is a big step toward a return to "normal life" for young people, including in-person school. Vaccine hesitancy—the reluctance or refusal to choose vaccination—identified by the World Health Organization as a top 10 global health threat, undermines these goals.[3] According to a June 2021 Kaiser Family Foundation COVID-19 poll, 42% of parents with adolescents aged 12-17 years said they had either already vaccinated their children or planned to vaccinate their children, 18% said they would "wait a while to see how it is working," 25% were definitely opposed, and 10% would choose vaccination only if required for school.[4]

Parental vaccine refusal has posed serious challenges to optimal coverage for childhood vaccines and led to outbreaks of measles and pertussis among unvaccinated children and surrounding communities.[5] Similar challenges are likely if parents refuse COVID-19 vaccination for their children, particularly as the more transmissible Delta variant continues to spread and should booster shots be recommended in the future. In response to measles outbreaks, development of COVID-19 vaccines, and vaccine resistance, in December 2020 the District of Columbia enacted a first-of-its-kind law allowing adolescents aged <18 years to give first-person informed consent to vaccines recommended by the Advisory Committee on Immunization Practices and directed development of age-appropriate information sheets for use with health care providers.[6] Recognizing the decisional rights of minors has 2 core components: adolescents' ability to give informed consent and the legal right to decide. Health care providers can and should determine that many adolescents possess the maturity and capacity to give independent consent to COVID-19 vaccination. Both health care providers and adolescents need clear legal guidance for authorizing consent over parental objection. State policy makers should enact laws, or interpret extant law, to provide this guidance.

Legal Background

Who decides whether minors will be protected against vaccine-preventable illnesses creates tension between 2 foundational traditions of American law and policy. A series of early 20th century US Supreme Court decisions established both the constitutionally protected rights of parents and the inherent constitutional authority of the state to provide for public health and welfare. Under *Meyer v Nebraska* (1923)[7] and *Pierce v Society of Sisters* (1925),[8] parents have extensive, constitutionally protected rights to provide for their children's welfare with substantial freedom from government interference. In health care, this authority presumes that parents invariably act in their children's best interests and that children lack autonomy to best decide for themselves. Law largely protects parental rights in health care, making exceptions when parental decisions risk serious harm to the child.

With regard to vaccination, states have inherent police power to provide for public health and well-being and related *parens patriae* authority and responsibility to protect society's most vulnerable members, especially children. The constitutional underpinning of the state's power was first established by the seminal Supreme Court case of *Jacobson*

[1]Center for Bioethics and Humanities, State University of New York Upstate Medical University, Syracuse, NY, USA
[2]Department of Internal Medicine, George Washington University School of Medicine and Health Sciences, Washington, DC, USA
[3]Center for Health Policy and Media Engagement, George Washington University, Washington, DC, USA
[4]Department of Pediatrics, State University of New York Upstate Medical University, Syracuse, NY, USA

Corresponding Author:
Robert S. Olick, JD, PhD, Center for Bioethics and Humanities, State University of New York Upstate Medical University, 618 Irving Ave, Syracuse, NY 13210, USA.
Email: olickr@gmail.com

v Massachusetts (1905) that upheld a local health department's power to require smallpox vaccination to protect the public's health under threat of a $5 fine for noncompliance.[9] Subsequent cases have reaffirmed this basic principle.[10] In *Zucht v King* (1922), the Supreme Court upheld a San Antonio school district's requirement that children be vaccinated against smallpox to attend school.[11] Relying on both police powers and *parens patriae* authority, with advances in vaccine development, states enacted more laws mandating childhood vaccinations for highly contagious illnesses (eg, measles, mumps, rubella) and gradually expanded the list of vaccinations required for school entry. Today, all states and the District of Columbia have mandatory school-age vaccination programs.[12] These programs recognize parental rights to decline vaccination for their children for medical reasons; some states allow exemptions for religious or philosophical reasons.[12]

Law is largely silent on whether minors may independently consent to vaccination[13]; hence, parents generally retain authority to decide for adolescents when vaccines are not mandated. Five states and the District of Columbia clearly authorize independent adolescent consent to general medical care including vaccination,[14] and these laws would apply to COVID-19 vaccination.[14,15] Philadelphia[16] and San Francisco[17] authorize independent adolescent consent to COVID-19 vaccines. In a few states, minors can consent to vaccination for specific conditions, for example, sexually transmitted infections,[13] such as human papillomavirus (HPV; New York),[18] and hepatitis B (Minnesota).[19]

In a range of other circumstances, state laws establish numerous exceptions to parental control that grant minors rights to consent to their own health care. All states grant adolescents broad health care rights based on independent status (eg, emancipation, marriage, living independently). Most target some health issues, for example, emergencies, drugs and alcohol, outpatient mental health, reproductive health, and sexually transmitted infections; the latter overlaps to an extent with minor consent laws for diagnosis and treatment of reportable, contagious diseases. Many states authorize minor consent to general (routine) medical care.[20] By court decision or statute, some states have a "mature minor doctrine" that gives minors rights to self-consent in certain circumstances; some states require that courts make this determination.[20,21] Privacy and confidentiality protections under state and federal laws (eg, the Health Information Portability and Accountability Act) direct health care providers not to share personal information with parents without patient consent in a range of circumstances. For purposes of minor consent, states typically set the minimum age of maturity at 12-16 years, with variation across states and depending on the nature of adolescent health concerns.[20] States that recognize general minor consent including vaccination set the age of consent at 14, 15, or 16 years or specify no minimum age.[14] The age for minor consent to treatment for sexually transmitted infections is 12 in Illinois[22] and 13 in New Jersey.[23]

This patchwork of minor consent laws shares the traditional view that age is an important and clear marker of transition from the legal status of minor to adult and also embraces the contemporary understanding that as children grow into adolescence, they typically develop the requisite maturity and autonomy to responsibly make many personal medical decisions before age 18. Assurances of confidentiality encourage adolescents to seek care they might otherwise avoid because of the sensitive or stigmatizing nature of their health concerns and thereby promote patient and population health. Statutes identify age, education, employment, reasoning, and judgment among indicia of maturity and rely on the professional assessment of health care providers.[20] In clinical practice, health care providers look to these and other factors to determine adolescent maturity and capacity. Health care providers nationally should be legally authorized to make these same judgments and to respect adolescents' moral agency with respect to COVID-19 vaccination.

Capacity to Consent to COVID-19 Vaccination

Maturity and consent capacity are interrelated but also distinct concepts. Assessing adolescent maturity typically considers several factors, including age, stage of development, work, education level, social context, and personal history. Capacity to give informed consent focuses on adolescents' demonstrated understanding and ability to reason about the nature, risks, benefits, and complexity of care, including short- and long-term consequences of treatment options, to make a specific decision.[24,25] Many physicians presume adolescent patients to be capable of making decisions, regularly engage them in development of care plans, and have the experience and skills to make these assessments.[14,26] When patients are about 11-14 years of age, health care providers introduce confidential health visits to patients and parents, allocating private time to counsel adolescents about sensitive matters. Confidentiality encourages adolescents to share personal information,[27] and visits often address adolescent-recommended vaccines (eg, HPV).

Adolescents want to participate in their own health care. In a study of students aged 12 and 13 years, one-third wanted to participate in vaccination decisions; the same number wanted more specific information.[28] Another study found that health care providers generally support minor consent to vaccination at (on average) age 14.[13] Since the World Health Organization declared a global pandemic on March 11, 2020,[29] awareness of the disease, loss, economic hardships, public health measures, school disruptions, isolation, and changes in relationships with family and friends wrought by COVID-19 has been ubiquitous. Early in the pandemic, most people in the United States felt COVID-19 had profoundly affected their lives in many ways.[30] A study of adolescents and young adults aged 14-24 years conducted in March 2020 found "high levels of engagement in learning about the

pandemic." Respondents quickly embraced social distancing and hand washing and expressed concern for the welfare of others, an important sign of maturity.[31] Data from the Centers for Disease Control and Prevention showed that 52% of adolescents aged 13-17 years would choose vaccination.[32] Thousands gave their consent/assent (along with parental consent) to participate in clinical trials, with sharing of essential information including safety, efficacy, risk, side effects, and the purpose of the study.[1]

In the process of obtaining informed consent to COVID-19 vaccination, emergency use authorization fact sheets given to all patients under federal law set forth the requisite disclosures of benefits, risks, and side effects of the COVID-19 vaccine, supplemented by a signed informed consent form. Vaccinators screen for medical contraindications and precautions and provide anticipatory guidance on follow-up, immunity, virus transmission risk, and safe practices when fully vaccinated. The consent process should include information presented in age-appropriate understandable terms (required by the District of Columbia law), with opportunities to ask questions.[24,25] The vaccine is free of charge,[2] and no billing information is sent to parents. Vaccination promotes the physical health of adolescents and prevents the spread of infection to families and communities. It also responds to the widespread pain and anguish of loss, remote learning, separation from friends and peers, and the associated challenges many adolescents have experienced in mental health and psychosocial development.[33,34] As the gateway to return to "normal" life, to pursuit of personal and social interests and life goals, choosing vaccination promotes adolescents' physical and mental health and best interests.[33,35] Compared with adolescent decisions about other familiar health issues, consent to COVID-19 vaccination is straightforward.

Confidential health visits may be especially important for adolescents with vaccine-resistant parents. Children and adolescents typically internalize their parents' values. Breaking from those values can be stressful. Strong disagreement strains family relationships, particularly if parents have a history of conscientious objection to vaccines. Family discord may also occur when parents adopt a cautious wait-and-see attitude, perhaps wanting more safety data with adolescents or full FDA approval.[4,36-38] Health care providers should prospectively engage patients and parents; explore sources of vaccine hesitancy, including apprehensions about safety and side effects, mis/disinformation, distrust of government, and religious, cultural, or political beliefs; and offer opportunities to address questions and concerns, during multiple visits if necessary. Health care providers should always pursue collaborative relationships that value both adolescent and parental autonomy while also advocating vaccination in the best interests of patients. Sensitivity to adolescents' family dynamics and emotional readiness is critical,[25] and health care providers should be prepared to refer adolescent patients to mental health providers when indicated. But when mature adolescent patients make the informed choice for vaccination over parental objection, it is ethically justified to respect this choice, within the bounds of state law.

The Path Forward

Respecting adolescents' autonomous, informed decisions for vaccination is ethical, but health care providers are often unsure whether it is legal. Health care providers are understandably reluctant to accept adolescent consent over parental objection absent express legal authority. They may believe, often correctly, that without express authority, or under conditions of uncertainty, parental consent is the legal default choice or that accepting adolescent consent exposes them to risk of legal liability.[13,21] Some legal scholars counsel that minor consent laws are best construed narrowly and that independent consent requires express or strongly supported legal basis.[21] Thus, adolescent consent to COVID-19 vaccination requires specific legislation. Other scholars contend that minor consent laws can sometimes be construed, such as through regulation, to reflect ethical norms in support of adolescent autonomy.[39] For example, relying on Pennsylvania law that authorizes minor consent to treatment for reportable diseases, the Philadelphia Department of Public Health added COVID-19 to its list of reportable diseases and enacted an emergency regulation to authorize people aged ≥11 years to consent to COVID-19 vaccination.[16] Under a public health emergency order from the City of San Francisco, minors aged ≥12 years can consent to any FDA-authorized COVID-19 vaccine. The order recites that COVID-19 vaccines are considered "general medical care" and that minors aged ≥12 years can consent to "treatment of infectious diseases, including specifically COVID-19," mostly limited to independent minors (status-based consent). (Because the San Francisco order requires health care providers to make reasonable efforts to notify a parent or guardian with opportunity to object and override adolescent consent, the order likely otherwise benefits only those adolescents with persuadable or unavailable parents[17])

Leading voices support the expansion of adolescent rights to choose vaccination. The Society for Adolescent Health and Medicine has urged health care providers and policy makers to consider all legal options to allow adolescent informed consent to vaccinations.[40] The American Medical Association has called for states to comprehensively expand adolescent rights to consent to vaccines.[41] Legal scholars propose setting the presumptive age of minor consent for vaccines at 12-14 years.[14,42] We favor broad expansion of adolescent rights, but this position requires analysis of vaccine-specific issues beyond the scope of this article, such as the complexities of informed consent or implications of HPV education for adolescent sexual behavior.[43] And comprehensive legislation would likely invite political opposition from antivaccination and parental rights groups that distracts from imminent public health concerns and risks costly legislative

delay (all concerns in efforts to establish minor consent to HPV vaccination)[43,44] and may also open established vaccine policy to new challenges.

In the battle against the COVID-19 pandemic, the most expedient path is COVID-19–specific legislation, consistent with the approach of most narrowly drawn minor consent laws. COVID-19–specific legislation recognizes adolescents' moral agency, promotes their best interests, prevents the spread of infection and disease in communities, and saves lives. Lawmakers should expressly sanction adolescent consent over parental objection to authorized COVID-19 vaccines and should set the age of consent at 12-14 years. Legislation should assure confidentiality of this decision, provide legal protection for health care providers who administer vaccination with informed consent, and support age-appropriate guidance for adolescents. Full biologics license approval, recently granted to the Pfizer vaccine for people aged ≥16 years,[45] may be a consideration for policy implementation, but these pandemic times call for swift action to establish the legal framework for independent adolescent consent to COVID-19 vaccines.

Conclusion

Achievement of herd immunity for many childhood diseases and routine parental consent have made vaccination a societal norm and expectation. However, widespread COVID-19 vaccine hesitancy and alarmism poses serious challenges to optimal coverage, putting both adolescents and communities at risk. Following the lead of the District of Columbia, states should enact specific legislation to authorize adolescent consent to vaccination when parental consent is withheld. Policy makers should also explore reasonable applications of existing law to permit adolescent consent to COVID-19 vaccination.

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ORCID iD

Robert S. Olick, JD, PhD https://orcid.org/0000-0001-8500-7196

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