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# Adolescent Consent for Human Papillomavirus Vaccine: Ethical, Legal, and Practical Considerations

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We address ethical, legal, and practical issues related to adolescent self-consent for human papillomavirus (HPV) vaccination. HPV vaccination coverage continues to lag well behind the national goal of 80% series completion. Structural and behavioral interventions have improved vaccination rates, but attitudinal, behavioral, and access barriers remain. A potential approach for increasing access and improving vaccination coverage would be to permit adolescents to consent to HPV vaccination for themselves. We argue that adolescent self-consent is ethical, but that there are legal hurdles to be overcome in many states. In jurisdictions where self-consent is legal, there can still be barriers due to lack of awareness of the policy among healthcare providers and adolescents. Other barriers to implementation of self-consent include resistance from antivaccine and parent rights activists, reluctance of providers to agree to vaccinate even when self-consent is legally supported, and threats to confidentiality. Confidentiality can be undermined when an adolescent's self-consented HPV vaccination appears in an explanation of benefits communication sent to a parent or if a parent accesses an adolescent's vaccination record via state immunization information systems. In the context of the COVID-19 pandemic, which has led to a substantial drop in HPV vaccination, there may be even more reason to consider self-consent. The atmosphere of uncertainty and distrust surrounding future COVID-19 vaccines underscores the need for any vaccine policy change to be pursued with clear communication and consistent with ethical principles. (*J Pediatr 2021;231:24-30*).

ealthy People 2020 set a goal of 80% series completion for the human papillomavirus (HPV) vaccine.<sup>1</sup> The 2019 National Immunization Survey-Teen shows that 54.2% of adolescents aged 13-17 years were up to date with the vaccine series.<sup>2</sup> Although this coverage level represents an incremental increase over 2018, it remains well below the Healthy People goal. Furthermore, HPV vaccine ordering and administration have dropped dramatically during the COVID-19 pandemic.<sup>2-4</sup>

Many structural and behavioral approaches to improving HPV vaccine coverage have been suggested or evaluated, including behavioral interventions targeted to healthcare providers (HCPs) and parents,<sup>5-8</sup> implementation of practice-wide or system-wide changes (eg, provider prompts),<sup>9</sup> and consideration of alternative sites for HPV vaccination (eg, schools, pharmacies, dental offices).<sup>10-14</sup>

An important additional approach for reducing access barriers to HPV vaccination is permitting adolescents to consent for themselves. Given that a low proportion of adolescents complete the HPV vaccine series by their thirteenth birthday, there is a need for catch-up vaccination into later adolescence.<sup>15</sup> Policies allowing older adolescents to consent to HPV vaccination offers a means to facilitate this catch-up.

Multiple dimensions to adolescent self-consent for HPV vaccination include ethical and legal considerations, messaging challenges, potential unintended consequences (eg, the potential to generate an

challenges, potential unintended consequences (eg, the potential to generate an antivaccine backlash), and implementation barriers, as well as questions of whether self-consent would increase HPV vaccination rates and special considerations in the context of the COVID-19 pandemic. Many of the legal and ethical issues associated with adolescent self-consent for HPV vaccination were addressed in previous articles.<sup>16-18</sup> We review the points raised by those articles and also address other critical issues, namely arguments against self-consent and responses to them, impediments to implementation of self-consent, and considerations regarding adolescent self-consent for HPV vaccination in the context of COVID-19.

HCPHealthcare providerHPVHuman papillomavirusIISImmunization information systemSTISexually transmitted infection

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# Legal and Ethical Framework

Informed consent is the active information sharing and decision making process for health care through which a provider engages the patient-and often, in the case of minors, a surrogate decision maker-to discuss the nature of care and its associated benefits, risks, and alternatives, while concurrently assessing patient/surrogate decisional capacity and values. This autonomy-facilitating process has roots in both ethics and law. In caring for adolescents, physicians are instructed to increase patient engagement in, and the direction of, the medical decision making process as the patient matures. This process begins with seeking assent from the patient to the care decided upon by the surrogate decision maker. As the patient ages, the clinician may determine that the patient has developed the capacity to independently navigate the informed consent process for a service such as HPV vaccination, which offers significant benefits to the patient and few risks. Although ideally, the adolescent and the parent/ surrogate decision maker would agree that vaccination is in the patient's best interest, in circumstances where the parent refuses to grant consent or is unavailable, clinicians might not feel comfortable delivering care to the minor without clear legal as well as ethical approval.<sup>19-21</sup>

The lack of authority for minors to consent is most often a barrier to vaccination during routine health care visits when parents are absent and during confidential adolescent health care visits.<sup>22</sup> Additional situations may arise when an adolescent wants to be vaccinated but a parent objects.<sup>23</sup> Adolescent health professionals recommend that to overcome such barriers, minor adolescents should be able to consent for vaccination, consistent with legal requirements, and that all legal options should be explored.<sup>16</sup> Implementing this recommendation would require expansion of the current legal framework.

State laws determine whether adolescent minors can consent for vaccination. Several state law provisions are relevant. Few state laws expressly authorize minors to consent for vaccination; however, other laws may enable them to do so, for example, laws allowing minors who have a certain status-such as those of a certain age, emancipated minors, or homeless youth-to consent for health care generally; laws allowing minors satisfying specific "mature minor" criteria to consent for their own health care; and laws allowing minors to consent for prevention of sexually transmitted infections (STIs) or for prevention of reportable, infectious, contagious, or communicable diseases (Table I).<sup>16</sup> Two states have explicitly authorized minors to consent for a specific vaccine: Minnesota allows minors to consent for hepatitis B virus immunization,<sup>24</sup> and New York State Department of Health regulations permit sexually active minors to consent to HPV vaccination "during confidential sexual and reproductive health care visits without consent or knowledge of the parent or guardian."25 The City of Philadelphia has authorized minors to consent for immunization to prevent "reportable disease, infection, or

Table I. Existing laws authorizing minors to consent to vaccination\*

Laws allowing minors with a certain status to consent to health care including vaccination

Status	Notes				
Minors who have attained a specific age	For example, 14, 15, or 16 y				
Emancipated minors "Mature" minors	Usually requires court order of emancipation Includes minors who meet statutory criteria of capacity to give consent				
Minors living apart from parents	May include homeless or runaway youth				
Minor parents Married minors	May authorize consent for self, for child, or both Married minors also considered emancipated				
Laws allowing minors to consent to type of service encompassing vaccines					
Service	Notes				
Specific vaccine Prevention of sexually transmitted infections Prevention of reportable, infectious, contagious,	For example, MN (hepatitis B) <sup>†</sup> , NY (HPV) <sup>‡</sup> Generally also allows consent for diagnosis and treatment Generally also allows consent for diagnosis and treatment				

\*Laws vary from state to state. Each of the listed categories is represented in the laws of one or more states; none is found in the laws of every state. †Minnesota Statutes § 144.3441.

‡NY Comp Codes R & Regs tit 10, § 23.4.

condition.<sup>26</sup> Thus, under the existing legal framework, whether an adolescent minor may consent for vaccination depends on several factors: the age and capacity of the adolescent, the locality in which the adolescent is seeking care, the legal status of the adolescent, and the disease for which vaccination is being administered.

Allowing minor adolescents with decisional capacity to consent to HPV vaccination advances important health care- and public health-related ethical principles.<sup>17,18</sup> Such policies facilitate autonomy, advancing the ability of adolescents to exercise their agency,<sup>17</sup> and promote flourishing, enhancing adolescents' collective opportunity to live lives free from a currently common illness-causing virus. They are grounded in health justice and equity, removing a structural barrier to health (parental refusal of a recommended public health intervention) faced by a vulnerable population (adolescents, particularly adolescents living in households that do not believe their children should receive safe, effective, recommended preventive care). They recognize our interdependence and solidarity in the face of a significant health risk, as HPV vaccination promotes both individual health and community health, preventing the sexual transmission of a virus connected with cancer and other adverse health effects and reducing the community presence of both the virus and the maladies to which it contributes. Finally, such policies communicate a state's commitment to supporting safe, effective, evidence-grounded public health policy in furtherance of socially beneficial public health goals.

Increasingly, state legislatures are considering proposals facilitating minor adolescent consent to vaccination generally, and also encompassing HPV vaccination. In 2019 and 2020, such bills were introduced in at least 5 state legislatures and in the District of Columbia (Table II). None of these bills became law, but an analysis of them suggests an ethical framework for laws expanding minor consent to vaccination. Specifically, 4 of the 6 bills expressly included language limiting self-consent to those adolescent minors with capacity for informed consent. Maryland<sup>27</sup> and Georgia<sup>28</sup> proposed bills to allow adolescents aged ≥16 years to consent to vaccination without parental consent, although the Maryland bill also would have required a discrete informed consent assessment by the health care practitioner. New York's bill<sup>29</sup> also required a health care practitioner to determine that the adolescent possessed the capacity to consent; however, its bill would have allowed teens aged  $\geq 14$  years to make such decisions. New Jersey's bill<sup>30</sup> would have deemed adolescents aged ≥14 capable of making vaccination-related decisions and authorized such vaccinations to be administered by health care practitioners or properly authorized pharmacists, increasing opportunities for teens to access such services. Under both the Virginia<sup>31</sup> and the District of Columbia<sup>32</sup> bills, there were no formal age limits for a minor to be deemed capable of making informed vaccination-related decisions by a health care practitioner.

# **Arguments Against Self-Consent and Responses to Those Arguments**

An argument against allowing minors to consent for their own health care, including vaccinations such as HPV vaccine, is that it contravenes the rights of parents. Generally, parents have the right to make medical decisions for their minor children. However, the requirement of parental consent has not been allowed to stand in the way of adolescent minors receiving care that is essential for their own health and protection of public health (eg, sexual health, mental health, substance use). In these circumstances, exceptions historically have been carved out in the laws of most states. At the same time, adolescent health professionals encourage minors to involve their parents even when it is not legally required, and many adolescents do so voluntarily.<sup>33</sup>

Facilitating adolescent consent through changes to state laws likely will draw the attention and opposition of antivaccination and parental rights groups, who often base their arguments on religious beliefs, moral assertions, and presumed safety concerns. These groups have increased their political and social media presence over the past 20 years and have been significant contributors to rising rates of vaccine hesitancy in the US and globally.<sup>34</sup> Proposed revisions to state child vaccination rules regularly provoke significant lobbying efforts by vaccine-resistant interest groups, as well as occasional lawsuits challenging such rule changes. However, many states have persisted in the face of such pressures, adopting new laws or regulations that increase public health protection against vaccine-preventable illnesses, despite claims of infringement on parental and other fundamental rights.<sup>35</sup> To foster confidence in evidence-grounded vaccine policy, jurisdictional immunization programs should develop and disseminate tools for immunization program staff and HCPs to address these concerns and challenges should they arise. Furthermore, although it is important to maintain public trust in vaccines, the decision as to whether adolescents should be allowed to self-consent for vaccination should not be determined by the desire to avoid criticism by antivaccine or parental rights activists.

Another argument advanced in opposition to self-consent is that adolescents lack the necessary decision making capacity. However, an average adolescent, especially by middle adolescence, likely has the capacity to make independent informed decisions about HPV vaccination.<sup>21,36</sup> A determination of decisional capacity requires that a HCP assess and conclude that the minor adolescent can demonstrate and communicate that they understand the clinical choice before them, appreciate the benefits and risks that the service might present, and understand how their treatment choice connects with their health and personal goals. These standards vary dependent on the complexity of the care to be delivered. By the time patients reach adolescence, clinical standards recommend that they at least be engaged in, and assent to, most decisions about their care. Regarding the capacity to make decisions related to HPV vaccination, the near- and long-term benefits and risks associated with receiving the vaccine are likely within the reasoning ability of most adolescents. A 2014 survey of clinicians who treated adolescent patients found that they generally felt comfortable with patients aged ≥14 years making decisions about HPV

Table II. Proposed legislation authorizing minors to consent to vaccination*						
			Clinical determination of	Scope of consent authorized		
State	Bill, year proposed	Minimum age	capacity to consent explicitly required	Any required or listed vaccines including HPV	Any CDC or ACIP recommended vaccines	
DC	B 23-0171, 2019	Any age	X		Х	
GA	HB 615, 2019	16 y		Х		
MD	SB 135, 2020	16 y	Х		Х	
NJ	S 3835, 2020	14 y		х		
NY	S 4244C, 2019	14 y	х		х	
VA	SB 104, 2020	Any age	х		х	

\*None of the bills had been enacted as of August 2020.

vaccinations.<sup>22</sup> However, as current HPV-related Vaccine Information Statements are written at a 10th grade or higher reading level, such materials should be simplified for use with adolescent patients.

A long history of exceptions to the basic rule requiring parental consent for minors' health care has evolved to further the public health and the health of adolescents. These exceptions have allowed minors to consent to their own care in a variety of circumstances and to receive that care confidentially. They are based on ethical principles and on decades of research findings documenting that without confidential access to critically important services and the ability to give their own consent, adolescents will forego or delay care.<sup>16,37</sup>

Although the focus of this article is on the ability of adolescents to consent to vaccination without parental involvement in that decision, this does raise an additional concern. Situations may arise in which a parent wants their adolescent to receive the HPV vaccine but the adolescent disagrees. A competent adolescent aged ≥18 years would have a clear right to decline. The right to refuse for an adolescent minor has not been explicitly addressed as a legal matter in the vaccine context. As an ethical matter, however-for both clinical care and research-even when a parent has the legal authority to consent, obtaining the adolescent's assent is important, even essential, in furtherance of the principle of respect for persons.<sup>17</sup> Little is known about the right of adolescents to decline assent or refuse consent in clinical practice, particularly with respect to refusal of vaccination. Examination of this topic is outside of the scope of this article but should be considered in future ethical and practical examinations of adolescent vaccination practices.

Together with the legal and ethical issues, it is worth considering whether granting adolescents the right to selfconsent will measurably increase HPV vaccination coverage. Unfortunately, little data are available to assess the impact of adolescent self-consent. However, the results of a national study of adolescent HCPs suggested that the lack of selfconsent laws would prevent many providers from vaccinating unaccompanied minor adolescents.<sup>22</sup> Since 2007, Philadelphia has allowed adolescents aged 11-17 years to consent to their own HPV vaccination,<sup>26</sup> but it is not clear what effect this policy has had on vaccination rates. Prior research has documented adolescents' willingness and interest to be more engaged in vaccination decisions<sup>38,39</sup>; however, without clear logistical support for this process, including appropriate HCP education on its legality, it is difficult to determine how to bridge that intention-to-action gap. The degree to which self-consent laws are effective likely depends on communication of those laws to HCPs and adolescents, and assurances that HPV vaccination for self-consenting adolescents can be done at low cost and confidentially.

#### Impediments to Implementation

In some settings, such as STI clinics in states in which adolescent self-consent is allowed during provision of these services (eg, New York), there is a clearly defined population of adolescents who may be able to self-consent. Providers and staff in these settings need to be aware of the potential for adolescent self-consent and how to navigate logistical challenges. Given that research studies have shown that a provider recommendation is the strongest predictor of vaccine receipt,<sup>40</sup> providers in these setting should make the same strong recommendation for HPV vaccination to adolescents, at all clinical encounters, as they would to the parents of adolescents.

Logistical considerations for self-consent include adolescents' awareness of the need for vaccines<sup>38,41</sup> and of their right to self-consent. Although adolescents' knowledge and attitudes about HPV vaccination have been studied, little is known about their perceptions of self-consent in localities that allow this. Traditionally, health communications campaigns for adolescent vaccination have directed their messages at parents, even though some adolescents express a desire to be involved in the decision-making process.<sup>38,39</sup> Although vaccination is not specifically mentioned in the National Health Education Standards,<sup>42</sup> methods to effect disease prevention, skills to identify and evaluate healthrelated information, and development of decision-making and self-advocacy are called out for students in grades 6-8.<sup>42</sup> The inclusion of specific vaccination-related education in health education programs should be evaluated, with standards for inclusion of this information developed and promulgated alongside other health promotion activities.

Additional logistical issues arise in other settings, such as pharmacies. State-level laws govern what vaccines can be given, and to whom, by pharmacists. A recent Department of Health and Human Services amendment to the PREP Act for the COVID-19 response expands the ability of pharmacists to vaccinate children; however, this amendment focuses on parental consent for vaccination without addressing issues of adolescent self-consent. Research indicates that pharmacists do not always perceive themselves as having the skills or training to address novel topics that are presented to them (eg, expedited partner therapy for sexually transmitted infection treatment).<sup>43</sup> For vaccination, specifically, numerous barriers exist to effective vaccination of adolescents, including lack of involvement in the Vaccines for Children program, reporting to state immunization registries, and low demand for noninfluenza vaccines in pharmacy settings.<sup>44</sup> Adding in state-level guidance around self-consent potentially puts another level of burden on pharmacists, and the impact of this, including pharmacists' willingness to add this to their responsibilities, needs to be evaluated.

Even if adolescent minors are legally allowed to consent for HPV and other vaccines, concerns about confidentiality are likely to persist. From an adolescent's perspective, part of the value of self-consent is the potential for receiving the services confidentially. Major logistical hurdles may arise in relation to billing and insurance coverage, and with respect to electronic health records, if uncommon but serious adverse events occur during the vaccine delivery process.<sup>45,46</sup> Although such events are rare, providers should be prepared to hold contingency planning discussions with their patients, given these events' potential significant impact on the ability to protect patient autonomy and confidentiality. When services are billed through insurance, particularly private insurance, the claims routinely result in the issuance of explanations of benefits and other communications that breach confidentiality for this medical action.<sup>46</sup> The potential for these breaches is less of a concern with Medicaid, because explanations of benefits would not be sent routinely. Although some protection is available under the HIPAA Privacy Rule and several states have new laws to address this problem, it remains a significant challenge.<sup>47</sup>

In addition to the billing issues described above, immunization records can be obtained from state immunization information systems (IIS) or from schools as part of their immunization verification process, providing another possible avenue for parents to identify if their adolescent received HPV vaccination without parental consent. State IIS are not typically configured to allow restriction of information about vaccinations based on who consented. The impact of a parent discovering that an adolescent child received HPV vaccine without parental consent is unknown, but may be problematic, particularly if a parent opposes vaccination.

# **HPV Vaccination and Self-Consent in the Context of the COVID-19 Pandemic**

Should the COVID-19 pandemic trigger reconsideration of efforts to promote adoption of rules promoting the rights of adolescents to consent to HPV vaccination? Public trust is critical to the success of health care and public health initiatives.<sup>48</sup> Although the government has been granted broad authority to protect the public's health, especially at the state and local levels, states must balance the execution of those duties against concerns that rash or overly strong application of that power may result in lasting public distrust. Furthermore, it is not yet clear what effects national, state, and local COVID-19 response efforts, including the testing and potential approval of a COVID-19 vaccine, will have on trust in other public health initiatives, including adolescent immunization.

Despite these concerns, it seems unwise to forego pursuing public health prevention policies that advance clear public health and ethical goals.<sup>49</sup> Although questions of efficacy and safety may remain concerning a potential COVID-19 vaccine—especially as such issues pertain to children, who have not yet begun to be enrolled in COVID-19 vaccine trials—the safety, efficacy, and benefits of adolescent vaccination against HPV are well documented over years of global implementation.<sup>50-52</sup> There has been a large drop in routine vaccination, including HPV vaccination, in 2020 due to the COVID-19 pandemic, relative to the same time period in 2019.<sup>4</sup> Given that some parents see HPV vaccination as "optional" or "less important" relative to other routine childhood and adolescent vaccines, it is critical that all potential avenues for HPV vaccination be utilized to get adolescents up to date.<sup>3</sup> In locations where adolescent self-consent is allowed for HPV vaccination, this provides a path forward to improve vaccine coverage during the COVID-19 pandemic. However, it needs to be clear where these vaccines can be given (eg, which states allow pharmacists to administer HPV vaccine with adolescent self-consent) and to highlight this in local health communications programs.

## Conclusions

Numerous research opportunities exist to understand the potential for adolescent self-consent for HPV vaccination to improve vaccine coverage. First, in settings where this is allowed, we need to understand the perspectives of HCPs and staff in promoting and providing vaccinations to adolescents without parental consent. Second, it is important that the concerns of parents regarding their adolescents getting vaccinated without parental consent be evaluated. These concerns may relate to HPV vaccine being viewed primarily as an STI vaccine, worries about vaccine safety, personal beliefs about the value of vaccines, and/or parental rights issues. There are potential repercussions to adolescents for taking this step. These risks should not be minimized and should be better understood. Third, we need to achieve a better understanding of logistical barriers, such as Vaccines for Children participation, IIS data management, and vaccine supply, particularly among non-primary care providers (eg, public health clinics, STI clinics, pharmacies) where adolescents may seek vaccination.

We have argued that opportunities exist for expanding access to HPV vaccine for adolescents through self-consent in a manner grounded in ethical principles and consistent with public health priorities. However, effective implementation of self-consent requires support through existing and new state laws, protections to ensure confidentiality across vaccine providers and insurance types, and clear communication to HCPs and adolescents that self-consent is permitted. HCPs also may need training on how to put confidentiality protections in place and encourage adolescents to take an active role in vaccine decision making. We have focused primarily on HPV vaccination, but many of the principles apply to other adolescent vaccines as well. However, HPV vaccine prevents a STI, which distinguishes it from the other adolescent vaccines and allows it to be considered as part of broader permissions for adolescents to selfconsent for STI prevention services. ■

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