${\small \mathsf{CLINICAL}} \ {\small \mathsf{REPORT}} \ {\small \mathsf{Guidance}} \ {\small \mathsf{for}} \ {\small \mathsf{the}} \ {\small \mathsf{Clinician}} \ {\small \mathsf{in}} \ {\small \mathsf{Rendering}} \ {\small \mathsf{Pediatric}} \ {\small \mathsf{Care}}$ 

American Academy of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN<sup>™</sup>

# Strategies for Improving Vaccine Communication and Uptake

Sean T. O'Leary, MD, MPH, FAAP,<sup>a</sup> Douglas J. Opel, MD, MPH,<sup>b</sup> Jessica R. Cataldi, MD, FAAP,<sup>a</sup> Jesse M. Hackell, MD, FAAP,<sup>c</sup> COMMITTEE ON INFECTIOUS DISEASES; COMMITTEE ON PRACTICE AND AMBULATORY MEDICINE; COMMITTEE ON BIOETHICS

Vaccines have led to a significant decrease in rates of vaccinepreventable diseases and have made a significant impact on the health of children. However, some parents express concerns about vaccine safety and the necessity of vaccines. The concerns of parents range from hesitancy about some immunizations to refusal of all vaccines. This clinical report provides information about the scope and impact of the problem, the facts surrounding common vaccination concerns, and the latest evidence regarding effective communication techniques for the vaccine conversation.

After reading this clinical report, readers can expect to:

- 1. Understand concepts and underlying determinants of vaccine uptake and vaccine hesitancy.
- 2. Understand the relationship between vaccine hesitancy and costs of preventable medical care.
- 3. Recognize and address specific concerns (eg, vaccine safety) with caregivers when hesitancy is present.

## VACCINE UPTAKE: DEFINITIONS AND UNDERSTANDING COMMON CAUSES OF VACCINE HESITANCY

It is critical to be clear about the terms used when discussing vaccine uptake. A helpful approach is to categorize terms within the attitudes, intentions, and behaviors framework. Vaccine attitudes signify how one thinks and feels about vaccination.<sup>1</sup> Vaccine attitudes shape vaccine intentions, which reflect one's willingness to act on these attitudes. Vaccine intentions, in turn, shape vaccine behavior, which comprises the actions one takes with respect to vaccination.

Vaccine confidence, which describes the belief that vaccines are safe, effective, and part of a trustworthy medical system,<sup>2–4</sup> is a vaccine attitude. Vaccine hesitancy, a motivational state of being conflicted about, or opposed to, getting vaccinated, is a vaccine intention. And vaccine uptake, defined as receipt of a vaccine, is a vaccine behavior. Barriers

## abstract

<sup>a</sup> Department of Pediatrics, University of Colorado School of Medicine, Aurora, Colorado; Adult and Child Center for Outcomes Research and Delivery Science (ACCORDS), University of Colorado School of Medicine/ Children's Hospital Colorado, Aurora, Colorado; <sup>b</sup> Treuman Katz Center for Pediatric Bioethics and Palliative Care, Seattle Children's Research Institute; Department of Pediatrics, University of Washington School of Medicine, Seattle, Washington; and <sup>c</sup> Department of Pediatrics, New York Medical College, Valhalla, New York

All authors contributed to conceptualizing the work; participated in drafting, reviewing, and revising the manuscript; and approved the final manuscript to be published.

This document is copyrighted and is property of the American Academy of Pediatrics and its Board of Directors. All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors. The American Academy of Pediatrics has neither solicited nor accepted any commercial involvement in the development of the content of this publication.

Clinical reports from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, clinical reports from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

DOI: https://doi.org/10.1542/peds.2023-065483

Address correspondence to Sean T. O'Leary, MD, MPH, FAAP. E-mail: seanolearymd@gmail.com

**To cite:** O'Leary ST, Opel DJ, Cataldi JR, Hackell JM; American Academy of Pediatrics, Committee on Infectious Diseases., Committee on Practice and Ambulatory Medicine, Committee on Bioethics. Strategies for Improving Vaccine Communication and Uptake. *Pediatrics*. 2024;153(3):e2023065483

000 005 (00 Jr

to accessing vaccines as well as intentional vaccine refusal and delay are two important predictors of vaccine behavior.

Vaccine hesitancy may result in a range of behaviors from refusal of all vaccinations to receipt of all recommended vaccinations while still having concerns about vaccinations.<sup>1,5,6</sup> The Centers for Disease Control and Prevention (CDC) National Immunization Survey found that 20% of US parents reported that they were "hesitant about childhood shots" in 2019.7 Several frameworks for categorization of parents with respect to their vaccine attitudes, intentions, and behaviors have emerged with an example shown in Table 1.8 A small proportion of parents (1% to 3%) refuse all vaccines and may have more fixed beliefs and attitudes about vaccines.<sup>5,9-12</sup> A Vaccine Safety Datalink (VSD) study confirmed that most children received early childhood vaccinations on time (68.4% for children born in 2017) and noted that consistently receiving fewer than the recommended number of vaccines at each visit was more common (2.04%) than the small but increasing number of children who received no vaccines in the first 2 years of life (0.35% in 2004 to 1.28% in 2017).<sup>13</sup> On-time routine vaccination decreased in the years immediately after the coronavirus disease 2019 (COVID-19) pandemic<sup>14-17</sup>; however, it is uncertain whether this decrease was more related to missed well-visit appointments rather than changes in vaccine hesitancy during the pandemic. Some US and Canadian surveys have shown that vaccine hesitancy has not changed significantly since the onset of the pandemic.<sup>18-20</sup> In contrast to the small number who adamantly refuse any vaccine, the majority of hesitant parents likely have some ambivalence toward vaccination decisions and many may be receptive to information and guidance about routine childhood vaccines that improve their confidence and uptake for their children.

A World Health Organization framework organizes determinants of vaccine hesitancy into contextual, individual and group, and vaccine factors (Table 2).<sup>3</sup> At the contextual level, both access to trusted sources of vaccine information and the spread of misinformation may influence beliefs about vaccines and the diseases they prevent. Individual and group preferences for "natural" or "organic" approaches to health are also associated with vaccine hesitancy,<sup>21–24</sup> and these preferences often overlap with distrust for health care professionals and medical systems.<sup>22–25</sup> Psychological factors underlying vaccine attitudes include valuing autonomy, conspiratorial thinking, and cognitive biases in how people weigh probabilities and present and future risks.<sup>26–29</sup> In contrast, social norms can help promote vaccine uptake.<sup>30–32</sup> Receiving a vaccine is also strongly associated with perceived disease risk or susceptibility.<sup>33</sup>

Refusing a vaccine, conversely, may be associated with a lower perceived disease risk and has been linked to increased risk of diseases like measles, pertussis, and pneumococcal infection at the individual and community level.<sup>34–37</sup> Geographic clustering of vaccine refusal further increases the risk of communicable disease outbreaks in certain communities even when vaccination rates at a state or national level remain high overall.<sup>36,38–40</sup> For example, large measles outbreaks in the United States in the 2010s frequently occurred in undervaccinated communities with shared religious and cultural beliefs.<sup>41–46</sup>

Disruption to routine pediatric vaccination during the COVID-19 pandemic has left many children vulnerable to vaccine-preventable diseases and more locations susceptible to outbreaks in the United States and around the world.<sup>47-50</sup> Although evidence remains inconclusive, <sup>51-54</sup> disease resurgence may help bolster vaccine uptake, and media coverage of recent measles outbreaks has been associated with more provaccine communication and positive parental vaccine attitudes.<sup>51,53-56</sup> In contrast, pediatric COVID-19 vaccine uptake has been slow as parents consider a new vaccine for a new disease amid ongoing spread of both disease, evolving recommendations, and misinformation. COVID-19 is a reminder that disease prevalence is only one of many factors that contribute to vaccine acceptance.

Distrust of health systems based on historic and ongoing discrimination and inequitable access to care are intertwined challenges that contribute to racial and ethnic disparities in vaccine uptake.<sup>57,58</sup> Although there has

TABLE 1         Example Archetypes of Pa	arental Attitudes, Intentions, and Behaviors Toward Vaccines <sup>5,11</sup>
Example Archetypes	
Immunization supporter	Parents recognize the importance of vaccines and vaccinate their children. Parents generally have a strong relationship with their health care provider or have strong trust in health care systems.
Go along to get along	Parents do not question vaccines and generally vaccinate their children but may lack a detailed knowledge of vaccines.
Cautious acceptor	Parents may have minor concerns about vaccines but ultimately vaccinate their children.
Fence-sitter	Parents have significant concerns about vaccines. Parents may be knowledgeable about or have spent time thinking about vaccines. Parents may vaccinate their child with some or all vaccines or may refuse or delay vaccines. Parents may not demonstrate trust in their health care provider regarding vaccine information.
Refuser	Parents refuse all vaccines for their child. Their reasons for refusal may include distrust in the medical system, safety concerns, and religious or other personal beliefs.

2

TABLE 2 Determinants of Vaccine Hesitancy Matrix (World Health Organization) <sup>3</sup>		
Determinants		
Contextual influences: influences from historic, sociocultural, environmental, health, system or institutional, economic, or political factors	<ul> <li>Communication and media environment;</li> <li>influential leaders, immunization program gatekeepers, and anti- or provaccination lobbies;</li> <li>historical influences;</li> <li>religion, culture, gender, or socioeconomic;</li> <li>politics or policies;</li> <li>geographic barriers;</li> <li>perception of the pharmaceutical industry</li> </ul>	
Individual and group influences: influences from personal perception of the vaccine or influences of the social or peer environment	<ul> <li>Personal, family, and/or community members' experience with vaccination, including pain;</li> <li>beliefs, attitudes about health and prevention;</li> <li>knowledge and awareness;</li> <li>health system and providers—trust and personal experience;</li> <li>risk and benefit (perceived, heuristic);</li> <li>immunization as a social norm versus not needed or harmful</li> </ul>	
Vaccine or vaccination-specific issues: Directly related to vaccine or vaccination	<ul> <li>Risk and benefit (epidemiologic and scientific evidence);</li> <li>introduction of a new vaccine or new formulation or a new recommendation for an existing vaccine;</li> <li>mode of administration;</li> <li>design of vaccination program or mode of delivery (eg, routine program or mass vaccination campaign);</li> <li>reliability and/or source of supply of vaccine and/or vaccination equipment;</li> <li>vaccination schedule;</li> <li>costs;</li> <li>the strength of the recommendation and/or knowledge base and/or attitude of health care professionals</li> </ul>	

been progress in reducing racial, ethnic, and socioeconomic disparities in childhood vaccination coverage,<sup>59</sup> the COVID-19 pandemic made clear how much work is vet to be done.<sup>60,61</sup> Solutions to reduce disparities and promote vaccine uptake must build trust, improve access to care and access to information for all communities, increase diversity and representation among the ranks of scientists and health care professionals,<sup>62</sup> and acknowledge the contribution of structural and interpersonal racism to health disparities. Promising approaches include partnering with trusted messengers to promote vaccination and community engagement to understand barriers to vaccine uptake and to build on existing sources of information and connection.<sup>32,63</sup> Vaccine conversations with parents from historically minoritized groups may also require more explicit acknowledgment of the medical mistreatment and exclusion experienced by these groups and the damaging effect this has had on trust in medical and public health authorities.

## THE FINANCIAL IMPACT OF VACCINE REFUSAL

When confidence in vaccines is lost, the effects are widespread. In addition to impacts on child and public health, medical practices, and the physician-parent relationship (addressed later in the Policies section), there are significant economic costs associated with vaccine refusal. The financial impacts of vaccine refusal and delayed vaccination of children fall in 4 groups: (1) society, which shoulders the added costs of dealing with the impact of vaccine-preventable diseases; (2) individual patients and families, who face the costs associated with caring for a person with illness; (3) payers, both private and public, who bear the costs associated with providing care; and (4) pediatricians and other pediatric clinicians, who are faced with the costs of extended discussions about vaccine safety and efficacy in their daily workflow. Although these costs are not necessarily an argument for vaccinating an individual child, they do have an impact on families and society as a whole and need to be acknowledged.

#### **Societal Costs**

The occurrences of many vaccine-preventable diseases are reportable events,<sup>64</sup> triggering a public health response aimed at determining their origin as well as their potential spread. This reporting is often followed by the rapid implementation of large-scale public health interventions, including disease surveillance, communication, and vaccination programs. The costs of this response are borne by public health agencies tasked with disease investigation and control, usually local and state health departments; ultimately, because these are government entities, these costs are borne by taxpayers.

In the 2018 to 2019 measles outbreak centered in New York City and eventually spreading to surrounding counties, in which 85% of the patients contracting measles were unvaccinated, the 1-year cost for the response (not including

vaccination programs) reached \$8.4 million,<sup>46</sup> which was paid with taxpayer funds. Similar impacts occurred in other outbreaks of measles<sup>65–68</sup> and mumps.<sup>69</sup> These unexpected and unbudgeted costs can strain the resources of local and state public health departments tasked with containing them and use funds that could otherwise be spent on other public health projects.

## **Individual Costs**

When a child is ill and cannot attend their usual school or child care setting, in addition to the cost to the child in terms of missed educational opportunity, parents often must miss work to provide care. Although this is the case with any childhood illness, these are avoidable indirect costs when the illness is vaccine-preventable. In the New York City measles outbreak, 81% of infected individuals were 18 years or younger, with a median age of 3 years,<sup>46</sup> implying a significant amount of missed work and lost income for these families. The cost may extend beyond families with an infected child to those whose children have been exposed or even to entire classrooms or schools in the event of an outbreak. This burden tends to fall disproportionally on populations that are already underresourced and lack access to alternative care arrangements and, thus, has a proportionally greater impact on family finances in these groups.

#### **Payer Costs**

The direct cost:benefit ratio of vaccination programs has been estimated to be at least 1:3 (1:10 if indirect costs are considered),<sup>70</sup> suggesting that payers will spend \$3 to provide care for every \$1 not spent on vaccination. Although this increased expenditure is, in the end, also funded by society, the immediate impact is on payers, including employers who self-insure and publicly funded programs such as Medicaid, with a net increased cost overall attributable to each missed vaccine dose. In addition, immunizations missed because of refusal will impact a payer's Healthcare Effectiveness Data and Information Set (HEDIS) scores, which can have an impact on the payer's marketing and profitability.

## **Pediatric Practice Costs**

4

Pediatric practices may incur costs when dealing with families who refuse vaccines for their children in 3 ways. First, when an unvaccinated patient presents to the practice with symptoms that are later diagnosed as a vaccine-preventable disease, practices must implement containment procedures, including contact tracing, enhanced personal protective equipment and sanitation procedures, and workflow changes that may affect the volume of patients who may be seen and the precautions needed to see them. These costs are not insignificant.<sup>71</sup>

Second, under value-based care models, pediatricians may receive a significant part of their payments based on performance metrics, one of which is completion of childhood and adolescent immunizations. Current pay-forperformance models do not recognize the impact of vaccine refusal on pediatricians' metrics, which can lead to reduced payments despite pediatricians' best efforts.

Finally, pediatricians incur added costs associated with the time needed to counsel parents who demonstrate vaccine hesitancy. Pediatricians counsel their patients and families about vaccines as a regular part of practice and as required by the National Childhood Vaccine Injury Act of 1986.<sup>72</sup> More than half of pediatricians surveyed in 2010 spent between 10 and 19 minutes counseling parents about vaccines and almost 1 in 10 spent more than 20 minutes, often several times per day.<sup>73</sup> Payment to pediatricians for this counseling is included in the payment for vaccine administration.<sup>74</sup> However, payment for counseling requires that a vaccine actually be administered at the time the counseling is performed, so counseling and discussion with parents who refuse a vaccine is uncompensated. Effective December 1, 2021, however, the Centers for Medicare and Medicaid Services has implemented a policy that counseling for the COVID-19 vaccine will be covered by all Medicaid plans, and that, moving forward, all vaccine-counseling visits (whether a vaccine is administered) for childhood vaccines will be covered under the Early and Periodic Screening, Diagnostic and Treatment program.<sup>75</sup> States are implementing this regulation with different requirements, but the eventual impact will be to reduce noncompensated counseling time for pediatricians. Adoption of this policy by private insurers is uncertain, however, so when a pediatrician spends time counseling a privately insured patient or parent and the vaccine is ultimately refused, there is, as yet, no way to be compensated for the time and effort spent in that counseling. This extra uncompensated time negatively impacts the office workflow, serves to reduce the number of patients a physician can care for during a clinic session, and contributes to the misconception that physicians are financially incentivized to ensure that vaccines are administered. Further, close to half of pediatricians have reported that parental requests to "spread out" vaccines decreased their job satisfaction<sup>76</sup>; these requests also have the potential to increase the rate of moral distress,<sup>77</sup> which can lead to burnout,<sup>78</sup> adversely impacting the pediatric workforce. Bringing children in multiple times for families who choose to "spread out" vaccines can also negatively impact other office staff, such as nurses, and result in logistical and scheduling burdens.

#### **VACCINE SAFETY AND STRATEGIES TO ADDRESS CONCERNS**

Among parents who refuse or express hesitancy about vaccines, safety has consistently been shown to be a top concern.<sup>5,9,73,79</sup> Therefore, it is important for pediatricians and other clinicians who care for children to have knowledge of the process for emergency use authorization and vaccine licensure, vaccine safety, and vaccine safety monitoring to address parents' questions and concerns. Because vaccines are generally given to healthy individuals to prevent disease, they are held to a higher safety standard than other medications.<sup>80</sup> Before a vaccine becomes part of the routine immunization schedule, there is a multistep process including preclinical animal studies, clinical trials in humans, submission of an application to the US Food and Drug Administration (FDA) for licensure (or, as in the case of COVID-19 vaccines, emergency use authorization), approval or authorization by the FDA, and recommendations for use by the Advisory Committee on Immunization Practices (ACIP) and CDC.<sup>81-85</sup> In each of these steps, safety is a top consideration.

Prelicensure clinical trials and progression through the phases of clinical development are under the oversight of the FDA. Prelicensure, phase 1 trials are conducted for the purpose of understanding the safety profile and side effects of a vaccine, generally among 20 to 100 healthy volunteers. If there are no safety concerns in this phase, a vaccine may move into phase 2 trials, generally among several hundred volunteers, where in addition to further expanding an understanding of the vaccine's safety profile, immunogenicity is assessed. For vaccines with acceptable phase 2 safety data and promising immunogenicity data, phase 3 trials may proceed, often with thousands of volunteers, to assess both effectiveness and detection of less common adverse events in a larger population. These prelicensure phases usually progress sequentially, but it is also not uncommon for phases of development to overlap. After completion of phase 3 trials, the manufacturer of the vaccine may submit an application to the FDA for licensure. The FDA then reviews the application; if it determines that the vaccine is safe and effective and confirmed that the manufacturing and facility information ensure product quality and consistency, it may grant a license for use. FDA reviews of license applications for vaccines that are approved by the FDA are publicly posted on the FDA Web site. The ACIP then examines the available data submitted to the FDA as well as other contributory data to decide whether the benefits of vaccination outweigh any possible risks for the target population. Although some of the deliberations are internal to the FDA and CDC, this process is highly transparent, with public ACIP meetings with the opportunity for written or oral public comment.<sup>86</sup> The process for authorization of COVID-19 vaccines under emergency use authorization and subsequent ACIP recommendation was very similar to fully licensed vaccine products, albeit on an accelerated timeline because of the emergent nature of the pandemic.<sup>87</sup>

Although prelicensure trials can identify common adverse events within a limited time frame after vaccination,

it is not feasible to conduct clinical trials large enough to detect all rare vaccine-related events (ie, <1 event per 10000 vaccinees). Therefore, the United States has developed a robust postlicensure vaccine safety surveillance system. Arguably, the 2 most widely known components are the Vaccine Adverse Event Reporting System (VAERS)<sup>88</sup> and the VSD,<sup>89-92</sup> both of which were established in 1990. A spontaneous surveillance system managed by the CDC and FDA, VAERS is the early warning system for vaccine adverse events in the United States. Although VAERS is crucial to vaccine safety surveillance, it cannot generally assess causality. VAERS, therefore, serves as a hypothesis-generating system. On the other hand, the VSD, a collaboration between the CDC and 13 integrated health care organizations, is a hypothesis-testing system and can assess causality. Using electronic health records (EHRs) with highly accurate data, if a signal for a possible vaccine adverse event is identified in its own monitoring, VAERS, or elsewhere, further studies can then be performed in the VSD to determine whether there is an association using several different types of methods, such as case-control (comparing the incidence of the possible adverse event in vaccinated and unvaccinated individuals) and self-controlled case series (in which only individuals who experienced the outcome of interest are examined using risk intervals around the time of vaccination).

The VSD has been able to identify rare adverse events after vaccination, such as the association between the measles, mumps, and rubella (MMR) vaccine and immune thrombocytopenic purpura<sup>93</sup> and the increased risk of febrile seizures after the measles, mumps, rubella, and varicella vaccine.<sup>94</sup> Perhaps more importantly, the VSD has been able to demonstrate the lack of association of numerous vaccines with purported vaccine adverse events.<sup>95–100</sup> The FDA's active surveillance efforts involve the Biologics Effectiveness and Safety (BEST) system,<sup>101</sup> covering more than 100 million persons and comprising large-scale claims data, EHRs, and linked claims-EHR databases. The BEST system makes use of multiple data sources and enables rapid queries to detect or evaluate adverse events as well as studies to answer specific safety questions for vaccines.

In addition to the VSD, VAERS, and BEST, the United States has several other important systems monitoring vaccine safety, including the Clinical Immunization Safety Assessment Project (CISA),<sup>102</sup> various surveillance systems through the Department of Defense, and, with onset of the COVID-19 pandemic, v-safe, the after-vaccination checker.<sup>103</sup> The United States also collaborates internationally to study vaccine safety through partnerships with the World Health Organization, the European Medicines Agency, and the Pan-American Health Organization, among others. Details of several of the major US vaccine safety surveillance systems are shown in Table 3.

TABLE 3 Examples of M	ajor Vaccine Safety Surveillance Syst	tems in the United Stat	tes			
		Population Under				
Surveillance System	Data Source	Surveillance	Management	Characteristics	Strengths	Limitations
Vaccine Adverse Event	Online reporting system;	Entire United States	FDA, CDC	"Nation's early warning system";	Accepts reports from	Generally cannot assess
Reporting System	Health care providers and vaccine			Passive, spontaneous reporting;	anyone;	causality;
(VAERS)	manufacturers are required by			Hypothesis-generating;	All data are publicly	Prone to both overreporting
	law to report certain events			85% to 90% of reports are	available	and underreporting
	after vaccination			nonserious;		
				Serious reports are followed up		
Vaccine Safety Datalink	Electronic health record data from	12.5 million	CDC, in collaboration	Active surveillance system;	Can estimate potential	Limited ability to assess
(NSD)	13 large health care		with integrated	Hypothesis-testing;	causal associations;	adverse events with delayed
	organizations across the United		health care	Can conduct medical record	Capable of real-time	or insidious onset;
	States		organizations	review to verify outcomes;	monitoring;	May not be able to control for
				Multiple methods developed to	High-quality data	all confounders;
				conduct valid, accurate vaccine		Represents an insured
				safety studies		population
Biologics Effectiveness	Large-scale claims data, electronic	100 million	FDA	Enables rapid queries to detect	Very large population;	Limited evaluation of pediatric
and Safety System	health records (EHRs), and			or evaluate adverse events as	Possible to study the	vaccines to date;
(BEST)	linked claims-EHR databases			well as studies to answer	safety of vaccines in	Statistical signals must be
				specific safety questions for	subpopulations with	further evaluated through
				vaccines	preexisting conditions	rigorous epidemiologic study
					or in pregnant persons	
Clinical Immunization	Generally medical records from	NA	CDC, in collaboration	In-depth clinical,	US health care providers	Limited in scope
Safety Assessment	clinicians		with medical	pathophysiological, and	with a complex vaccine	
(CISA)			research centers	vaccinology expertise to	safety question about a	
				assess causal relationships	specific patient may	
				between vaccines and	contact CISA to request	
				adverse events	a consult	
NA, not applicable.						

6

In summary, vaccines are comprehensively evaluated by the FDA for safety, effectiveness, and manufacturing quality before their authorization or licensure. Vaccines are developed and tested in large numbers of subjects, are regulated by the FDA, and undergo rigorous monitoring after licensure through a comprehensive safety surveillance system funded by the CDC and FDA. In instances in which safety concerns are identified, regulatory or other actions to safeguard public health are taken.

Having a broad understanding of vaccine safety monitoring systems and of the safety of the childhood immunization schedule in general enables pediatricians to be prepared to respond to parental concerns about vaccine safety. The safety of the recommended childhood vaccines and the recommended schedule has been affirmed by multiple independent reviews, including from the National Academy of Medicine and the Agency for Healthcare Research and Ouality.<sup>104,105</sup> The National Academy of Medicine's 2013 report included a review of the evidence for known vaccine adverse events and was used to inform the Vaccine Injury Compensation Program. The 2021 update to the Agency for Healthcare Research and Quality report identified no new safety risks associated with the recommended vaccination schedule, and pediatricians can use this information to explain the reasons for the timing of the recommended schedule. Many vaccine-preventable diseases like measles, pertussis, rotavirus, respiratory syncytial virus, and pneumococcal and Haemophilus influenzae infection are associated with higher morbidity and mortality in infancy and early childhood. Delaying vaccination leaves children unprotected at the age when they are most at risk. Vaccines are studied to ensure safety and adequate immune response at the age when they are recommended. For example, immune response to human papillomavirus (HPV) vaccine is stronger when given at an earlier age, and delaying vaccination may result in the need for more doses to achieve adequate protection.<sup>106</sup>

Pursuing a nonrecommended vaccination schedule is associated with lower likelihood of being up to date on early childhood vaccinations<sup>13,107,108</sup> and means pursuing an approach that has not been studied, in contrast to the recommended schedule, which has.<sup>104,105</sup> Delaying or limiting vaccinations directly contradicts the recommendations of the ACIP and the American Academy of Pediatrics (AAP) Committee on Infectious Diseases and puts children, their families, and their communities at risk for exposure to vaccine-preventable diseases. Delaying vaccination in the youngest children may also leave them unprotected against vaccine-preventable disease at a time in their lives when they are most vulnerable if infected. It is also important to have children fully vaccinated before they attend group settings with other children (eg, any type of center-based child care, preschool, or elementary school where the risk of exposure to a vaccinepreventable disease increases). When deviating from the vaccine schedule, this goal can be compromised. Deviation from the recommended schedule, therefore, is generally discouraged. After making a reasonable effort to discuss the recommended vaccination schedule with a family, deviation from the recommended schedule may be considered if it is the only way to move forward to vaccinate a child.

Some parents have concerns about the number of vaccinations children receive or the specific components in vaccines. Clinicians can respond to the concern among some parents that "too many" vaccines are given at once with evidence-based, valid, culturally sensitive statements to promote vaccine uptake. It may be helpful to explain that there are fewer antigens in the current schedule than historical schedules, which included the whole-cell pertussis vaccine.<sup>109</sup> The immune system has the capacity to respond to a large number of stimuli at once and responds to the many immunogenic substances it encounters outside of vaccinations through routine childhood food, environmental, and circulating disease exposures.

Parents sometimes raise concerns about vaccines causing the infection they are actually working to prevent. Pediatricians can explain that, with the exception of live attenuated products, vaccines contain only a portion of the bacteria or virus they are working to prevent and that most common vaccine side effects are from the immune system response and are not a sign of infection. Some vaccines (eg, COVID-19) contain only the genetic material for a specific protein and direct the body to produce a small amount of that protein, a process that has been shown to be both safe and effective. Live attenuated vaccines are contraindicated for some immunocompromised persons because of the risk of vaccine-strain viral replication causing vaccine-associated disease; however, these vaccines do not cause infection or disease in immunocompetent persons.

Other common concerns focus on specific vaccines or vaccine ingredients. A widely debunked and retracted study suggesting the MMR vaccine was associated with autism still leads many parents to assume vaccines cause autism.  $^{110\mathchar`-117}$  In the United States, mercury was removed from most vaccine products in the early 2000s. Thimerosal (which contains ethylmercury) is still used as a preservative to prevent contamination in some influenza vaccines supplied in multidose vials, but other routine childhood vaccines in the United States, including single-dose vial influenza vaccines, do not contain ethylmercury. Concerns about neurologic effects of mercury exposure, such as autism, are based on risks associated with methylmercury, whereas ethylmercury is metabolized more quickly and not associated with the same risks.<sup>118</sup> Aluminum is used in some vaccines as an adjuvant that facilitates a strong immune response. The amount of aluminum in vaccines is safe, regulated, and comparable to the amount of aluminum infants are exposed to through human milk and formula feeding.<sup>119,120</sup> A recent VSD study showed a possible weak but statistically significant association between the amount of aluminum received in vaccines and a diagnosis of asthma revealed in EHRs.<sup>121</sup> Although this study has limitations (eg, unmeasured confounders, such as secondhand smoke, breastfeeding, child care attendance, and environmental pollutants, were not able to be fully accounted for), it is an example of the rigorous safety monitoring that is integrated into the vaccine surveillance system and will require more definitive follow-up studies.

Fetal cell lines have been used in the development, testing, and production of some vaccines and other medications, but vaccines do not contain cells or DNA from aborted fetuses. Most major religions have published statements clarifying that the use of vaccines do not go against the religion's doctrine and that the use of fetal cells in vaccine development does not prohibit use of these vaccines, and some have pointed out the moral good of vaccination to protect the health of children and the people around them.<sup>122</sup>

The CDC's Epidemiology of Vaccine Preventable Disease: The Pink Book and Morbidity and Mortality Weekly Report containing ACIP vaccination recommendations are useful resources for more detailed information about vaccine contraindications and precautions, ingredients, schedules, and side effects.<sup>123,124</sup> A summary of common misconceptions with accompanying facts is provided in Table 4.

## EVIDENCE-BASED COMMUNICATION STRATEGIES TO INCREASE UPTAKE OF CHILDHOOD VACCINES

It is now well-understood that pediatricians play an influential role in parental vaccine decision-making. Pediatricians are the most common source of vaccine information for parents,125 are the most trusted source for vaccinesafety information,<sup>126</sup> and can positively influence a parent's vaccine behavior,<sup>9</sup> even among parents with concerns about vaccines.<sup>127</sup> Many vaccine-related facts that pediatricians may use when discussing vaccines with parents have already been shared earlier in this report. How those facts are communicated is also important. It is important to establish an honest dialogue, take time to listen, and solicit and welcome questions. Recent evidence has further improved our understanding of specific clinician communication strategies that can improve uptake of childhood vaccines. Although many techniques for working with vaccinehesitant parents have been suggested, relatively few have been studied to determine efficacy in improving vaccination uptake, although recent years have seen an uptick in large, funded randomized trials.

There is evidence that some parents have already formed attitudes toward vaccination during the prenatal period<sup>128</sup> and arrive at their infant's initial well-child visit having already decided on their plans regarding

8

acceptance of vaccines. Therefore, the discussion about childhood vaccines can ideally begin during the prenatal period to help expectant parents understand both the indications for and safety of these vaccines as early as possible.<sup>129</sup> This discussion can occur both during prenatal obstetric visits as well as prenatal consultations with the pediatrician.

## Use a Strong Vaccine Recommendation and the Presumptive Format for Initiating the Vaccine Discussion

One of the vaccine communication strategies for pediatricians and other pediatric clinicians with strong evidence for increased uptake of childhood and adolescent vaccines is providing a vaccine recommendation.<sup>130,131</sup> The strength and quality of this recommendation is also important. There is higher vaccine receipt among children whose parents receive a very strong clinician vaccine recommendation than those who do not.<sup>132</sup> The ability to confidently provide such a strong recommendation is based on decades of broad national and international pediatric health care experience, data collection, and rigorous, well-designed studies of vaccine safety, efficacy, and effectiveness.

A related communication strategy with similarly strong evidence for increased vaccine uptake is a pediatrician or clinician's use of a presumptive format to initiate the vaccine discussion.<sup>133–137</sup> A presumptive format is one in which the clinician asserts a position regarding vaccines using a closed-ended statement, such as "Sara is due for several vaccines today" or "Well, we have to do some shots."<sup>138</sup> This strategy is in contrast to a participatory format, in which an open-ended question is used to more explicitly invite the parent to voice an opinion, such as "How do you feel about vaccines today?"

Clinician use of a presumptive format is associated with increased vaccine uptake, even among parents with negative vaccine attitudes. For instance, significantly fewer parents with negative vaccine attitudes, as defined as those who scored  $\geq$  50 on the validated Parent Attitudes about Childhood Vaccines survey,<sup>139-145</sup> refused vaccine recommendations when providers used a presumptive (versus participatory) initiation format.<sup>135</sup> In addition, clinicians' repeated use of a presumptive (versus participatory) format with parents with negative vaccine attitudes over several visits, given the longitudinal nature of vaccine administration and discussions, yielded significantly less underimmunization among children.<sup>146</sup> Overall, implementation of the presumptive format in practice has been perceived by clinicians as time-saving, easy to use, and a way to promote vaccination as part of routine care.147 Front desk staff, medical assistants, nurses, and other staff often play a major role in vaccination processes, so engaging all team members in the office

TABLE 4 Common Misconceptions and Myths About Immunizations		
Claims	Facts	
"Natural" methods of enhancing immunity, such as contracting the disease and breastfeeding, are better than vaccinations.	Vaccinations are the safest way to achieve immunity; having immunity the "natural way" means being sick with a potentially very serious infectious disease. Immunity from a preventive vaccine provides protection against disease when a person is exposed to it in the future. That immunity is usually similar to what is acquired from natural infection, although several doses of a vaccine may have to be administered for a child to develop an adequate immune response. Although breastfeeding has many benefits, including immunologic, it does not provide anywhere near the same level of protection from vaccine-preventable diseases as vaccines.	
Giving multiple vaccines at the same time causes an "overload" of the immune system.	Vaccination does not overburden a child's immune system; the recommended vaccines use only a small portion of the immune system's "memory." Although the number of unique vaccines administered has risen over recent decades, the number of antigens administered has decreased because of advances in science and manufacturing. The National Academy of Medicine (NAM) has concluded that there is no evidence that the immunization schedule is unsafe.	
Vaccines are ineffective.	Vaccines have spared millions of people the effects of devastating diseases.	
Before the use of vaccinations, these diseases had begun to decline because of improved nutrition and hygiene.	In the 19 <sup>th</sup> and 20 <sup>th</sup> centuries, some infectious diseases began to be better controlled because of improvements in sanitation, clean water, pasteurized milk, and pest control. However, vaccine-preventable diseases decreased dramatically after the vaccines for those diseases were approved and were administered to large numbers of children.	
Vaccines cause poorly understood illnesses or disorders, such as autism, sudden infant death syndrome (SIDS), immune dysfunction, diabetes, neurologic disorders, allergic rhinitis, and eczema.	These claims are false. Multiple, high-quality scientific studies have failed to substantiate any link between vaccines and these health conditions. See NAM reports.	
Vaccines weaken the immune system.	Vaccines actually strengthen the immune system. Vaccinated children have decreased risk of infections. Importantly, natural infections like influenza, measles, and varicella (chickenpox) can weaken the immune system, increasing the risk of other infections.	
Giving many vaccines at the same time is untested.	New vaccines are tested in concomitant use studies with existing vaccines that are administered on the same or overlapping schedule. These studies are performed to confirm that new vaccines do not affect the safety or effectiveness of existing vaccines administered at the same time and that existing vaccines administered at the same time do not affect the safety or effectiveness of new vaccines.	
Vaccines can be delayed, separated, and spaced out without consequences. Adapted from American Academy of Pediatrics. <i>Red Book: 2021 Report of the Commi</i>	Many vaccine-preventable diseases occur in early infancy. Optimal vaccine-induced immunity may require a series of vaccines over time. Any delay in receiving age-appropriate immunization increases the risk of diseases that vaccines are administered to prevent. Spacing out vaccines may also have psychological consequences, because many more office visits will be associated with injections. ittee on Immunization Practices. Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. 32nd	

Adapted from American Academy of Pediatrics. Red Book: 2021 Report of the Committee on Immunization Practices. Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. 32nd ed. American Academy of Pediatrics; 2021; and Myers MG, Pineda D. Do Vaccines Cause That? A Guide for Evaluating Vaccine Safety Concerns. Immunizations for Public Health; 2008:79.

setting or inpatient unit who communicate with parents about vaccines on the rationale and technique for initiating the vaccine discussion using the presumptive format could maximize its effect.

The presumptive format is likely effective at improving childhood vaccine uptake by leveraging choice architecture as a means to achieving a desired goal. Choice architecture refers to how a decision is presented. For instance, a decision presented as an opt-in or opt-out affects the choice made, with the large majority of choosers sticking with the default option.<sup>148,149</sup> The default option is the event or condition set into place when no alternatives are actively chosen<sup>150</sup> and differs from the neutral position, in which individuals are required to choose an option. Use of the presumptive format presents the vaccination decision as opt-out by making vaccination the default option.<sup>151,152</sup> The participatory format is akin to the neutral position. The primary driver behind the effectiveness of setting the default option by using an opt-out is likely status quo bias, a cognitive bias inherent to human decision-making that

results in an aversion to changing a decision that has already been made.  $^{153,154}$ 

Utilizing defaults in communication with parents merits careful consideration. Defaults ought not be used indiscriminately and are most justifiable where there is a high degree of certainty that an intervention is of low risk and high benefit.<sup>155</sup> Childhood vaccines that are recommended by the ACIP and the AAP fulfill these criteria. Given this justification, as well as the strength of evidence for the presumptive format and a strong clinician vaccine recommendation in improving childhood vaccine uptake, both strategies are now considered as integral to vaccine communication.<sup>156</sup>

## For Parents Who Express Hesitancy, Use Additional Evidence-Based Communication Strategies

Although a strong recommendation and use of a presumptive format for initiating the vaccine discussion with parents are effective, they are not a panacea: despite use of these strategies, a proportion of parents with negative vaccine attitudes will still voice initial resistance to vaccinating their child.<sup>135</sup> There are additional vaccine communication strategies needed with parents who continue to express hesitancy. One such strategy is motivational interviewing (MI). MI is a patient-centered framework for behavior change that helps leverage one's inherent motivation for behaviors.<sup>157–159</sup> There are several MI communication techniques that have been found to be effective even when delivered in a single session (see Fig 1 for specific MI examples).<sup>160,161</sup>

Evidence from observational studies to support the use of MI in the vaccination context is growing.<sup>162-166</sup> The strongest evidence for MI has come from a large cluster randomized controlled trial.<sup>167</sup> Clinicians in intervention practices were trained to use the presumptive format for initiating the HPV vaccine discussion for all parents followed by use of MI in discussions with parents who voiced initial reluctance in having their child receive the HPV vaccine. Clinicians in control practices provided usual care. Investigators found a significant increase in HPV vaccine initiation and completion among children of parents who received care in intervention (versus control) practices. The results of a trial designed to assess the effect of a similar communication strategy on childhood vaccination status by 2 years of age are expected in 2024.168,169

Other adjunctive clinician vaccine communication strategies with some evidence supporting their effectiveness include (1) pursuing adherence to the recommended vaccines for which the child is due at a visit despite parent initial reluctance, and (2) bundling the discussion of all vaccines for which a child is eligible at the visit at once. Pursuing adherence refers to responding immediately to a parent's initial reluctance to the vaccines for which

10

their child is due with a reiteration of the importance of the recommended vaccines for the child, such as "He really needs these shots."<sup>138</sup> In several observational studies, parental verbal acceptance of vaccines for their child was significantly higher when clinicians pursued their vaccine recommendations (versus acquiesced) after initial parent reluctance.<sup>133,135,170</sup> Bundling the discussion of all vaccines for which a child is due at a visit at once is supported by observational work in which investigators found concurrent discussion of the influenza vaccine with other vaccines for which a child was also due was associated with higher influenza vaccine uptake.<sup>133</sup> Clinicians may also mention that they use strategies to minimize the pain associated with vaccination, as this is a common concern among parents.<sup>171,172</sup>

Finally, clinicians can emphasize their own experiences when discussing the need for vaccination, including personal experience with vaccine-preventable diseases and the fact that they and their families are vaccinated because of their confidence in the safety and efficacy of the vaccines.<sup>76</sup> A summary of the recommended approach to vaccine communication based on existing evidence, including use of the presumptive approach and MI, is shown in Fig 1,<sup>169</sup> and an overall summary of strategies and recommendations for improving vaccine communication and uptake is provided in Table 5.

## Leverage Systems, Organizational Approaches, and Community Initiatives to Improve Parental Access to Vaccines

Pediatrician-parent communication is only one of the many efforts required to achieve and maintain high vaccination coverage. It is important for pediatricians and other clinicians who serve children to work toward cultural competency and an understanding of the communities they serve. There are also many established and long-standing evidence-based practices for increasing vaccination coverage, such as standing orders for vaccination, reminder and recall, use of immunization information systems, school and child care entry requirements, and audit and feedback, among others.<sup>173</sup> There are also emerging community-based approaches designed to build trust and address the concerns of specific populations, including religious and vulnerable populations.<sup>32,174-176</sup> These may include community- and school-based vaccination programs, which may help to demonstrate vaccination as a social norm and encourage greater uptake.<sup>177</sup> Although these are not the focus of this clinical report, pediatricians may be able to use them to the extent feasible in their own clinical setting. Effectively implementing these strategies has the potential to save time in the clinical encounter by reducing the time needed to discuss vaccines. The US Community Preventive Services Task Force maintains a robust Web site detailing the evidence behind these strategies,<sup>178</sup> and



#### **FIGURE 1**

Recommended approach to vaccine conversations based on existing evidence. Reprinted from: *Vaccine*, 41(10), 0'Leary ST, Spina Cl, Spielvogle H, et al. Development of PIVOT with MI: a motivational interviewing-based vaccine communication training for pediatric clinicians. Pages 1763–1764, © 2023, with permission from Elsevier.

Motivational Interviewing Skills
Open-ended Questions:       helps explore and understand a parent's stance on vaccination         Examples:       "Tell me more about what you already know?"         "What might be one good reason to vaccinate your child today?"         "In your mind, what is the harm if you choose not to vaccinate her today?"         "What are some reasons for getting the vaccination?"
<ul> <li>Affirmations: improves parent engagement in an open discussion with you by helping them feel supported, appreciated, and understood <i>Examples:</i> <ul> <li>"You are a good parent. Your concern shows how much you care about your child's safety."</li> <li>"You are a good mom and you care about your daughter's health."</li> <li>"You've always tried to be a good role model for your kids."</li> <li>"If you thought the vaccine was safe, you would not hesitate because you want what's best for your daughter."</li> <li>"It sounds like you're comfortable with the other vaccines."</li> </ul> </li> </ul>
Reflections:       encourages partnerships, deepens rapport, and allows a parent to understand themselves and their motivations on a deeper level; reflections are particularly useful when encountering strong emotion or hesitancy         Examples:       • "You're frightened by what you've read on the Internet."         • "You're really worried and you want to make the best decision."       • "You're the type of person who really likes to do her research."         • "So it sounds like you're worried about the possibility that the MMR vaccine might cause autism."
Ask Permission to Share: puts parents in a less defensive posture and makes them more receptive to the information you'd like to share         Examples:         • "Could I provide you with some information based on what you just shared?"         • "Would you mind if I shared with you why I think this is such an important vaccine?"         • "May I share what I know about?"         • "I have a different view, may I share it with you?"
<ul> <li>Autonomy Support: enhances a parent's sense of control and makes them feel more at ease with the conversation         Examples:         <ul> <li>"That said, this is a decision only you can make."</li> <li>"Only you can choose what is best for your child."</li> </ul> </li> </ul>
MI Conversation Example
<u>Provider:</u> "You sound pretty certain that you don't want Johnny to get the MMR vaccine." (Reflection) <u>Parent:</u> "No, I don't." <u>Provider:</u> "Well, I just want to say right up front that this is your choice. My job is to share the best information I have about the vaccines to help with your decision, but you are the one who decides." (Autonomy Support) <u>Parent:</u> "OL"
Provider: "Tell me what you know about the MMR vaccine and autism." (Open-ended Question) Parent: "Well, my cousin says that her daughter was fine until she got the MMR shot and I've read a lot about this on the Internet, too. How can it be a coincidence?"
(Reflection, Affirmation) <u>Parent:</u> (nodding head) "I mean, really!" <u>Provider:</u> "I've done some careful study of the MMR/autism connection and I have information that may help. May I share that with you?" (Asks Permission to Share)
Parent:       "I guess."         Provider       shares information about the negative association between MMR and autism and reinforces positives of getting vaccinated. Provider then ends with: "So what do you make of what I've shared?" (Open-ended Question)         Parent:       "I'm not sure. I guess it makes sense though."         Provider:       "Well, how would you like to proceed today?" (Open-ended Question)
Portions, "I don't brown (nouse) I guess we can go should with it this time."

FIGURE 1 Continued

12

<b>TABLE 5</b> Strategies and Recommendations for Improving Vaccine Communication and Uptake		
Provider communication		
Pediatricians play an influential role in parental vaccine decision-making		
Use a strong vaccine recommendation and the presumptive format for initiating the vaccine discussion		
Be prepared to respond to questions about the safety of vaccines, vaccine ingredients, vaccine safety surveillance systems, and the childhood vaccination schedule with evidence-based, valid, culturally sensitive statements to promote vaccine uptake		
Use additional vaccine communication strategies with parents who express hesitancy (eg, motivational interviewing)		
Vaccination schedule		
The recommended vaccine schedule is the one endorsed by the CDC and the AAP; alternative schedules have not been evaluated		
Deviation from the recommended schedule may be considered after making a reasonable effort to discuss the recommended vaccination schedule with a family and if it is the only way to move forward to vaccinate a child		
Efforts beyond the examination room		
Support vaccination uptake initiatives outside the clinical encounter (eg, reminder or recall, school and child care entry requirements, use of immunization information systems, partnering with trusted messengers)		
Practice-level policies		
Practices should consider having uniform policies across providers for families who refuse or delay vaccination		
There are ethical concerns with the practice of dismissing families		
Dismissal of a vaccine-refusing family can be an acceptable option, however, after repeated attempts to help understand and address parental values and vaccine concerns, engender trust, and strengthen the therapeutic alliance. Before dismissal, other considerations include:		
Less drastic alternatives are not feasible and the clinician has tried to minimize potential negative impacts on the child		
It is done in a manner consistent with applicable state laws prohibiting abandonment of patients		
Official notification of the parents or legal guardian is required, along with the provision of information for finding a new physician		
The dismissing physician is obligated to continue current treatment and provide emergency care for a reasonable period of time, usually 30 d		
Other policies practices sometimes use include:		
Not accepting new patients whose parents do not agree to give their children all vaccines according to the recommended schedule		
Requiring parents to sign a contract stating that their children must be up to date by a certain age, but the parents may spread out the vaccines		
Practice policies concerning families who refuse vaccinations should be applied uniformly to all such families		
Evidence is lacking for the impact of any type of practice-level policy on vaccination uptake of individual children or surrounding communities, the impact on vaccines attitudes and trust in the medical system, or where children who are dismissed from practices receive medical care		

the AAP has many online resources for implementing them in the office setting (Table 6).

In addition, there has been a great deal of research in recent years in developing and testing vaccine communication tools for use before (and sometimes after) the clinical encounter.<sup>179–186</sup> Although there is no single tool as of this writing that has emerged that is clearly effective and widely available, this area of work shows promise in easing the burden of discussing vaccines with hesitant families.

## POLICIES FOR FAMILIES WHO REFUSE OR DELAY VACCINATION

Pediatric practices and individual pediatricians have taken a variety of approaches to address families who choose to refuse or delay vaccinations for their children. A national survey among pediatricians in 2019 showed that 51% of pediatricians reported that their office had a policy to dismiss families if they refused vaccines in the primary series for their children, and 37% of pediatricians reported that they often or always do this.<sup>187</sup> The practice of dismissing families appears to be on the rise as only 21% of pediatricians reported in 2013 that they often or always dismissed families.<sup>188</sup>

Fewer pediatricians report dismissing families for "spreading out" vaccines (28% report office policies, 8% of individual pediatricians report often or always dismissing these families). Nineteen percent of pediatricians report that their office has a policy requiring parents to sign a contract stating that their children must be up to date on vaccinations by a certain age, but the parents may spread out the vaccines.<sup>187</sup> Another approach that pediatricians have taken is simply not accepting new patients whose parents do not agree to give their children all vaccines according to the recommended schedule (46% report such office policies). The overwhelming majority of pediatricians who report having dismissal policies are in private practice.187,188 Employees of hospitals and large health care organizations are often unable to dismiss patients because of organizational policies, and pediatricians working in safety net systems or rural settings may not dismiss families based on similar organizational policies and the fact that children in these practices are less likely to find care elsewhere.

There are ethical arguments both in favor of and against dismissal policies. One argument in support of dismissal policies is that parents have a moral obligation to vaccinate their children to reduce the risk of infecting

TABLE 6 Resources for Vaccine Information and Communication		
Resources		
Government		
Centers for Disease Control and Prevention: Vaccines and Immunization	http://www.cdc.gov/vaccines	
Centers for Disease Control and Prevention: Vaccine Safety Monitoring	https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/index.html	
Vaccine Safety Datalink (VSD)	https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html	
Clinical Immunization Safety Assessment (CISA) Project	www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa	
National Institute of Allergy and Infectious Diseases	http://www.njaid.nih.gov	
US Food and Drug Administration: Vaccines, Blood and Biologics	http://www.fda.gov/vaccines-blood-biologics/vaccines	
National Vaccine Injury Compensation Program	http://www.hrsa.gov/vaccine-compensation/index.html	
Vaccine Adverse Event Reporting System	http://www.vaers.hhs.gov/index	
Office of Infectious Diseases and HIV/AIDS Policy	http://www.hhs.gov/vaccines	
National Vaccine Advisory Committee	http://www.hhs.gov/nvpo/nvac	
International	· · · · · · · · · · · · · · · · · · ·	
Pan American Health Organization	http://www.paho.org/hq	
World Health Organization	http://www.who.int/en	
Professional organizations		
American Academy of Pediatrics	https://www.aap.org/immunization	
American Academy of Family Physicians	https://www.aafp.org/family-physician/patient-care/prevention-wellness/ immunizations-vaccines.html	
American Medical Association	http://www.ama-assn.org	
American College Health Association	http://www.acha.org	
American College of Nurse Midwives	http://www.midwife.org	
American College of Physicians	http://www.acponline.org	
American College of Obstetricians and Gynecologists	http://www.acog.org	
American Immunization Registry Association	http://www.immregistries.org	
American Nurses Association	http://www.nursingworld.org	
American Osteopathic Association	http://www.osteopathic.org	
American Pharmacists Association	http://www.pharmacist.com	
American Public Health Association	http://www.apha.org	
Association for Prevention Teaching and Research	http://www.aptrweb.org	
Association of State and Territorial Health Officials	http://www.astho.org	
Association of Immunization Managers	http://www.immunizationmanagers.org	
Council of State and Territorial Epidemiologists	http://www.cste.org	
Infectious Diseases Society of America	http://www.idsociety.org	
National Association of County and City Health Officials	http://www.naccho.org	
National Association of Pediatric Nurse Practitioners	http://www.napnap.org	
National Foundation of Infectious Diseases	http://www.nfid.org	
National Medical Association	http://www.nmanet.org	
Pediatric Infectious Diseases Society	http://www.pids.org	
Society for Adolescent Health and Medicine	http://www.adolescenthealth.org	
Society for Healthcare Epidemiology of America	http://www.shea-online.org	
Society of Teachers of Family Medicine	http://www.stfm.org	
Advocacy, education, and implementation		
American Academy of Pediatrics	https://www.healthychildren.org/immunizations	
Comprehensive Vaccine Education Program (Pediatric Infectious Diseases Society)	https://pids.org/education-training/vaccine-education-program/	
Children's Hospital of Philadelphia Vaccine Education Center	http://www.chop.edu/centers-programs/vaccine-education-center	
Families Fighting Flu	http://www.familiesfightingflu.org	
Global Alliance for Vaccines and Immunization	http://www.gavi.org	
Immunize.org (formerly Immunization Action Coalition)	http://www.immunize.org	
Immunization for Women (American College of Obstetricians and Gynecologists)	http://www.immunizationforwomen.org	

TABLE 6 Continued		
Resources		
National Foundation for Infectious Diseases	http://www.nfid.org	
National HPV Vaccination Roundtable	http://www.hpvroundtable.org	
Texas Children's Hospital Center for Vaccine Awareness and Research	http://www.texaschildrens.org/departments/center-vaccine-awareness- and-research-cvar	
Vaccinate Your Family	http://www.vaccinateyourfamily.org	
Voices for Vaccines	http://www.voicesforvaccines.org	
Communication resources		
American Academy of Pediatrics	https://www.aap.org/vaccinecommunication; https://downloads.aap.org/AAP/ PDF/Frameworks%20Report.pdf	
Centers for Disease Control and Prevention	https://www.cdc.gov/vaccines/hcp/conversations/index.html	
Association of Immunization Managers	https://www.immunizationmanagers.org/category/communication-templates/	
National Academies of Sciences, Engineering and Medicine	https://nap.nationalacademies.org/resource/26068/interactive/ vaccine-confidence.html	
Debunking Handbook	https://www.climatechangecommunication.org/wp-content/uploads/2020/10/ DebunkingHandbook2020.pdf	

others, given the small cost associated with vaccination.<sup>189</sup> According to this duty of easy rescue argument, herd immunity is a collective good and achieving herd immunity is a collective moral obligation as long as it comes at a small cost (eg, costs such as making a vaccine appointment, receiving the vaccine, incurring the small risks of side effects, etc). Dismissal policies, therefore, may be justified by disincentivizing parents from shirking this moral obligation.

A similar argument is based in contractualism, in which vaccination is viewed as a social contract: if nearly everyone is vaccinated, everyone is protected because of herd immunity. To share in this collective benefit, however, individuals, out of fairness, must accept the small burdens associated with vaccination. Individuals benefiting from the actions of those who accept these small burdens without sharing in the burden themselves is unfair and a violation of the social contract. Dismissal policies help uphold this social contract and limit the unfair distribution of the burdens of vaccinating.

These ethical arguments for dismissal policies, however, are not without weaknesses. For instance, although parents may have a moral obligation to vaccinate their child, enforcing this obligation through a dismissal policy requires additional justifications regarding why this moral obligation supersedes other competing moral claims, such as the right to bodily integrity. Similarly, although dismissal policies may limit the unfair distribution of the burdens of vaccinating among parents and their children, they can create unequal burdens among clinicians and practices. For instance, unless all practices have dismissal policies, the irregular implementation of such policies will unjustly redistribute the burdens of caring for unimmunized patients.<sup>190</sup>

There are several other practical arguments for dismissal policies. Proponents suggest that dismissal policies help convince the majority of vaccine-refusing parents to accept

vaccines; that they are needed to protect other children in the practice from vaccine-preventable diseases; that parents within the practice advocate for such policies; that allowing parents to refuse vaccines for their children exposes physicians to medicolegal risks; that there are hidden financial costs to a pediatric practice for accepting nonvaccinators; and that they help promote the "highest standard of medical care."<sup>191-193</sup> These arguments, too, have weaknesses.<sup>194</sup> A notable weakness is that there is little empirical evidence for claims of positive outcomes from dismissal policies. For example, the following remain unknown about the practice of dismissing families: (1) the extent to which having a dismissal policy increases the likelihood of a child being vaccinated; (2) whether keeping vaccine-refusing families within a practice increases the likelihood of being vaccinated; (3) where children of families who have been dismissed receive medical care; (4) the impact on vaccination attitudes and trust in the medical system in general among parents facing the prospect of dismissal; and (5) the impact and interaction of these policies on vaccination and vaccinepreventable diseases at the population level.

Ethical arguments against dismissal policies or policies designed not to accept vaccine refusers at all are centered on the foundational principle in medical ethics to promote the well-being of the patient.<sup>194</sup> This obligation is certainly fulfilled by vaccinating a child with the parent's permission. However, when a parent withholds their permission, dismissing the parent and child from the practice arguably neglects this obligation. For instance, some children, such as those in rural areas, may receive little health care supervision after being dismissed, given the lack of availability of other primary care alternatives. This practice may serve to worsen disparities, since families from historically disenfranchised communities represent a group whose distrust in government and organized medicine may lead them to resist

vaccination. As such, opponents of dismissal policies advocate for an approach that is more aligned with promoting the well-being of the patient than policies that result in discharging patients from one's care.<sup>194</sup> This approach involves cultural humility and a respectful exploration of value differences between clinician and parent that can create opportunities to change the parent's mind along with implementation of less drastic alternatives to dismissal policies that can mitigate some of the potential risks of including underimmunized children in the practice (such as sequestering unimmunized and underimmunized children in a separate waiting room).<sup>190,194-199</sup> Evidence that vaccine refusal is a modifiable behavior and that vaccine-hesitant parents can change their mind after conversations with their child's pediatrician, 133,167 particularly when pediatricians employ the evidence-based communication strategies described above, supports this approach.

Dismissal of child patients of vaccine-refusing parents can be a difficult decision arrived at after considering multiple factors and documented attempts to counsel vaccine-refusing families. However, if repeated attempts to help understand and address parental values and vaccine concerns fails to engender trust, move parents toward vaccine acceptance, or strengthen the therapeutic alliance, dismissal can be an acceptable option. When considering the dismissal of a vaccine-refusing parent, it is important to verify that less drastic alternatives are not feasible and work to minimize potential negative impacts on the child. The consideration, design, and implementation of office policies for dismissal, for instance, will ideally take into account practice setting, patient population, availability of other nearby, reputable sources of medical care for children, and the framing of the policy (stressing the importance of vaccination). Transparency and equitable application of such policies is also important. Dismissal must also be conducted in a manner consistent with applicable state laws prohibiting abandonment of patients. Although these laws vary from state to state, official notification of the parents or legal guardian is required, along with the provision of information for finding a new physician. The parental refusal of recommended vaccines and attempts to counsel the family should be documented in the patient's medical record. Furthermore, the dismissing physician is obligated to continue current treatment and provide emergency care for a reasonable period of time, usually 30 days.<sup>200</sup>

### CONCLUSIONS

16

The majority of US parents vaccinate their children according to the recommended schedule. Implementation of evidence-based techniques for increasing vaccination uptake may be all that is needed to convince many hesitant parents to vaccinate their children. This includes use of a presumptive approach ("She's due for some vaccines today") for introducing vaccines, which can potentially overcome mild or moderate levels of hesitancy. For parents who remain reluctant to vaccinate their child, a strong recommendation from the pediatrician may convince them of the importance of vaccination. For others, more detailed conversations may be necessary, and communication techniques such as motivational interviewing show promise as effective frameworks for the vaccine conversation. Ultimately, there are some parents who will refuse vaccination even after lengthy conversations.

It is important for pediatricians to appreciate that vaccine-hesitant parents are a heterogeneous group and that specific parental vaccine concerns need to be individually identified and addressed. Listening to parental concerns and responding to questions about vaccine safety, the science behind the current vaccine schedule, the extensive testing of each vaccine before and after licensure, and the severity of the diseases being prevented is a normal part of any preventive care encounter.

Improving vaccine uptake can best be accomplished in the course of clinical practice through open communication and discussion between the pediatrician and the parents. Because most parents agree to vaccinate their children, this dialogue, which can be started as early as the prenatal interview visit, is an ongoing process. Providing vaccine-related information before the first immunization visit may permit parents to clearly formulate their concerns so that they can be fully addressed by the pediatrician.<sup>201</sup> Working with parents who have questions about vaccines is a wonderful opportunity to build rapport and trust with a family and, ultimately, protect their children from the scourge of vaccine-preventable diseases.

#### **LEAD AUTHORS**

Sean T. O'Leary, MD, MPH, FAAP Douglas J. Opel, MD, MPH Jessica R. Cataldi, MD, FAAP Jesse M. Hackell, MD, FAAP

#### **COMMITTEE ON INFECTIOUS DISEASES, 2022–2023**

Sean T. O'Leary, MD, MPH, FAAP, Chairperson James D. Campbell, MD, MS, FAAP Monica I. Ardura, DO, MSCS, FAAP Ritu Banerjee, MD, PhD, FAAP Kristina A. Bryant, MD, FAAP Mary T. Caserta, MD, FAAP Robert Frenck, Jr., MD, FAAP Robert Frenck, Jr., MD, FAAP Jeffrey S. Gerber, MD, PhD, FAAP Chandy C. John, MD, MS, FAAP Athena P. Kourtis, MD, PhD, MPH, FAAP Angela Myers, MD, MPH, FAAP Pia Pannaraj, MD, MPH, FAAP Adam J. Ratner, MD, MPH, FAAP Samir S. Shah, MD, MSCE, FAAP

## **EX OFFICIO**

David W. Kimberlin, MD, FAAP – *Red Book* Editor Elizabeth D. Barnett, MD, FAAP – *Red Book Associate* Editor

Ruth Lynfield, MD, FAAP – *Red Book Associate* Editor Mark H. Sawyer, MD, FAAP – *Red Book Associate* Editor Henry H. Bernstein, DO, MHCM, FAAP – immediate past *Red Book* Online Lead

## LIAISONS

Cristina Cardemil, MD, MPH, FAAP – National Institutes of Health

Karen M. Farizo, MD - US Food and Drug Administration

Lisa M. Kafer, MD, FAAP – AAP Committee on Practice Ambulatory Medicine

David Kim, MD – HHS Office of Infectious Disease and HIV/AIDS Policy

Eduardo López Medina, MD, MSc – Sociedad Latinoamericana de Infectología Pediátrica

Denee Moore, MD, FAAFP – American Academy of Family Physicians

Lakshmi Panagiotakopoulos, MD, MPH – Centers for Disease Control and Prevention

José R. Romero, MD, FAAP – Centers for Disease Control and Prevention

Laura Sauvé, MD, MPH, FAAP, FRCPS – Canadian Paediatric Society (via Web Ex)

Jeffrey R. Starke, MD, FAAP – American Thoracic Society

Jennifer Thompson, MD – American College of Obstetricians and Gynecologists

Melinda Wharton, MD, MPH – Centers for Disease Control and Prevention

Charles R. Woods, Jr, MD, MS, FAAP – Pediatric Infectious Diseases Society

## **STAFF**

Jennifer M. Frantz, MPH Gillian Gibbs, MPH

## **COMMITTEE ON BIOETHICS, 2022–2023**

Naomi Tricot Laventhal, MD, FAAP, Chairperson Gina Marie Geis, MD, FAAP Deborah Susan Loeff, MD, FAAP Kelly Michelson, MD, MPH, FAAP Mary Ott, MD, MA, FAAP

## CONSULTANT

Nanette Elster, JD, MPH

### LIAISON

Douglas S. Diekema, MD, MPH, FAAP – American Board of Pediatrics Kavita Arora, MD, MBE, MS – American College of Obstetricians and Gynecologists Maria McGee, MD, MPH – American Academy of Child and Adolescent Psychiatry

## STAFF

Anjie Emanuel, MPH

## COMMITTEE ON PRACTICE AND AMBULATORY MEDICINE, 2022–2023

Jesse M. Hackell, MD, FAAP, Chairperson Yvette Marie Almendarez, MD, FAAP Abeba Mebrahtu Berhane, MD, FAAP Patricia E. Cantrell, MD, FAAP Lisa Michele Kafer, MD, FAAP Tomitra Latimer, MD, FAAP Robin Warner, MD, FAAP Robert H. Wiskind, MD, FAAP

## LIAISONS

Katherine Schafer, DO, FAAP – AAP Section on Administration and Practice Management Alisa Skatrud – Family Liaison

## STAFF

Mackenzie A. Magnus, MBA, MPH

## ACKNOWLEDGMENT

The authors would like to acknowledge the important contributions of Jeremy Michel, MD, MHS, on behalf of the Partnership for Policy Implementation.

## **ABBREVIATIONS**

AAP: American Academy of Pediatrics ACIP: Advisory Committee on Immunization Practices BEST: Biologics Effectiveness and Safety CDC: Centers for Disease Control and Prevention CISA: Clinical Immunization Safety Assessment Project EHR: electronic health record FDA: US Food and Drug Administration HPV: human papillomavirus vaccine MI: motivational interviewing MMR: measles, mumps, and rubella vaccine VAERS: Vaccine Adverse Event Reporting System VSD: Vaccine Safety Datalink

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Copyright © 2024 by the American Academy of Pediatrics

FUNDING: No external funding.

FINANCIAL/CONFLICT OF INTEREST DISCLOSURE: The authors have indicated they have no potential conflicts of interest to disclose.

#### REFERENCES

- Brewer NT, Chapman GB, Rothman AJ, Leask J, Kempe A. Increasing vaccination: putting psychological science into action. *Psychol Sci Public Interest.* 2017;18(3):149–207
- Dudley MZ, Privor-Dumm L, Dubé È, MacDonald NE. Words matter: vaccine hesitancy, vaccine demand, vaccine confidence, herd immunity and mandatory vaccination. *Vaccine*. 2020;38(4): 709–711
- SAGE Working Group; World Health Organization. Report of the SAGE working group on vaccine hesitancy. Available at: https:// www.who.int/immunization/sage/meetings/2014/october/1\_ Report\_WORKING\_GROUP\_vaccine\_hesitancy\_final.pdf. Accessed April 21, 2021
- Centers for Disease Control and Prevention. What is vaccine confidence?. Available at: https://www.cdc.gov/vaccines/covid-19/ vaccinate-with-confidence/building-trust.html. Accessed March 29, 2022
- Gust D, Brown C, Sheedy K, Hibbs B, Weaver D, Nowak G. Immunization attitudes and beliefs among parents: beyond a dichotomous perspective. *Am J Health Behav.* 2005;29(1):81–92
- Dubé E, Laberge C, Guay M, Bramadat P, Roy R, Bettinger J. Vaccine hesitancy: an overview. *Hum Vaccin Immunother*: 2013;9(8): 1763–1773
- Santibanez TA, Nguyen KH, Greby SM, et al. Parental vaccine hesitancy and childhood influenza vaccination. *Pediatrics*. 2020; 146(6):e2020007609
- Edwards KM, Hackell JM; Committee on Infectious Diseases; The Committee on Practice and Ambulatory Medicine. Countering vaccine hesitancy. *Pediatrics*. 2016;138(3):e20162146
- Gust DA, Darling N, Kennedy A, Schwartz B. Parents with doubts about vaccines: which vaccines and reasons why. *Pediatrics*. 2008;122(4):718–725
- Smith PJ, Humiston SG, Marcuse EK, et al. Parental delay or refusal of vaccine doses, childhood vaccination coverage at 24 months of age, and the Health Belief Model. *Public Health Rep.* 2011;126 Suppl 2(Suppl 2):135–146
- Leask J, Kinnersley P, Jackson C, Cheater F, Bedford H, Rowles G. Communicating with parents about vaccination: a framework for health professionals. *BMC Pediatr.* 2012;12:154
- 12. Kahan DM. Vaccine risk perceptions and ad hoc risk communication: an empirical assessment (January 27, 2014). CCP Risk Perception Studies Report No. 17. Yale Law & Economics Research Paper No. 491. Available at: https://ssrn.com/abstract=2386034. Accessed January 10, 2024

18

- Daley MF, Reifler LM, Shoup JA, et al. Temporal trends in undervaccination: a population-based cohort study. *Am J Prev Med.* 2021;61(1):64–72
- Hill HA, Chen M, Elam-Evans LD, Yankey D, Singleton JA. Vaccination coverage by age 24 months among children born during 2018–2019 - national immunization survey-child, United States, 2019–2021. *MMWR Morb Mortal Wkly Rep.* 2023;72(2):33–38
- Patel Murthy B, Zell E, Kirtland K, et al. Impact of the COVID-19 pandemic on administration of selected routine childhood and adolescent vaccinations - 10 U.S. jurisdictions, March-September 2020. *MMWR Morb Mortal Wkly Rep.* 2021;70(23):840–845
- Seither R, Laury J, Mugerwa-Kasujja A, Knighton CL, Black CL. Vaccination coverage with selected vaccines and exemption rates among children in kindergarten - United States, 2020-21 school year. *MMWR Morb Mortal Wkly Rep.* 2022;71(16):561–568
- Seither R, Calhoun K, Yusuf OB, et al. Vaccination coverage with selected vaccines and exemption rates among children in kindergarten - United States, 2021-22 school year. *MMWR Morb Mortal Wkly Rep.* 2023;72(2):26–32
- Opel DJ, Furniss A, Zhou C, et al. Parent attitudes towards childhood vaccines after the onset of SARS-CoV-2 in the United States. Acad Pediatr. 2022;22(8):1407–1413
- Humble RM, Scott SD, Dubé E, Olson J, MacDonald SE. The impact of the COVID-19 pandemic on parents' perceptions and acceptance of routine childhood vaccination in Canada: a national longitudinal study. *Vaccine*. 2023;41(2):407–415
- 20. Funk C, Tyson A, Kennedy B, Pasquini G. Americans' largely positive views of childhood vaccines hold steady. Available at: https://www.pewresearch.org/science/2023/05/16/americanslargely-positive-views-of-childhood-vaccines-hold-steady/. Accessed May 25, 2023
- Gidengil C, Chen C, Parker AM, Nowak S, Matthews L. Beliefs around childhood vaccines in the United States: a systematic review. *Vaccine.* 2019;37(45):6793–6802
- Díaz Crescitelli ME, Ghirotto L, Sisson H, et al. A meta-synthesis study of the key elements involved in childhood vaccine hesitancy. *Public Health.* 2020;180:38–45
- 23. Majid U, Ahmad M. The factors that promote vaccine hesitancy, rejection, or delay in parents. *Qual Health Res.* 2020;30(11): 1762–1776
- 24. Olson O, Berry C, Kumar N. Addressing parental vaccine hesitancy towards childhood vaccines in the United States: a systematic literature review of communication interventions and strategies. *Vaccines (Basel)*. 2020;8(4):590

- Salmon DA, Moulton LH, Omer SB, DeHart MP, Stokley S, Halsey NA. Factors associated with refusal of childhood vaccines among parents of school-aged children: a case-control study. *Arch Pediatr Adolesc Med.* 2005;159(5):470–476
- Pomares TD, Buttenheim AM, Amin AB, et al. Association of cognitive biases with human papillomavirus vaccine hesitancy: a crosssectional study. *Hum Vaccin Immunother*. 2020;16(5):1018–1023
- Callaghan T, Motta M, Sylvester S, Lunz Trujillo K, Blackburn CC. Parent psychology and the decision to delay childhood vaccination. Soc Sci Med. 2019;238:112407
- 28. Finkelstein SR, Boland WA, Vallen B, Connell PM, Sherman GD, Feemster KA. Psychological reactance impacts ratings of pediatrician vaccine-related communication quality, perceived vaccine safety, and vaccination priority among U.S. parents. *Hum Vaccin Immunother*: 2020;16(5):1024–1029
- Cataldi JR, Sevick C, Pyrzanowski J, et al. Addressing personal parental values in decisions about childhood vaccination: measure development. *Vaccine*. 2019;37(38):5688–5697
- 30. Korn L, Böhm R, Meier NW, Betsch C. Vaccination as a social contract. *Proc Natl Acad Sci USA*. 2020;117(26):14890–14899
- Attwell K, Freeman M. I immunise: an evaluation of a valuesbased campaign to change attitudes and beliefs. *Vaccine*. 2015; 33(46):6235–6240
- Schoeppe J, Cheadle A, Melton M, et al. The immunity community: a community engagement strategy for reducing vaccine hesitancy. *Health Promot Pract.* 2017;18(5):654–661
- Brewer NT, Chapman GB, Gibbons FX, Gerrard M, McCaul KD, Weinstein ND. Meta-analysis of the relationship between risk perception and health behavior: the example of vaccination. *Health Psychol.* 2007;26(2):136–145
- 34. Glanz JM, McClure DL, Magid DJ, et al. Parental refusal of pertussis vaccination is associated with an increased risk of pertussis infection in children. *Pediatrics.* 2009;123(6): 1446–1451
- Glanz JM, McClure DL, O'Leary ST, et al. Parental decline of pneumococcal vaccination and risk of pneumococcal related disease in children. *Vaccine*. 2011;29(5):994–999
- 36. Omer SB, Enger KS, Moulton LH, Halsey NA, Stokley S, Salmon DA. Geographic clustering of nonmedical exemptions to school immunization requirements and associations with geographic clustering of pertussis. Am J Epidemiol. 2008;168(12):1389–1396
- Phadke VK, Bednarczyk RA, Salmon DA, Omer SB. Association between vaccine refusal and vaccine-preventable diseases in the United States: a review of measles and pertussis. *JAMA*. 2016; 315(11):1149–1158
- May T, Silverman RD. 'Clustering of exemptions' as a collective action threat to herd immunity. *Vaccine*. 2003;21(11-12):1048–1051
- Sinclair DR, Grefenstette JJ, Krauland MG, et al. Forecasted size of measles outbreaks associated with vaccination exemptions for schoolchildren. *JAMA Netw Open.* 2019;2(8):e199768
- 40. Gromis A, Liu KY. Spatial clustering of vaccine exemptions on the risk of a measles outbreak. *Pediatrics.* 2022;149(1):e2021050971

- 41. Gastañaduy PA, Budd J, Fisher N, et al. A measles outbreak in an underimmunized Amish community in Ohio. N Engl J Med. 2016;375(14):1343–1354
- 42. Leslie TF, Delamater PL, Yang YT. It could have been much worse: the Minnesota measles outbreak of 2017. *Vaccine*. 2018;36(14): 1808–1810
- Hall V, Banerjee E, Kenyon C, et al. Measles outbreak Minnesota April-May 2017. MMWR Morb Mortal Wkly Rep. 2017;66(27): 713–717
- Carlson A, Riethman M, Gastañaduy P, et al. Notes from the field: community outbreak of measles - Clark County, Washington, 2018-2019. MMWR Morb Mortal Wkly Rep. 2019;68(19):446–447
- McDonald R, Ruppert PS, Souto M, et al. Notes from the field: measles outbreaks from imported cases in orthodox Jewish communities - New York and New Jersey, 2018-2019. MMWR Morb Mortal Wkly Rep. 2019;68(19):444–445
- 46. Zucker JR, Rosen JB, Iwamoto M, et al. Consequences of undervaccination - measles outbreak, New York City, 2018-2019. N Engl J Med. 2020;382(11):1009–1017
- Causey K, Fullman N, Sorensen RJD, et al. Estimating global and regional disruptions to routine childhood vaccine coverage during the COVID-19 pandemic in 2020: a modelling study. *Lancet.* 2021;398(10299):522–534
- 48. World Health Organization. COVID-19 pandemic leads to major backsliding on childhood vaccinations, new WHO, UNICEF data shows. Available at: https://www.who.int/news/item/15-07-2021covid-19-pandemic-leads-to-major-backsliding-on-childhood-vaccinationsnew-who-unicef-data-shows. Accessed October 15, 2021
- 49. DeSilva MB, Haapala J, Vazquez-Benitez G, et al. Association of the COVID-19 pandemic with routine childhood vaccination rates and proportion up to date with vaccinations across 8 US health systems in the vaccine safety datalink. *JAMA Pediatr*: 2021;176 (1):68–77
- Feldman AG, O'Leary ST, Danziger-Isakov L. The risk of resurgence in vaccine-preventable infections due to coronavirus disease 2019-related gaps in immunization. *Clin Infect Dis.* 2021; 73(10):1920–1923
- Cacciatore MA, Nowak G, Evans NJ. Exploring the impact of the us measles outbreak on parental awareness of and support for vaccination. *Health Aff (Millwood)*. 2016;35(2):334–340
- 52. Oster E. Does disease cause vaccination? Disease outbreaks and vaccination response. *J Health Econ.* 2018;57:90–101
- 53. Schober T. Effects of a measles outbreak on vaccination uptake. *Econ Hum Biol.* 2020;38:100871
- Wolf ER, Opel D, DeHart MP, Warren J, Rowhani-Rahbar A. Impact of a pertussis epidemic on infant vaccination in Washington state. *Pediatrics*. 2014;134(3):456–464
- Deiner MS, Fathy C, Kim J, et al. Facebook and Twitter vaccine sentiment in response to measles outbreaks. *Health Informatics* J. 2019;25(3):1116–1132
- Cataldi JR, Dempsey AF, O'Leary ST. Measles, the media, and MMR: impact of the 2014-15 measles outbreak. *Vaccine*. 2016; 34(50):6375–6380

- Marcelin JR, Swartz TH, Bernice F, et al. Addressing and inspiring vaccine confidence in black, indigenous, and people of color during the coronavirus disease 2019 pandemic. *Open Forum Infect Dis.* 2021;8(9):ofab417
- 58. Goldenberg MJ. *Vaccine Hesitancy: Public Trust, Expertise, and the War on Science.* University of Pittsburgh Press; 2021
- Walsh B, Doherty E, O'Neill C. Since the start of the vaccines for children program, uptake has increased, and most disparities have decreased. *Health Aff (Millwood)*. 2016;35(2):356–364
- Hammershaimb EA, Campbell JD, O'Leary ST. Coronavirus disease-2019 vaccine hesitancy. *Pediatr Clin North Am.* 2023; 70(2):243–257
- 61. Opel DJ, Brewer NT, Buttenheim AM, et al. The legacy of the COVID-19 pandemic for childhood vaccination in the USA. *Lancet.* 2023;401(10370):75–78
- Diekema DS. Rhetoric, persuasion, compulsion, and the stubborn problem of vaccine hesitancy. *Perspect Biol Med.* 2022; 65(1):106–123
- Milien E, Enoma E, Pierre-Louis L, et al. We got us: a communitycentered approach to increasing vaccine access for minoritized groups. J Hosp Med. 2022;17(9):765–768
- Adams DA, Thomas KR, Jajosky RA, et al; Nationally Notifiable Infectious Conditions Group. Summary of notifiable infectious diseases and conditions United States, 2015. *MMWR Morb Mortal Wkly Rep.* 2017;64(53):1–143
- Rosen JB, Arciuolo RJ, Khawja AM, Fu J, Giancotti FR, Zucker JR. Public health consequences of a 2013 measles outbreak in New York City. *JAMA Pediatr*. 2018;172(9):811–817
- 66. Pike J, Leidner AJ, Gastañaduy PA. A review of measles outbreak cost estimates from the United States in the postelimination era (2004–2017): estimates by perspective and cost type. *Clin Infect Dis.* 2020;71(6):1568–1576
- 67. Pike J, Melnick A, Gastañaduy PA, et al. Societal costs of a measles outbreak. *Pediatrics*. 2021;147(4):e2020027037
- 68. Ortega-Sanchez IR, Vijayaraghavan M, Barskey AE, Wallace GS. The economic burden of sixteen measles outbreaks on United States public health departments in 2011. *Vaccine*. 2014;32(11): 1311–1317
- Barskey AE, Schulte C, Rosen JB, et al. Mumps outbreak in Orthodox Jewish communities in the United States. N Engl J Med. 2012;367(18):1704–1713
- Zhou F, Shefer A, Wenger J, et al. Economic evaluation of the routine childhood immunization program in the United States, 2009. *Pediatrics*. 2014;133(4):577–585
- Wendorf KA, Kay M, Ortega-Sanchez IR, Munn M, Duchin J. Cost of measles containment in an ambulatory pediatric clinic. *Pediatr Infect Dis J.* 2015;34(6):589–593
- 72. Cook KM, Evans G. The national vaccine injury compensation program. *Pediatrics*. 2011;127(Suppl 1):S74–S77
- Kempe A, Daley MF, McCauley MM, et al. Prevalence of parental concerns about childhood vaccines: the experience of primary care physicians. *Am J Prev Med.* 2011;40(5):548–555

- 74. American Academy of Pediatrics. Vaccine counseling and preventive care visits. Available at: https://www.aap.org/en/practicemanagement/practice-financing/coding-and-valuation/vaccinefinancing-and-coding/vaccine-counseling-and-preventive-carevisits/. Accessed February 27, 2022
- 75. Center for Medicare and Medicaid Services. Biden-Harris administration makes 100% federal Medicaid matching funds available for state expenditures on certain COVID-19 vaccine counseling visits for children and youth. Available at: https://www.cms.gov/ newsroom/press-releases/biden-harris-administration-makes-100federal-medicaid-matching-funds-available-state-expenditures. Accessed May 4, 2022
- Kempe A, O'Leary ST, Kennedy A, et al. Physician response to parental requests to spread out the recommended vaccine schedule. *Pediatrics.* 2015;135(4):666–677
- 77. Dean W, Talbot S, Dean A. Reframing clinician distress: moral injury not burnout. *Fed Pract.* 2019;36(9):400–402
- Klitzman R. Needs to address clinicians' moral distress in treating unvaccinated COVID-19 patients. *BMC Med Ethics*. 2022; 23(1):110
- Ugale JL, Spielvogle H, Spina C, et al. "It's like 1998 again": why parents still refuse and delay vaccines. *Glob Pediatr Health*. 2021;8:2333794X211042331
- Salmon DA, Pavia A, Gellin B. Editors' introduction: vaccine safety throughout the product life cycle. *Pediatrics*. 2011;127(Suppl 1): S1–S4
- Marshall V, Baylor NW. Food and Drug Administration regulation and evaluation of vaccines. *Pediatrics*. 2011;127 (Suppl 1):S23–S30
- Curlin G, Landry S, Bernstein J, et al. Integrating safety and efficacy evaluation throughout vaccine research and development. *Pediatrics.* 2011;127(Suppl 1):S9–S15
- 83. Ball R, Horne D, Izurieta H, Sutherland A, Walderhaug M, Hsu H. Statistical, epidemiological, and risk-assessment approaches to evaluating safety of vaccines throughout the life cycle at the Food and Drug Administration. *Pediatrics*. 2011;127(Suppl 1): S31–S38
- Kanesa-thasan N, Shaw A, Stoddard JJ, Vernon TM. Ensuring the optimal safety of licensed vaccines: a perspective of the vaccine research, development, and manufacturing companies. *Pediatrics*. 2011;127(Suppl 1):S16–S22
- Pickering LK, Meissner HC, Orenstein WA, Cohn AC. Principles of vaccine licensure, approval, and recommendations for use. *Mayo Clin Proc.* 2020;95(3):600–608
- Pickering LK, Orenstein WA, Sun W, Baker CJ. FDA licensure of and ACIP recommendations for vaccines. *Vaccine*. 2017;35(37): 5027–5036
- Oliver SE, Gargano JW, Marin M, et al. The Advisory Committee on Immunization Practices' interim recommendation for use of Pfizer-BioNTech COVID-19 vaccine - United States, December 2020. *MMWR Morb Mortal Wkly Rep.* 2020;69(50):1922–1924
- Shimabukuro TT, Nguyen M, Martin D, DeStefano F. Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS). *Vaccine*. 2015;33(36):4398–4405

- Baggs J, Gee J, Lewis E, et al. The Vaccine Safety Datalink: a model for monitoring immunization safety. *Pediatrics*. 2011;127(Suppl 1): S45–S53
- McNeil MM, Gee J, Weintraub ES, et al. The Vaccine Safety Datalink: successes and challenges monitoring vaccine safety. *Vaccine*. 2014;32(42):5390–5398
- Yih WK, Kulldorff M, Fireman BH, et al. Active surveillance for adverse events: the experience of the Vaccine Safety Datalink project. *Pediatrics*. 2011;127 (Suppl 1):S54–S64
- Chen RT, Glasser JW, Rhodes PH, et al; The Vaccine Safety Datalink Team. Vaccine Safety Datalink project: a new tool for improving vaccine safety monitoring in the United States. *Pediatrics*. 1997;99(6):765–773
- 93. France EK, Glanz J, Xu S, et al; Vaccine Safety Datalink Team. Risk of immune thrombocytopenic purpura after measlesmumps-rubella immunization in children. *Pediatrics*. 2008;121(3): e687–e692
- 94. Klein NP, Fireman B, Yih WK, et al; Vaccine Safety Datalink. Measles-mumps-rubella-varicella combination vaccine and the risk of febrile seizures. *Pediatrics*. 2010;126(1):e1–e8
- 95. Glanz JM, Clarke CL, Daley MF, et al. The childhood vaccination schedule and the lack of association with type 1 diabetes. *Pediatrics*. 2021;148(6):e2021051910
- 96. Kharbanda EO, Vazquez-Benitez G, DeSilva MB, et al. Association of inadvertent 9-valent human papillomavirus vaccine in pregnancy with spontaneous abortion and adverse birth outcomes. *JAMA Netw Open*. 2021;4(4):e214340
- Panagiotakopoulos L, McCarthy NL, Tepper NK, et al. Evaluating the association of stillbirths after maternal vaccination in the vaccine safety datalink. *Obstet Gynecol.* 2020;136(6):1086–1094
- 98. Glanz JM, Clarke CL, Xu S, et al. Association between rotavirus vaccination and type 1 diabetes in children. JAMA Pediatr. 2020; 174(5):455–462
- Sukumaran L, McCarthy NL, Kharbanda EO, et al. Infant hospitalizations and mortality after maternal vaccination. *Pediatrics*. 2018;141(3):e20173310
- 100. Donahue JG, Kieke BA, Yih WK, et al; Vaccine Safety DataLink Team. Varicella vaccination and ischemic stroke in children: is there an association? *Pediatrics*. 2009;123(2):e228-e234
- 101. Deady M, Ezzeldin H, Cook K, et al. The Food and Drug Administration biologics effectiveness and safety initiative facilitates detection of vaccine administrations from unstructured data in medical records through natural language processing. *Front Digit Health*. 2021;3:777905
- 102. LaRussa PS, Edwards KM, Dekker CL, et al. Understanding the role of human variation in vaccine adverse events: the Clinical Immunization Safety Assessment Network. *Pediatrics*. 2011; 127(Suppl 1):S65–S73
- 103. Gee J, Marquez P, Su J, et al. First month of COVID-19 vaccine safety monitoring - United States, December 14, 2020-January 13, 2021. MMWR Morb Mortal Wkly Rep. 2021;70(8):283–288

- 104. Gidengil C, Goetz MB, Maglione M, et al. Safety of Vaccines Used for Routine Immunization in the United States: An Update. Agency for Healthcare Research and Quality; 2021
- 105. Institute of Medicine. *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence, and Future Studies.* The National Academies Press; 2013:236
- 106. Meites E, Kempe A, Markowitz LE. Use of a 2-dose schedule for human papillomavirus vaccination - updated recommendations of the Advisory Committee on Immunization Practices. *MMWR Morb Mortal Wkly Rep.* 2016;65(49):1405–1408
- 107. Offit PA, Moser CA. The problem with Dr Bob's alternative vaccine schedule. *Pediatrics*. 2009;123(1):e164-e169
- 108. Robison SG, Groom H, Young C. Frequency of alternative immunization schedule use in a metropolitan area. *Pediatrics*. 2012; 130(1):32–38
- 109. Offit PA, Quarles J, Gerber MA, et al. Addressing parents' concerns: do multiple vaccines overwhelm or weaken the infant's immune system? *Pediatrics*. 2002;109(1):124–129
- 110. Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet.* 1998;351(9103):637–641
- 111. Deer B. Wakefield's "autistic enterocolitis" under the microscope. *BMJ.* 2010;340:c1127
- 112. Deer B. How the case against the MMR vaccine was fixed. *BMJ*. 2011;342:c5347
- 113. Deer B. Secrets of the MMR scare. How the vaccine crisis was meant to make money. *BMJ.* 2011;342:c5258
- 114. Deer B. Secrets of the MMR scare. The Lancet's two days to bury bad news. *BMJ*. 2011;342:c7001
- 115. Deer B. Pathology reports solve "new bowel disease" riddle. *BMJ.* 2011;343:d6823
- 116. Deer B. More secrets of the MMR scare. Who saw the "histological findings"? *BMJ.* 2011;343:d7892
- 117. Gerber JS, Offit PA. Vaccines and autism: a tale of shifting hypotheses. *Clin Infect Dis.* 2009;48(4):456–461
- 118. Offit PA. Thimerosal and vaccines—a cautionary tale. N Engl J Med. 2007;357(13):1278—1279
- 119. Keith LS, Jones DE, Chou CH. Aluminum toxicokinetics regarding infant diet and vaccinations. *Vaccine*. 2002;20(Suppl 3):S13–S17
- 120. Mitkus RJ, King DB, Hess MA, Forshee RA, Walderhaug MO. Updated aluminum pharmacokinetics following infant exposures through diet and vaccination. *Vaccine*. 2011;29(51):9538–9543
- 121. Daley MF, Reifler LM, Glanz JM, et al. Association between aluminum exposure from vaccines before age 24 months and persistent asthma at age 24 to 59 months. *Acad Pediatr*. 2022;23(1): 37–46
- 122. Grabenstein JD. What the world's religions teach, applied to vaccines and immune globulins. *Vaccine*. 2013;31(16):2011–2023
- 123. Hall E, Wodi AP, Hamborsky J, Morelli V, Schillie S. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* US Department of Health and Human Services; 2021

- 124. Centers for Disease Control and Prevention. ACIP vaccine recommendations and guidelines. Available at: https://www.cdc. gov/vaccines/hcp/acip-recs/index.html. Accessed February 2022
- 125. Eller NM, Henrikson NB, Opel DJ. Vaccine information sources and parental trust in their child's health care provider. *Health Educ Behav.* 2019;46(3):445–453
- 126. Freed GL, Clark SJ, Butchart AT, Singer DC, Davis MM. Sources and perceived credibility of vaccine-safety information for parents. *Pediatrics*. 2011;127(Suppl 1):S107–S112
- 127. Smith PJ, Kennedy AM, Wooten K, Gust DA, Pickering LK. Association between health care providers' influence on parents who have concerns about vaccine safety and vaccination coverage. *Pediatrics.* 2006;118(5):e1287–e1292
- 128. Rubincam C, Greyson D, Haselden C, Saunders R, Bettinger JA. Is the pre-natal period a missed opportunity for communicating with parents about immunizations? Evidence from a longitudinal qualitative study in Victoria, British Columbia. *BMC Public Health*. 2022;22(1):237
- 129. Danchin MH, Costa-Pinto J, Attwell K, et al. Vaccine decisionmaking begins in pregnancy: correlation between vaccine concerns, intentions and maternal vaccination with subsequent childhood vaccine uptake. *Vaccine*. 2018;36(44):6473–6479
- 130. Smith LE, Amlôt R, Weinman J, Yiend J, Rubin GJ. A systematic review of factors affecting vaccine uptake in young children. *Vaccine.* 2017;35(45):6059–6069
- 131. Newman PA, Logie CH, Lacombe-Duncan A, et al. Parents' uptake of human papillomavirus vaccines for their children: a systematic review and meta-analysis of observational studies. *BMJ Open.* 2018;8(4):e019206
- 132. Dempsey AF, Pyrzanowski J, Lockhart S, Campagna E, Barnard J, O'Leary ST. Parents' perceptions of provider communication regarding adolescent vaccines. *Hum Vaccin Immunother*. 2016; 12(6):1469–1475
- 133. Hofstetter AM, Robinson JD, Lepere K, Cunningham M, Etsekson N, Opel DJ. Clinician-parent discussions about influenza vaccination of children and their association with vaccine acceptance. *Vaccine*. 2017;35(20):2709–2715
- 134. Opel DJ, Mangione-Smith R, Robinson JD, et al. The influence of provider communication behaviors on parental vaccine acceptance and visit experience. *Am J Public Health.* 2015;105(10): 1998–2004
- 135. Opel DJ, Heritage J, Taylor JA, et al. The architecture of provider-parent vaccine discussions at health supervision visits. *Pediatrics.* 2013;132(6):1037–1046
- 136. Sturm L, Donahue K, Kasting M, Kulkarni A, Brewer NT, Zimet GD. Pediatrician-parent conversations about human papillomavirus vaccination: an analysis of audio recordings. *J Adolesc Health.* 2017;61(2):246–251
- 137. Brewer NT, Hall ME, Malo TL, Gilkey MB, Quinn B, Lathren C. Announcements versus conversations to improve HPV vaccination coverage: a randomized trial. *Pediatrics*. 2017;139(1):e20161764
- 138. Opel DJ, Robinson JD, Heritage J, Korfiatis C, Taylor JA, Mangione-Smith R. Characterizing providers' immunization communication

practices during health supervision visits with vaccine-hesitant parents: a pilot study. *Vaccine*. 2012;30(7):1269–1275

- 139. Opel DJ, Taylor JA, Zhou C, Catz S, Myaing M, Mangione-Smith R. The relationship between parent attitudes about childhood vaccines survey scores and future child immunization status: a validation study. *JAMA Pediatr.* 2013;167(11):1065–1071
- 140. Opel DJ, Taylor JA, Mangione-Smith R, et al. Validity and reliability of a survey to identify vaccine-hesitant parents. *Vaccine*. 2011;29(38):6598–6605
- 141. Opel DJ, Mangione-Smith R, Taylor JA, et al. Development of a survey to identify vaccine-hesitant parents: the parent attitudes about childhood vaccines survey. *Hum Vaccin*. 2011;7(4):419–425
- 142. Hofstetter AM, Simon TD, Lepere K, et al. Parental vaccine hesitancy and declination of influenza vaccination among hospitalized children. *Hosp Pediatr*. 2018;8(10):628–635
- 143. Strelitz B, Gritton J, Klein EJ, et al. Parental vaccine hesitancy and acceptance of seasonal influenza vaccine in the pediatric emergency department. *Vaccine*. 2015;33(15):1802–1807
- 144. Cunningham RM, Minard CG, Guffey D, Swaim LS, Opel DJ, Boom JA. Prevalence of vaccine hesitancy among expectant mothers in Houston, Texas. *Acad Pediatr*. 2018;18(2):154–160
- 145. Williams SE, Morgan A, Opel D, Edwards K, Weinberg S, Rothman R. Screening tool predicts future underimmunization among a pediatric practice in Tennessee. *Clin Pediatr (Phila)*. 2016;55(6): 537–542
- 146. Opel DJ, Zhou C, Robinson JD, et al. Impact of childhood vaccine discussion format over time on immunization status. Acad Pediatr. 2018;18(4):430–436
- 147. Malo TL, Hall ME, Brewer NT, Lathren CR, Gilkey MB. Why is announcement training more effective than conversation training for introducing HPV vaccination? A theory-based investigation. *Implement Sci.* 2018;13(1):57
- 148. Ariely D. Predictably Irrational. Harper-Collins; 2009
- 149. Johnson EJ, Goldstein D. Medicine. Do defaults save lives? *Science*. 2003;302(5649):1338–1339
- 150. Halpern SD, Ubel PA, Asch DA. Harnessing the power of default options to improve health care. *N Engl J Med.* 2007;357(13): 1340–1344
- 151. Reñosa MDC, Landicho J, Wachinger J, et al. Nudging toward vaccination: a systematic review. *BMJ Glob Health.* 2021;6(9): e006237
- 152. Opel DJ, Omer SB. Measles, mandates, and making vaccination the default option. *JAMA Pediatr*: 2015;169(4):303–304
- 153. Bazerman MH, Moore DA. Judgment in Managerial Decision-Making. Wiley; 2013
- 154. Samuelson W, Zeckhauser R. Status quo bias in decision making. J Risk Uncertain. 1988;1(1):7–59
- 155. Blumenthal-Barby JS, Opel DJ. Nudge or grudge? choice architecture and parental decision-making. *Hastings Cent Rep.* 2018;48(2):33–39
- 156. National Center for Immunization and Respiratory Diseases CfDCaP. Talking with parents about vaccines for infants. Available

at: https://www.cdc.gov/vaccines/hcp/conversations/talkingwith-parents.html. Accessed February 12, 2022

- 157. Miller WR, Rollnick S. *Motivational Interviewing: Preparing People for Change.* The Guilford Press; 1991
- 158. Rollnick S, Miller WR, Butler CC. *Motivational Interviewing in Health Care: Helping Patients Change Behavior*. The Guilford Press; 2008
- 159. Miller WR. Motivational interviewing: research, practice, and puzzles. *Addict Behav.* 1996;21(6):835–842
- Brand V, Bray K, Macneill S, Catley D, Williams K. Impact of single-session motivational interviewing on clinical outcomes following periodontal maintenance therapy. *Int J Dent Hyg.* 2013;11(2):134–141
- 161. Hides L, Carroll S, Scott R, Cotton S, Baker A, Lubman DI. Quik fix: a randomized controlled trial of an enhanced brief motivational interviewing intervention for alcohol/cannabis and psychological distress in young people. *Psychother Psychosom.* 2013;82(2):122–124
- 162. Gagneur A. Motivational interviewing: a powerful tool to address vaccine hesitancy. *Can Commun Dis Rep.* 2020;46(4):93–97
- 163. Lemaitre T, Carrier N, Farrands A, Gosselin V, Petit G, Gagneur A. Impact of a vaccination promotion intervention using motivational interview techniques on long-term vaccine coverage: the PromoVac strategy. *Hum Vaccin Immunother*. 2019;15(3): 732–739
- 164. Gagneur A, Battista MC, Boucher FD, et al. Promoting vaccination in maternity wards — motivational interview technique reduces hesitancy and enhances intention to vaccinate, results from a multicentre non-controlled pre- and post-intervention RCT-nested study, Quebec, March 2014 to February 2015. *Euro Surveill.* 2019;24(36):1800641
- 165. Gagneur A, Lemaître T, Gosselin V, et al. A postpartum vaccination promotion intervention using motivational interviewing techniques improves short-term vaccine coverage: PromoVac study. *BMC Public Health.* 2018;18(1):811
- 166. Glanternik JR, McDonald JC, Yee AH, et al. Evaluation of a vaccine-communication tool for physicians. J Pediatr. 2020;224: 72–78.e1
- 167. Dempsey AF, Pyrznawoski J, Lockhart S, et al. Effect of a health care professional communication training intervention on adolescent human papillomavirus vaccination: a cluster randomized clinical trial. *JAMA Pediatr*. 2018;172(5):e180016
- 168. Opel DJ, Robinson JD, Spielvogle H, et al. 'Presumptively Initiating Vaccines and Optimizing Talk with Motivational Interviewing' (PIVOT with MI) trial: a protocol for a cluster randomised controlled trial of a clinician vaccine communication intervention. *BMJ Open.* 2020;10(8):e039299
- 169. O'Leary ST, Spina CI, Spielvogle H, et al. Development of PIVOT with MI: a motivational interviewing-based vaccine communication training for pediatric clinicians. *Vaccine*. 2023;41(10): 1760–1767
- 170. Shay LA, Baldwin AS, Betts AC, et al. Parent-provider communication of HPV vaccine hesitancy. *Pediatrics*. 2018;141(6):e20172312

- 171. Taddio A, McMurtry CM, Logeman C, et al. Prevalence of pain and fear as barriers to vaccination in children - systematic review and meta-analysis. *Vaccine*. 2022;40(52):7526–7537
- 172. Thomas JB, David K. Taking fear and pain out of needles—for your child and you. Available at: https://www.healthychildren. org/English/safety-prevention/immunizations/Pages/managingyour-childs-pain-while-getting-a-shot.aspx. Accessed May 26, 2023
- 173. Cataldi JR, Kerns ME, O'Leary ST. Evidence-based strategies to increase vaccination uptake: a review. *Curr Opin Pediatr*. 2020;32(1):151–159
- 174. Brewer SE, Nederveld A, Simpson M. Engaging communities in preventing human papillomavirus-related cancers: two boot camp translations, Colorado, 2017-2018. *Prev Chronic Dis.* 2020;17:E02
- 175. Brewer SE, Simpson MJ, Rice JD, Skenadore A, O'Leary ST. Engaging practices and communities in the development of interventions to promote HPV vaccine uptake: a protocol for implementing Boot Camp Translation in the private practice setting. *BMJ Open.* 2020;10(12):e041685
- 176. Williams JTB, O'Leary ST. Denver religious leaders' vaccine attitudes, practices, and congregational experiences. J Relig Health. 2019;58(4):1356–1367
- 177. Fairlie T, Chu B, Thomas ES, et al. School-based interventions to increase student covid-19 vaccination coverage in public school populations with low coverage - Seattle, Washington, December 2021-June 2022. MMWR Morb Mortal Wkly Rep. 2023;72(11): 283–287
- 178. The Community Guide. Vaccination. Available at: https://www. thecommunityguide.org/topic/vaccination. Accessed August 12, 2022
- 179. Glanz JM, Wagner NM, Narwaney KJ, et al. Web-based social media intervention to increase vaccine acceptance: a randomized controlled trial. *Pediatrics*. 2017;140(6):e20171117
- O'Leary ST, Narwaney KJ, Wagner NM, Kraus CR, Omer SB, Glanz JM. Efficacy of a web-based intervention to increase uptake of maternal vaccines: an RCT. *Am J Prev Med.* 2019;57(4):e125–e133
- Salmon DA, Limaye RJ, Dudley MZ, et al. MomsTalkShots: an individually tailored educational application for maternal and infant vaccines. *Vaccine*. 2019;37(43):6478–6485
- Scott VP, Opel DJ, Reifler J, et al. Office-based educational handout for influenza vaccination: a randomized controlled trial. *Pediatrics.* 2019;144(2):e20182580
- Glanz JM, Wagner NM, Narwaney KJ, et al. Web-based tailored messaging to increase vaccination: a randomized clinical trial. *Pediatrics*. 2020;146(5):e20200669
- 184. Fadda M, Galimberti E, Fiordelli M, Romanò L, Zanetti A, Schulz PJ. Effectiveness of a smartphone app to increase parents' knowledge and empowerment in the MMR vaccination decision: a randomized controlled trial. *Hum Vaccin Immunother*. 2017; 13(11):2512–2521
- 185. Kaufman J, Attwell K, Hauck Y, et al. Designing a multi-component intervention (P3-MumBubVax) to promote vaccination in antenatal care in Australia. *Health Promot J Austr.* 2021;32(3): 391–398

- 186. Montagni I, Mabchour I, Tzourio C. Digital gamification to enhance vaccine knowledge and uptake: scoping review. JMIR Serious Games. 2020;8(2):e16983
- 187. O'Leary ST, Cataldi JR, Lindley MC, et al. Policies among US pediatricians for dismissing patients for delaying or refusing vaccination. JAMA. 2020;324(11):1105–1107
- 188. O'Leary ST, Allison MA, Fisher A, et al. Characteristics of physicians who dismiss families for refusing vaccines. *Pediatrics*. 2015;136(6):1103–1111
- 189. Giubilini A, Douglas T, Savulescu J. The moral obligation to be vaccinated: utilitarianism, contractualism, and collective easy rescue. *Med Health Care Philos*. 2018;21(4):547–560
- 190. Deem MJ, Navin MC, Lantos JD. Considering whether the dismissal of vaccine-refusing families is fair to other clinicians. *JAMA Pediatr.* 2018;172(6):514–516
- 191. Block SL. The pediatrician's dilemma: refusing the refusers of infant vaccines. *J Law Med Ethics*. 2015;43(3):648–653
- 192. Lessin HR, Hackell JM. Real world vaccine ethics. *J Pediatr.* 2016;175:243–244
- 193. Marshall GS, O'Leary ST. Dismissal policies for vaccine refusal. JAMA Pediatr. 2018;172(11):1101

- Diekema DS. Physician dismissal of families who refuse vaccination: an ethical assessment. J Law Med Ethics. 2015;43(3):654–660
- 195. Buttenheim AM, Cherng ST, Asch DA. Provider dismissal policies and clustering of vaccine-hesitant families: an agentbased modeling approach. *Hum Vaccin Immunother*. 2013; 9(8):1819–1824
- 196. Chervenak FA, McCullough LB, Brent RL. Professional responsibility and early childhood vaccination. *J Pediatr*: 2016;169:305–309
- 197. Diekema DS; American Academy of Pediatrics Committee on Bioethics. Responding to parental refusals of immunization of children. *Pediatrics*. 2005;115(5):1428–1431
- 198. Williams JTB, O'Leary ST, Nussbaum AM. Caring for the vaccinehesitant family: evidence-based alternatives to dismissal. J Pediatr. 2020;224:137–140
- 199. Navin MC, Wasserman JA, Opel DJ. Reasons to accept vaccine refusers in primary care. *Pediatrics*. 2020;146(6):e20201801
- 200. Management CoMLaR. How to end physician-patient relationship legally. Available at: https://publications.aap.org/aapnews/article/ 33/4/1/24309/How-to-end-physician-patient-relationship-legally? autologincheck=redirected. Accessed May 26, 2023
- 201. O'Leary ST, Brewer SE, Pyrzanowski J, et al. Timing of informationseeking about infant vaccines. *J Pediatr*. 2018;203:125–130.e1