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Countering Vaccine Hesitancy

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Immunizations have led to a significant decrease in rates of vaccine-preventable 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 addressing parental concerns about vaccination.

INTRODUCTION

Immunizations have had an enormous impact on the health of children, and the prevention of disease by vaccination is one of the single greatest public health achievements of the last century. However, over the past decade acceptance of vaccines has been challenged by individuals and groups who question their benefit.[1] Increasing numbers of people are requesting alternative vaccination schedules[2,3] or postponing or declining vaccination.[4] In a national telephone survey of 1500 parents of children 6 to 23 months of age conducted in 2010 with a response rate of 46%, approximately 3% of respondents had refused all vaccines and 19.4% had refused or delayed at least 1 of the recommended childhood vaccines.[5] A study conducted in a metropolitan area of Oregon reported that rates of alternative immunization schedule usage have increased nearly fourfold in recent years,[3] and in some parts of the country the use of "personal belief exemptions" from vaccinations has grown to rates in excess of 5% of the school-aged population.[6]

The Periodic Survey of Fellows (PS#66) conducted by the American Academy of Pediatrics (AAP) in 2006 revealed that 75% of pediatricians surveyed had encountered parents who refused a vaccine,[7] and a follow-up survey in 2013 (PS#84) revealed that this figure had increased to 87% of pediatricians.[8] According to the survey, pediatricians stated that the proportion of parents who refused 1 or more vaccines increased from 9.1% to 16.7% during the 7-year interval between surveys.[7,8] Physicians stated that the most common reasons parents refused vaccines were that they believed that vaccines are unnecessary (which showed an increase over the 7-year span) and that they had concerns

abstract

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TABLE 1 Categorization of Parental Attitudes Toward Vaccines[12,14]

Immunization advocate	Parents agree that vaccines are necessary and safe. Parents have a strong relationship with their health care provider.
Go along to get along	Parents do not question vaccines, would like to 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 and tend to be knowledgeable about vaccines. Parents may vaccinate their child or may refuse or delay vaccines. Parents may have significant concerns about vaccines and may have a neutral relationship with their health care provider.
Refuser	Parents refuse all vaccines for their child. Their reasons for refusal may include distrust in the medical system, safety concerns, and religious beliefs.

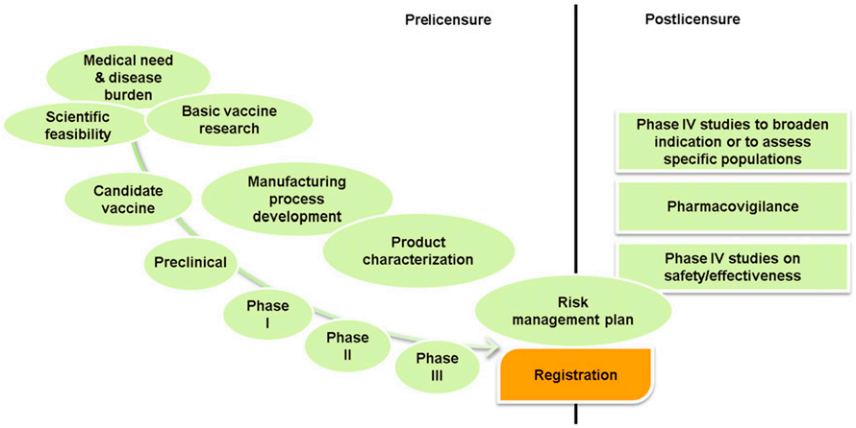

FIGURE 1
Vaccine pipeline: prelicensure and postlicensure vaccine development activities. From Hardt K, Schmidt-Ott R, Glismann S, Adegbola RA, Meurice F. Sustaining vaccine confidence in the 21st century. *Vaccines*. 2013;1(3):204–224. Copyright © 2013 by the authors; licensee MDPI, Basel, Switzerland. Reproduced under the terms and conditions of the Creative Commons Attribution license (http://creativecommons.org/licenses/by/3.0/).

about autism (which declined between survey years). In both 2006 and 2013, pediatricians reported that they were able to convince approximately 30% of parents to vaccinate their children when they initially refused. Another observational study found that when physicians continued to engage parents, up to 47% of parents ultimately accepted vaccines after initially refusing them.[9] Although the majority of parents accept vaccines, the increasing frequency of refusal and the requests for alternative vaccine schedules indicate that there are still significant barriers to overcome.[10]

TERMINOLOGY

The term *vaccine hesitancy* has emerged to depolarize the "pro" versus "anti" vaccination alignment and to express the spectrum of parental attitudes toward vaccines.[1] Vaccine hesitancy has been characterized recently by a committee at the World Health Organization as "a behavior, influenced by a number of factors including issues of confidence (do not trust a vaccine or a provider), complacency (do not perceive a need for a vaccine or do not value the vaccine), and convenience (access)."[11] Vaccine-hesitant individuals are a heterogeneous group who hold varying degrees of indecision about specific vaccines or about vaccinations in general. Vaccine-hesitant individuals may accept all vaccines but remain concerned about them, they may refuse or delay some vaccines but accept others, or they may refuse all vaccines. The latter group refusing all vaccines is estimated at approximately 3% of parents, although the prevalence may vary geographically.[4,12,13]

The concept that parental vaccine hesitancy is a spectrum has been confirmed in several studies[4,14,15] and was well described in a recent review by Leask et al[12] (Table 1). Some parents who totally refuse vaccines may be fixed and unswayable in their beliefs and may not respond to the pediatrician attempting to change their views. The AAP recommends that pediatricians continue to engage with vaccine-hesitant parents, provide other health care services to their children, and attempt to modify their opposition to vaccines.[16–18] Fortunately, most vaccine-hesitant parents are responsive to vaccine information, consider vaccinating their children, and are not opposed to all vaccines. Responding to vaccine-hesitant parents is the focus of this clinical report.

VACCINES ARE TESTED THOROUGHLY

Vaccine development is a long and arduous process, often lasting many years and involving a combination of public and private partnerships. The current system for developing, testing, and regulating vaccines requires that the vaccines demonstrate both safety and efficacy before licensure and that long-term safety is monitored (http://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation; Fig 1). The first step in vaccine discovery involves the identification of a need for a vaccine and an understanding of the mechanism of protective immunity against that disease.

If the vaccine appears promising in preclinical studies, the vaccine sponsor submits an application for an Investigational New Drug to the US Food and Drug Administration (FDA). Law requires that the sponsor describe the manufacturing and testing processes, summarize the laboratory reports, and describe the proposed studies to evaluate the vaccine. As with therapeutic drugs, vaccine evaluation includes phase I through phase III testing. Phase I trials are intended to assess the safety of the candidate vaccine and to determine the type and extent of immune response that the vaccine provokes.

Phase II testing involves several hundred volunteers, some of whom belong to groups at risk for acquiring the disease. These trials generally are randomized and controlled and usually include a placebo group or a standard licensed vaccine when a new vaccine for that disease is being tested.

Phase III vaccine trials are designed to determine whether the vaccine will prevent the disease in question and to assess the vaccine's safety when administered to a large number of subjects. These studies often involve thousands or tens of thousands of participants, depending on the incidence of disease and the rates of adverse events to be detected. If these studies show the vaccine to be effective and safe, it is then licensed.

VACCINE SAFETY IS ACTIVELY MONITORED AFTER LICENSURE

Once vaccines are licensed, a number of processes are in place to ensure that the safety of vaccines is monitored. In 1990, the Centers for Disease Control and Prevention (CDC) and FDA established the Vaccine Adverse Events Reporting System (VAERS), a voluntary passive reporting system that serves as a signal detection system for adverse events associated with vaccines (http://vaers.hhs.gov/index). Anyone who suspects an association between a vaccination and an adverse event can report the event to VAERS. The CDC and the FDA then investigate the event.[19] VAERS has successfully identified several adverse events related to vaccination in the past, such as intussusception after administration of the RotaShield (Wyeth Laboratories Inc, Marietta, PA) rotavirus vaccine, which was identified in 1999, leading to the ultimate withdrawal of that vaccine from the market.[20]

In 1990, the CDC also established the Vaccine Safety Datalink (VSD) to monitor vaccine safety. The VSD is composed of a number of large health provider groups with linked databases with comprehensive information about vaccines administered and health care encounters.[21] Because the VSD involves millions of individuals, it can be used to detect rare events and was used to study the possible, but subsequently disproven, association between Guillain–Barré syndrome and meningococcal vaccination.[22] Another parallel system to the VSD is the Post-Licensure Rapid Immunization Safety Monitoring system.[23] This system uses health insurance claims data from 107 million individuals to actively monitor vaccine safety. In addition, the CDC has also established the Clinical Immunization Safety Assessment Project, a group of academic health care centers, to address specific questions about vaccine safety from individual health care providers (http://www.cdc.gov/vaccinesafety/activities/cisa.html).[24]

In summary, vaccines are comprehensively evaluated before their licensure. They are developed and tested in large numbers of subjects, regulated by the FDA, and carefully monitored after licensure through a comprehensive safety surveillance system funded by the CDC and the FDA. In rare instances in which safety concerns are identified, regulatory or other actions to safeguard public health are taken.

HISTORICAL VACCINE OPPOSITION

Before discussing the recent increase in vaccine hesitancy, it is valuable to recall that opposition to vaccination is not a new occurrence. In the early 1800s in Europe, Jenner promoted vaccination against smallpox by using material obtained from cowpox lesions.[25] However, over the next several decades, increasing rates of opposition to smallpox vaccination were seen in the United Kingdom, requiring vaccination to be mandated by law.[25] Similar obstacles to universal smallpox vaccination were also encountered in the United States. In the 1850s, a number of parents and physicians challenged mandatory smallpox vaccination, and in 1905 in the case *Jacobson v Massachusetts,* the US Supreme Court supported the rights of states to pass laws mandating smallpox vaccine.[6] However, although vaccine hesitancy is not a new phenomenon, it may have a greater effect on public health today. With the ease of global travel, vaccine-preventable diseases are spread more quickly and may unexpectedly appear in areas where health care professionals are unfamiliar with their clinical presentation.

CURRENT VACCINE EXEMPTIONS

Herd immunity is a fundamental concept that contributes to the success of many vaccination programs. Control of many vaccine-preventable diseases is contingent on a significant proportion of the population in a community being immune.[26] Depending on the disease, the percentage of individuals required to achieve herd immunity in a community ranges from 30% to 95%.[27] Traditionally,

immunization rates have been maintained in the United States through mandatory vaccination requirements for entry into and advancement through licensed child care centers and schools. However, recent years have seen a marked increase in the availability and use of "philosophical" or "personal belief" exemptions from vaccination. Over the period from 2005 through 2011, Omer et al[28] reported that the unadjusted rates for nonmedical exemptions in states that allowed for philosophical exemptions were 2.5 times higher than in states that allowed only religious exemptions. In Arkansas, rates of overall exemptions increased an average of 23% per year once philosophical exemptions were allowed.[29] Studies have demonstrated that parents who refuse vaccines are more likely to be white and more highly educated than those who do not.[4,6,30,31] In addition, the prevalence of vaccine-hesitant parents seems to vary geographically.[6,32] It is unclear whether requiring a mandatory physician visit or educational module for parents who apply for vaccine exemption in states with philosophical exemptions is effective in reducing refusals.[32]

Children who are philosophically exempted from vaccination not only are at greater risk of developing vaccine-preventable disease but also put vaccinated children and medically exempt children who live in the same area at risk.[33–35] Vaccine-preventable diseases occurring in vaccinated children may result from waning immunity after immunization or may be attributable to an ineffective immune response to vaccine initially. In January 2015, a measles outbreak occurred in California, where an estimated 3.1% of kindergartners had a nonmedical exemption from receiving the measles–mumps–rubella (MMR) vaccine.[36] The majority of cases occurred in children who either had not received measles vaccine (45%) or had unknown vaccination status (38%).[37] Of the cases in unvaccinated children, 43% of parents cited philosophical or religious objects to vaccine. An additional 40% of unvaccinated children could not receive the vaccine because they were too young. This outbreak, which spread to multiple states, has sparked intense debate about vaccine exemptions and the government's role in limiting nonmedical exemptions. Whether the 2015 outbreak and legislation resulting from this outbreak will have a long-lasting effect on public policy and parental choices is not clear at this time. For these reasons, we believe the better approach is to work to eliminate all nonmedical exemptions for childhood vaccines, a position that is shared by the American Medical Association and the Infectious Diseases Society of America and is currently the basis of a policy statement being developed by the AAP. There has also been greater recognition among pediatricians that delayed or incomplete vaccination schedules are probably responsible, at least in part, for the spread of measles in that outbreak.[38–40] As a result, more pediatricians are becoming concerned about the risk unimmunized children pose to other children in their practices, both immunized children and those too young or otherwise unable to be immunized. Some are electing to dismiss families who refuse vaccines from their practices.[7] The ethical considerations of patient dismissal are complex and are discussed in a subsequent section of this statement as well as in a comprehensive review by Diekema.[41]

FACTORS INVOLVED IN VACCINE ACCEPTANCE

The evolution of vaccine confidence over the course of vaccine introduction is summarized in a figure that first appeared in a 1994 article by Chen et al[19] (Fig 2), which succinctly outlines many of the pivotal factors that must be considered when discussing vaccine hesitancy. As shown in Fig 2, disease incidence is highest before the development and implementation of a vaccine program. At this time, the public generally is eager to accept a new vaccine, particularly if the morbidity and mortality associated with the disease are considerable. Then, after the vaccine is developed and proven efficacious, individuals are eager to be vaccinated, and coverage increases, with subsequent declines in disease incidence ("increasing coverage" phase). However, as vaccine uptake peaks, the disease incidence declines, and the total number of adverse events after vaccination increases. Whether the adverse events were causally related or only temporally associated with vaccine administration can be difficult to determine, but these adverse events may lead to loss of confidence in the vaccine as the public perceives the risk of vaccination to outweigh the risk of disease ("loss of confidence" phase). This, in turn, may increase vaccine refusal and ultimately lead to disease resurgence. Then, after disease resurgence or an outbreak, as the public again appreciates the increasing burden of disease, vaccine acceptance is restored and vaccination rates increase ("resumption of confidence" phase). Unfortunately, a recent study during an outbreak of pertussis in the state of Washington suggested that, despite an increase in pertussis cases, parents did not have a "resumption in vaccine confidence" and did not increase pertussis vaccine uptake.[42] In the rare incidents in which disease is eradicated by vaccine, as occurred with smallpox, vaccination can stop ("eradication" phase). This conceptual framework is more applicable to diseases for which the time between exposure and infection is short, such as measles, pertussis,

or polio, and less relevant to, for example, vaccines against human papillomavirus (HPV), for which the benefits of immunization in preventing cancer may take years or decades to become apparent. Figure 2 clearly highlights the delicate balance between perceived risk and benefit for each vaccine and how this balance is linked integrally to vaccine acceptance.

PARENTS' VARIED CONCERNS ABOUT VACCINES SHOULD BE ADDRESSED

A number of studies have attempted to define the reasons why parents are vaccine hesitant, and these factors are summarized in Table 2.[1,4,5,15,43–45] In 1 study, 44% of parents reported concern over pain associated with receiving multiple injections during a single visit, 34% expressed unease about receiving too many vaccines at a single visit, 26% worried about the development of autism or other potential learning difficulties after receiving vaccines, 13.5% expressed concern that vaccines could lead to chronic illnesses, and 13.2% stated that vaccines were not tested enough for safety before their use.[45] Concerns about vaccine safety and questions about the necessity of vaccines are often cited as reasons for vaccine refusal.[43,46–48] One survey found that parents who decide to not vaccinate their children have a greater distrust of health care professionals and the government and are more likely to use complementary and alternative medicine, compared with parents who vaccinate their children.[47] Freed et al[43] also conducted an online survey of several thousand parents to identify vaccine concerns. Most of the surveyed parents agreed that vaccines protected their children from diseases; however, more than half expressed concerns regarding serious adverse effects of vaccines. Overall, 11.5% of parents in that study had refused at least 1 recommended vaccine, and the fear that vaccines could cause autism was often cited as a reason for refusal.[43]

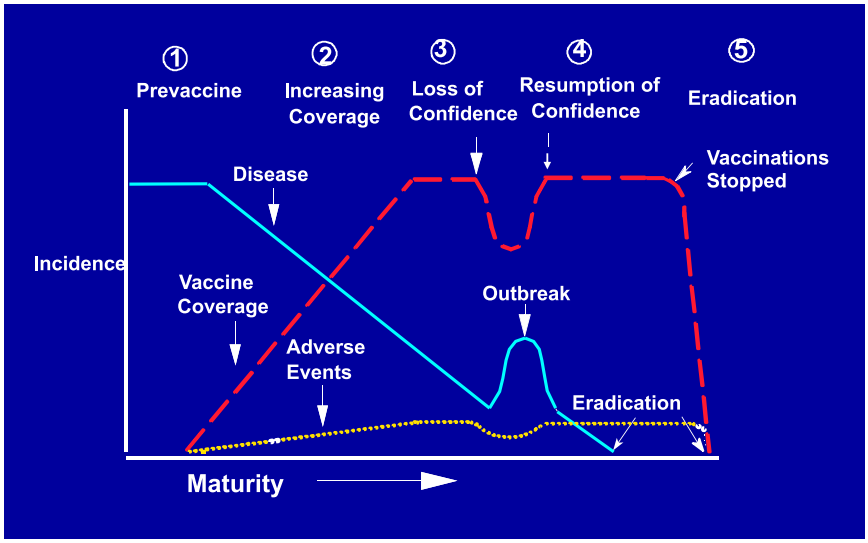

FIGURE 2
Evolution of a vaccine program. Reproduced with permission. Chen RT, Orenstein WA. Epidemiologic methods in immunization programs. *Epidemiol Rev.* 1996;18(2):102. Copyright © 1996 by the Oxford University Press.

TABLE 2 Parental Concerns About Vaccines

Vaccine safety
Too many vaccines
Development of autism
Vaccine additives (thimerosal, aluminum)
Overload the immune system
Serious adverse reactions
Potential for long-term adverse events
Inadequate research performed before licensure
May cause pain to the child
May make the child sick
Necessity of vaccines
Disease is more "natural" than vaccine
Parents do not believe diseases being prevented are serious
Vaccine-preventable diseases have disappeared
Not all vaccines are needed
Vaccines do not work
Freedom of choice
Parents have the right to choose whether to immunize their child
Parents know what's best for their child
Believe that the risks outweigh the benefits of vaccine
Do not trust organized medicine, public health
Do not trust government health authorities
Do not trust pharmaceutical companies
Ethical, moral, or religious reasons

Parental concerns must be addressed, and concerns will vary among parents. For example, vaccine safety and triggering early sexual activity are often cited as parental concerns about the HPV vaccine.[49] Reassuring parents that the vaccine is safe and that there is no evidence that HPV vaccine increases sexual activity may dispel their concerns.[50] Some parents are concerned primarily about the pain associated with immunizations. Strategies to reduce pain include administering vaccines quickly without aspirating, holding the child upright, administering the most painful vaccine last, and

TABLE 3 Number of Immunogenic Proteins and Polysaccharides Contained in Vaccines Over the Past 100 Years

1890		1960		1980		2000	
Vaccine	Proteins	Vaccine	Proteins	Vaccine	Proteins	Vaccine	Proteins and Polysaccharides
Smallpox	~200	Smallpox	~200	Diphtheria	1	Diphtheria	1
Total	~200	Diphtheria	1	Tetanus	1	Tetanus	1
		Tetanus	1	WC-pertussis	~3000	AC-pertussis	2–5
		WC-pertussis	~3000	Polio	15	Polio	15
		Polio	15	Measles	10	Measles	10
		Total	~3217	Mumps	9	Mumps	9
				Rubella	5	Rubella	5
				Total	~3041	Hib	2
						Varicella	69
						Pneumococcus	8
						Hepatitis B	1
						Total	123–126

Adapted from Offit et al.[52]

AC-pertussis, acellular pertussis vaccine; WC-pertussis, whole cell pertussis vaccine.

providing tactile stimulation.[51] Breastfeeding, feeding sweet-tasting solutions, and topical anesthetics are other tools that can be used before vaccine administration to decrease pain. Distraction strategies, including pinwheels, deep breathing exercises, and toys, can be used in older children to decrease anxiety and pain. Although rigorously controlled studies of these techniques have not been performed, studies of other painful procedures lend support to their use in vaccination.[51,52]

Providers should address specific parental questions about the production and composition of the vaccines by directly providing the information requested. For example, for concerns about the presence of mercury (thimerosal) in vaccines, parents can be reassured that currently, none of the single-dose vaccine preparations given to infants contain any mercury. The opposition to the presence of aluminum as an adjuvant in some vaccines can be addressed by providing evidence for both the necessity of the aluminum for a vigorous immune response and the lack of evidence for its toxicity. The religious argument that vaccines contain cells derived from aborted human fetuses can be answered in statements from major religious denominations either acknowledging that the vaccines do not contain such cells or that the earlier use of fetal cell lines in vaccine production does not prohibit the use of these vaccines many years after the fetal cells were obtained.[53]

A specific response to the parental concern of "too many vaccines" and the potential for "overwhelming the immune system" was provided by Offit et al.[54] As shown in Table 3, the number of immunogenic proteins and polysaccharides contained in currently licensed vaccines is significantly smaller than the number of antigens contained in earlier vaccines and in naturally circulating organisms that infected children before universal vaccination. Sharing a copy of Table 3 could provide the necessary reassurance to parents who have concerns regarding "too many vaccines."

COUNTERING VACCINE HESITANCY CAN BE CHALLENGING

Even the use of targeted discussion strategies may not be adequate to counter vaccine hesitancy. A recent study reported by Nyhan et al[55] recruited a nationally representative sample of parents through random digit dialing and address-based sampling and randomly assigned them to 1 of 5 groups: providing textual information explaining the lack of evidence that MMR vaccine causes autism, supplying textual information about the dangers of the diseases prevented by MMR vaccine, showing visual images of children who have diseases prevented by MMR vaccine, providing a dramatic audio narrative about an infant who almost died of measles, and no intervention. None of the interventions increased parental intent to vaccinate a future child. Thus, the authors concluded that current public health communications about vaccines may not be effective, and for some vaccine-hesitant parents, they may actually increase misperceptions and reduce vaccination intention. However, a limitation of this study was that it was Web based and did not examine the effect of direct one-to-one personal communication between the pediatrician and the parent.

Providing vaccine information is time consuming. Kempe et al[56] found that 53% of physicians spend 10 to 19 minutes discussing vaccines with concerned parents, and 8% of physicians spend 20 minutes or more with these parents. They also reported that pediatricians experienced decreased job satisfaction because of time spent with parents with significant vaccine concerns. Physicians have several options to deal with this problem, ranging from scheduling longer well-care visits, with some loss of overall efficiency; simply not having

the discussion and acceding to a parent's request to defer, delay, or skip a vaccination; or dismissing such families from their practice. Permitting alternative vaccine schedules reduces vaccine timeliness and complicates an already complex vaccine schedule.[57] A study by Robison et al[3] demonstrated that children whose parents chose to limit vaccinations had more total visits for immunizations and by both 9 and 19 months of age were substantially less likely to be caught up on their immunization series. The additional time and costs associated with longer and more frequent well-child and immunization visits for parents with vaccine concerns are substantial, and by decreasing the efficiency of primary care providers, they may have a significant effect on access to health care services for all children.

PEDIATRICIANS PLAY AN IMPORTANT ROLE

With all the challenges acknowledged, the single most important factor in getting parents to accept vaccines remains the one-on-one contact with an informed, caring, and concerned pediatrician.[58] In a study reported in *Pediatrics,* parents of more than 7000 children 19 to 35 months of age were surveyed to determine whether they believed vaccines were safe and what influence their primary care providers had on their decisions to vaccinate.[45] Nearly 80% of parents stated that their decision to vaccinate was positively influenced by their primary care provider. The study concluded, "Health care providers have a positive influence on parents to vaccinate their children, including parents who believe that vaccinations are unsafe. Physicians, nurses, and other health care professionals should increase their efforts to build honest and respectful relationships with parents, especially when parents express concerns about vaccine safety or have misconceptions about the benefits and risks of vaccinations." In another study, Smith et al[59] clearly demonstrated that parents whose children were vaccinated listed their pediatrician as a strong influence on their decision to vaccinate. A well-informed pediatrician who effectively addresses parental concerns and strongly supports the benefits of vaccination has enormous influence on parental vaccine acceptance.

ATTENTIVENESS TO PARENTS' CONCERNS IS IMPORTANT WHILE CORRECTING MISCONCEPTIONS

After acknowledging the varied concerns of vaccine-hesitant parents, the pediatrician needs to communicate with the parents about the development and safety testing of vaccines, the reasons for immunizing, and the risks of not doing so. An important aspect of communication with vaccine-hesitant parents is to clearly articulate the message that vaccines are safe and effective, and serious disease can occur if your child and family are not immunized. The safety of the currently recommended vaccines administered according to their established schedules was strongly affirmed by the Institute of Medicine in 2013.[60] A recent report commissioned by the Agency for Healthcare Research and Quality, on behalf of the National Vaccine Program Office, and an accompanying editorial also affirmed the safety of vaccines recommended for routine immunization of children.[61,62] It is important to present this safety information in a nonconfrontational dialogue with the parents while listening to and acknowledging their concerns. Misconceptions should be corrected, because both parents and pediatricians are in agreement in wanting the best for the children's health and well-being.[63]

THE CURRENT VACCINE SCHEDULE IS THE ONLY RECOMMENDED SCHEDULE

It is extremely important that the pediatrician remain up to date on the current recommended vaccine schedule and support it as the only evidence-based schedule that has been tested and approved by multiple authoritative experts for safety and efficacy.[60] No alternative vaccine schedules have been evaluated and found to provide better safety or efficacy than the recommended schedule, supported by the Advisory Committee on Immunization Practices of the CDC and the Committee on Infectious Diseases of the AAP (the committee that produces the *Red Book*). Pediatricians who routinely recommend limiting the numbers of vaccines administered at a single visit such that vaccines are administered late are providing care that deviates from the standard evidence-based schedule recommended by these bodies. Situational deviation from these recommendations may be considered a last resort if, after reasonable attempts to convince hesitant parents, it is the only way to achieve the ultimate goal of immunizing a child. All who provide vaccines must be capable of articulating the safety and efficacy of the standard schedule and refrain from suggesting that delaying or deferring vaccines may be safer or more effective, because there is no evidence to support this viewpoint.

Pediatricians should not overestimate parental vaccine hesitancy or mistake a simple lack of knowledge for hesitancy or opposition.[64] Opel et al[9] reported that only 55% of practitioners routinely provide parents with the rationale for why vaccines are administered and their potential adverse effects. They reported that nearly half of parents who were initially vaccine hesitant ultimately accepted vaccines after practitioners provided a rationale for vaccine administration. Parental education can be provided through Vaccine Information Statements (VISs) given to parents before vaccine administration, through

an online review of the VIS before the routine immunization visit, or through referral to authoritative Web sites, such as that of the CDC (http://www.cdc.gov/vaccines/vpd-vac/default.htm). One study reported that the majority of mothers preferred receiving vaccine information before the initial immunization visit.[65] The provision of a VIS is required at each immunization encounter for each vaccine, and counseling about vaccine-preventable diseases and vaccine adverse effects is required to correctly bill for vaccine administration. If parents refuse vaccination, a vaccine refusal waiver, used by many pediatricians in the event of deviations from the recommended vaccine schedule, can be obtained from the AAP Web site (https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/refusal-to-vaccinate.aspx), and parents may be asked to sign it.

PRESUMPTIVE DELIVERY STRATEGY

Another effective communication approach is the presumptive delivery strategy. Opel et al[9] demonstrated that the majority of parents accepted the provider's vaccine recommendations when they were presented as required immunizations to maintain optimal disease prevention. This approach may not work well with some parents, however, and pediatricians may use it selectively based on their experience. In addition, pediatricians who began practicing medicine before the introduction of many of today's routinely recommended vaccines have first-hand knowledge of these preventable diseases and often use that experience to effectively communicate the need for vaccines and the rationale for their administration according to established recommendations. One study conducted among 542 primary care providers in the United States demonstrated that recent graduates were less likely to believe that vaccines were safe and efficacious than their older colleagues[66]; whether this is attributable to lack of first-hand experience with vaccine-preventable diseases or lack of comprehensive vaccine education is unclear. Educational efforts during residency training programs should provide trainees with a comprehensive understanding of the effect of vaccines on disease burden and the knowledge to evaluate the safety of vaccines as well as effective communication strategies. Only 48.5% of 303 US pediatric residents surveyed reported training in communication strategies for vaccine-hesitant patients during residency, and nearly 80% requested more education about the adverse effects of vaccines.[67] One study found that a brief single educational intervention may not be sufficient to provide physicians with the skills to counteract vaccine hesitancy and suggested that more research is needed to determine the most effective educational interventions.[68]

PERSONALIZING THE MESSAGE THAT VACCINES ARE SAFE AND EFFECTIVE CAN BE POWERFUL

The presentation of basic medical information may not be sufficient to reassure parents about the safety and necessity of vaccines. Developing a trusting relationship with parents is key to influencing parental decision-making around vaccines.[69] Parents often are more likely to be persuaded by stories and anecdotes about the successes of vaccines. Personal examples of children who were sick with vaccine-preventable illnesses can be much more effective than simply reading the numbers of children infected with a disease each year in the VIS. The Web site www.immunize.org/reports is an excellent source of such cases. A recent study by Kempe et al[56] demonstrated that physicians reported the greatest success convincing skeptical parents using messages that relied on their personal choices and experiences. Physicians relating that they have immunized all of their children, their grandchildren, or themselves provide a compelling message that they are confident in the safety of the vaccines.

Other techniques, such as the use of parent-centered motivational interviewing, have been suggested as an effective way to personalize communication. Having parents verbalize their questions and concerns, followed by a focused response to their concerns, may be an effective communication strategy. However, the effect of motivational interviewing and other communication techniques requires careful assessment. It is encouraging that both AAP Periodic Surveys of Fellows from 2006 and 2013 indicated that one-third of parents who initially refused ≥1 vaccines ultimately changed their minds and gave permission for vaccination. Although these conversations may be difficult and frustrating, they clearly represent time well spent. A summary of points that may be useful in these conversations is found in Table 4.

DISMISSAL OF PATIENTS WHO REFUSE VACCINATION

Some families still will not be persuaded to vaccinate.[56] After multiple attempts to convince families to vaccinate have failed, some pediatricians have chosen to dismiss families as a last resort.[7,8,70] Arguments have been made that these families should not be dismissed on the basis of public health principles, because nonvaccinating families might cluster in certain practices, making them the focal point for outbreaks.[71] Ethical arguments against dismissal have also been made.[41,72,73] In addition, there are dilemmas for the many

pediatricians who continue to care for these families, including potentially exposing other patients to vaccine-preventable diseases from those who are unimmunized. Finally, many pediatricians may feel obligated to continue to care for children in families who refuse immunizations.

There are no published data regarding the eventual outcome of strict "vaccinate or be dismissed" policies on the eventual acceptance of vaccines, and additional studies are needed. However, there is anecdotal evidence that when pediatricians give parents the choice between immunizing their child or being dismissed, some parents accept vaccination, even when other efforts at persuasion have failed.

It should be noted that the same legal and ethical constraints exist to dismissal for any permissible reason, including failure to vaccinate. Dismissal must 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. Furthermore, the dismissing physician is obligated to continue current treatment and provide emergency care for a reasonable period of time, usually 30 days.[74,75]

Certain practice settings may also limit the ability to dismiss a patient. Employees of hospitals and large health care organizations are often unable to dismiss patients by official organizational policy. In areas of the country where there may be limited access to pediatric care, the pediatrician should carefully evaluate the availability of other qualified providers for the family. If there are no other qualified physicians in the area, the pediatrician is faced with the problem of leaving a family without adequate health care. In these situations, the pediatrician should continue to provide care to the patient and family.

The decision to dismiss a family who continues to refuse immunization is not one that should be made lightly, nor should it be made without considering and respecting the reasons for the parents' point of view.[44] Nevertheless, the individual pediatrician may consider dismissal of families who refuse vaccination as an acceptable option. In all practice settings, consistency, transparency, and openness regarding the practice's policy on vaccines is important.

TABLE 4 Communication Highlights

Vaccines are safe and effective, and serious disease can occur if your child and family are not immunized.
Vaccine-hesitant individuals are a heterogeneous group, and their individual concerns should be respected and addressed.
Vaccine are tested thoroughly before licensure, and vaccine safety assessment networks exist to monitor vaccine safety after licensure.
Nonmedical vaccine exemptions increase rates of unvaccinated children.
Unvaccinated children put vaccinated children and medically exempt children who live in that same area at risk.
Pediatricians and other health care providers play a major role in educating parents about the safety and effectiveness of vaccines. Strong provider commitment to vaccination can influence hesitant or resistant parents.
Personalizing vaccine acceptance is often an effective approach.
The majority of parents accepted the provider's vaccine recommendations when they were presented as required immunizations to maintain optimal disease prevention.
The current vaccine schedule is the only one recommended by the CDC and the AAP. Alternative schedules have not been evaluated.

CONCLUSIONS

Vaccine discussions continue to occupy the media and Internet, and every parent of a child for whom vaccination is recommended is exposed to these messages on a regular basis. Data have shown that participation in social media reinforces one's beliefs about vaccination, no matter what those beliefs are.[76] The pediatrician is often the only medically trained person available to discuss vaccine matters with parents, and it is incumbent on him or her to provide scientifically based and balanced information when these questions are asked. Table 5 provides a summary of some of the available resources to aid the pediatrician.

The pediatrician should also appreciate that vaccine-hesitant parents are a heterogeneous group and that specific parental vaccine concerns should be individually identified and addressed. Although many techniques for working with vaccine-hesitant parents have been suggested, scant data are available to determine the efficacy of these methods.[77] Additional research on communication techniques is needed. The clear message parents should hear is that vaccines are safe and effective, and serious disease can occur if your child and family are not immunized. Pediatricians should keep in mind that many, if not most, vaccine-hesitant parents are not opposed to vaccinating their children; rather, they are seeking guidance about the issues involved, beginning with the complexity of the schedule and the number of vaccines proposed. Parents may be unsure of the need for vaccines, because most have never experienced the diseases vaccines are designed to prevent, and they have concerns about possible adverse effects of these vaccines.

Pediatricians facing concerned parents on a regular basis should be prepared to discuss the science behind the current vaccine schedule and the extensive testing of each

TABLE 5 Vaccine Resources

Tools
- AAP refusal to vaccinate form: https://www.aap.org/en-us/Documents/immunization_refusaltovaccinate.pdf
- Risk communication videos: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/vaccine-hesitant-parents.aspx#Video
- Navigating Vaccine Hesitancy: https://www.aap.org/en-us/Documents/immunization_hesitancy.pdf (will be available soon)

Education
- Pedialink modules: https://pedialink.aap.org/visitor
  - Adolescent Immunizations: Strongly Recommending the HPV Vaccine: http://shop.aap.org/Adolescent-Immunizations-Strongly-Recommending-the-HPV-Vaccine
  - Challenging Cases: Vaccine Hesitancy: http://bit.ly/cc-vaccinehesitancy. This module is the educational component of the clinical report.
- AAP Immunization Web site: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/default.aspx

(The following are some of the specific pages within the above site)
  - Parental Refusal Resource Page: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/refusal-to-vaccinate.aspx
  - Vaccine-Hesitant Parents: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/vaccine-hesitant-parents.aspx
  - Information for families: https://www.healthychildren.org/english/safety-prevention/immunizations/pages/default.aspx
  - Common Parental Concerns: https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/immunization/Pages/Common-Parental-Concerns.aspx
- HealthyChildren.org (for parents): http://www.healthychildren.org/English/safety-prevention/Pages/default.aspx (same as above)
- CDC/AAP Provider Resources for Vaccine Conversations With Parents: http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/index.html
- Immunization Action Coalition: http://www.immunize.org/
- Children's Hospital of Philadelphia: http://www.chop.edu/service/vaccine-education-center/home.html
- National Foundation for Infectious Diseases: http://www.nfid.org/
- Families Fighting flu: www.familiesfightingflu.org
- Vaccine Resource library: www.path.org/vaccineresources
- Every Child by Two: www.ecbt.org
- Parents of Kids With Infectious Diseases: www.pkids.org

Policy
- Responding to Parental Refusals of Immunization of Children: http://pediatrics.aappublications.org/content/115/5/1428.full
- Medical Versus Nonmedical Immunization Exemptions for Child Care and School Attendance: http://www.pediatrics.org/cgi/doi/10.1542/peds.2016.2146
- 2016 Immunization Schedules: http://www2.aap.org/immunization/IZSchedule.html
- COID Policy Collection page: http://pediatrics.aappublications.org/cgi/collection/committee_on_infectious_diseases
- *Red Book*
  - Discussing Vaccines With Patients and Parents
    - Discussing Vaccines With Patients and Parents (pp. 7–9)
    - Addressing Parents' Questions About Vaccine Safety and Effectiveness (p. 9)
    - Common Misconceptions About Immunizations and the Institute of Medicine Findings (pp. 10–11)
    - Resources for Optimizing Communications With Parents About Vaccines (p. 12)
    - Parental Refusal of Immunizations (pp. 12–13)
- Assessing the State of Vaccine Confidence in the United States: Recommendations From the National Vaccine Advisory Committee: http://www.hhs.gov/sites/default/files/nvpo/nvac/reports/nvac-vaccine-confidence-public-health-report-2015.pdf

Journal articles
- Childhood Immunization: When Physicians and Parents Disagree: http://pediatrics.aappublications.org/content/128/Supplement_4/S167.full
- Safety of Vaccines Used for Routine Immunization of US Children: A Systematic Review: http://pediatrics.aappublications.org/content/early/2014/06/26/peds.2014-1079.full.pdf+html
- Commentary in *Pediatrics*: Vaccines: Can Transparency Increase Confidence and Reduce Hesitancy? http://pediatrics.aappublications.org/content/early/2014/06/26/peds.2014-1494.full.pdf+html
- Children whose parents refused vitamin K at birth are 14.6 times more likely to be unimmunized by age 15 mo. This provides an opportunity to identify a subset of likely vaccine-hesitant parents at birth and engage them with targeted information.
  - News release: http://www.aap.org/en-us/about-the-aap/aap-press-room/Pages/Parents-Who-Refuse-Vitamin-K-for-Newborn-Also-More-Likely-to-Refuse-Vaccines.aspx
  - Study: http://pediatrics.aappublications.org/content/early/2014/08/12/peds.2014-1092
- A survey found that parents who were informed about the MMR vaccine's direct benefits to their child, rather than the vaccine's benefits to society as a whole, were more likely to immunize.
  - News release: http://www.aap.org/en-us/about-the-aap/aap-press-room/Pages/Emphasizing-MMR-Vaccine%27s-Benefits-for-Children-Increases-Parents%27-Intent-to-Immunize.aspx
  - Study: http://pediatrics.aappublications.org/content/early/2014/08/12/peds.2013-4077
  - MedScape story: http://www.medscape.com/viewarticle/830062?src=rss
- A pertussis epidemic in Washington State did not increase parents' intent to vaccinate their children.
  - Study: http://pediatrics.aappublications.org/content/early/2014/08/12/peds.2013-3637.full.pdf+html
  - Commentary: http://pediatrics.aappublications.org/content/early/2014/08/12/peds.2014-1883.full.pdf+html
  - HealthDay story: http://health.usnews.com/health-news/articles/2014/08/18/doctors-id-new-ways-to-get-more-kids-vaccinated

Research
- Periodic Survey #66 (2006): Vaccine Refusals: http://www.aap.org/en-us/professional-resources/Research/Pages/PS66_Executive_Summary_PediatriciansAttitudesandPracticesSurroundingtheDeliveryofImmunizationsPart2.aspx
- Periodic Survey #84(2013) Vaccine Delays/Refusals and Risk–Benefit Information Abstracts
  - Vaccine Refusals and Requests for Alternate Vaccine Schedules (AVS): National Surveys of Pediatricians Pediatric Academic Societies (PAS) May 2014

TABLE 5 Continued

Images

Red Book Online Visual Library: http://aapredbook.aappublications.org/site/visual

Photos, videos, and family stories regarding vaccine-preventable diseases: http://www2.aap.org/immunization/illnesses/illnesses.html

vaccine before and after licensure, remind the parents of the severity of the diseases being prevented, address the questions that are causing parental concerns and, most importantly, emphasize that infants and children are the ones at greatest risk of disease. The on-time administration of vaccines is the most effective way to prevent what have in the past been severe and often fatal childhood illnesses. Delaying any vaccine past the recommended administration date greatly increases the period of time that a child remains susceptible to disease and also exposes even vaccinated children to additional risk.[35,78]

Countering vaccine hesitancy 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[79] if possible, should be an ongoing process. Continued research is needed on the best methods to communicate the safety and effectiveness of vaccines. 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. Most parents need and want education about the best way to provide care for their children, including vaccinations. Dealing with vaccine hesitancy is a wonderful opportunity to continue to provide this information and education to families.

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ABBREVIATIONS

AAP: American Academy of Pediatrics
CDC: Centers for Disease Control and Prevention
FDA: US Food and Drug Administration
HPV: human papillomavirus
MMR: measles–mumps–rubella
VAERS: Vaccine Adverse Events Reporting System
VIS: Vaccine Information Statement
VSD: Vaccine Safety Datalink

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