



Putting Vaccine Benefits and Risks into Perspective: TALKING POINTS FOR DISCUSSIONS WITH PARENTS

Immunizations represent one of the most significant public health achievements of the 20th century.¹ Compared with other clinical preventive services in the US, childhood immunizations are associated with the greatest quality adjusted life years (QALYs) saved.² Paradoxically, because of the success of vaccination programs, there has been a shift from fear of disease to fear of adverse events associated with vaccines. As a result, parental concern about vaccine safety is an issue that clinicians confront frequently. A 2009 survey indicated that 90% of parents felt that vaccines were a good way to protect children, but over half also expressed concern about adverse effects associated with vaccines.³ Providers can create an environment where parents feel comfortable discussing their concerns about vaccines. The following information can support your efforts to effectively address questions about immunizations.

Vaccine-Preventable Diseases Are Still a Real Threat

Initiation of immunization programs has resulted in a dramatic decline in morbidity and mortality from vaccine-preventable diseases.⁴ However, many vaccine-preventable diseases are still around, such as pertussis, invasive *Streptococcus pneumoniae*, and influenza, and others, like measles, are easily imported from overseas. These are serious, potentially fatal diseases associated with long-term complications. Some diseases that circulate at low levels can easily re-emerge if immunization rates decline (in the US, outbreaks of mumps [2006], measles [2008, 2011], and pertussis [2010] are examples of this).⁵ Diseases can also be imported from other parts of the world; polio and diphtheria are still present in other countries.

Vaccine Safety

Fear of vaccines has been advanced by certain celebrities and various anti-vaccine groups and is amplified by misinformation available on the Internet. Many organizations are dedicated to convincing parents that vaccines are dangerous. Such claims are not derived from scientifically rigorous evidence-based studies. It is important for parents to understand that vaccines are among the most thoroughly tested pharmaceutical products. Clinical development of vaccines is an extensive, highly-regulated process. Data from clinical trials are critically evaluated by the FDA prior to granting vaccine licensure. Authoritative bodies such as the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians review and make recommendations for the use of licensed vaccines.⁵ Even with extensive testing, the level of safety assurance is not 100%—once a vaccine is on the market, phase IV studies and pharmacovigilance programs continue to monitor for any potential safety signals associated with receipt of a given vaccine. This ongoing surveillance is critical for the detection of low frequency events, which may be hard to distinguish from background rates in the general population.

It is important to put the risks associated with vaccines into perspective. Measles is highly contagious; 6 of 100 children with measles will develop pneumonia and 2 of 1,000 with measles will die.⁶ In contrast, the occurrence of encephalopathy among recipients of MMR is no greater than the background rate⁶ (approximately 1 in 1,000,000). Parents should be reminded

about background rates for events that may be considered potential side effects of a vaccine. In addition, it is important to consider the number of children who received a given vaccine and do not have a specific side effect. The ‘big picture’ is essential.

The decision *not* to immunize is associated with risk—risk of disease and disease-related complications for the child, and risk of disease for other children in the community, some of whom may be too young or not eligible to receive vaccines due to medical conditions.

Vaccines and Autism

The most prominent safety issue associated with vaccines is the development of autism. The *purported* link between receipt of the MMR vaccine and autism can be traced back to a study published by Wakefield et al in 1998.⁷ In this paper, the authors claimed that the MMR vaccine caused a form of inflammatory bowel disease that ultimately led to altered brain development and autism. The result of this publication was a new wave of anti-vaccinationism and many parents refused the MMR vaccine for their children. It is now clear that this original study was fraudulent; 10 of the authors of the *Lancet* paper retracted their original interpretation of the study in 2004, the UK’s General Medical Council found evidence of serious professional misconduct, and in 2010 the *Lancet* formally retracted the original publication.⁸⁻⁹ MMR does not cause autism, and the evidence to support this includes case-control, population-level, cohort, and biological studies.⁵

Many anti-vaccine champions have claimed that there is a link between the mercury-based preservative thimerosal and autism. The levels of thimerosal that were present in vaccines as a preservative were very low. However, the cumulative exposure associated with receipt of all childhood vaccines prompted calls for the manufacturers of vaccines to eliminate thimerosal from vaccines as a precautionary measure in July of 1999. Childhood vaccines at that time were considered safe, but the additional measure of removing thimerosal was seen as an added step to make the vaccines even safer. It is well established that thimerosal in vaccines did not cause autism, including evidence from biological, epidemiological, case-control, and cohort studies.⁵



The Consequences of Fear of Vaccines

In 1974, a paper was published from England and Wales suggesting a link between pertussis vaccination and neurological problems. This was not a rigorous scientific study, but it received publicity and gave rise to an anti-vaccine movement. When this anti-vaccine movement was strongest, vaccine coverage dropped from 81% to around 31%, and not surprisingly outbreaks of pertussis occurred following this decline in immunization coverage. Loss of public confidence in the vaccine directly resulted in a decline in vaccination coverage (and the death of ~600 children).¹⁰ A case-control study from Colorado showed that the risk of pertussis was 23 times higher among vaccine refusers compared with those who vaccinated their children.¹¹ The risk for varicella was 9 times higher in vaccine refusers.¹² In the aftermath of Wakefield's 1998 *Lancet* publication about the MMR vaccine and autism (now-retracted), MMR coverage in the United Kingdom declined, and the incidence of measles increased accordingly.¹³

Antigen Burden and Alternative Schedules

With the current immunization schedule, children are protected from 16 different diseases by the time they reach 18 years of age. However, parents may be concerned about the antigen burden associated with the immunization schedule, particularly for very young children. Even though children receive more vaccines today than 40–50 years ago, the antigen burden is actually considerably less. In 1960, the total antigen burden associated with recommended vaccines was 3,217. Elimination of smallpox vaccine (200 antigens) and the transition from whole cell pertussis (3,000 antigens) to acellular pertussis (5 antigens) account in large part for the significantly lower antigen burden today (177).^{5,14}

Parental concern about children receiving too many vaccines at one visit or the potential for vaccine-related side effects has prompted consideration of alternative vaccine schedules. More visits are required to give the vaccines according to alternative schedules, and with more visits required, the greater chance that immunization rates will decline. The problem with this approach is that it greatly increases the risk for the diseases that the vaccines are designed to prevent.

There is no harm in giving vaccines according to the recommended immunization schedule. A study by Smith et al demonstrated that there was no difference in neuropsychological outcomes among children who received timely immunizations during their first year versus those who did not.¹⁵

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Communication Strategies

Start the vaccine discussion with parents early (during prenatal or newborn visits) and emphasize the importance of vaccinations as part of routine care. Engage parents in an ongoing decision-making partnership, and empower them with validated sources of information about vaccines and vaccine-preventable diseases. Use a team approach, with all members of your practice endorsing the importance of vaccines and offering a consistent message. Make office visits efficient, and allow time for communication about parental concerns. Recognize that people with different backgrounds may have different views on immunizations or different abilities to understand scientific information. Think about what kind of information will be most appropriate for each family. Be sure to put risks into perspective (risk of vaccine side effects and risk of disease). Clinicians should not underestimate the importance of their own recommendations, and should share their choices about vaccines for their own children. As their health care provider, you can help parents make well-informed decisions about immunizations for their children.

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