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SPECIAL ARTICLE

The Problem With Dr Bob's Alternative Vaccine Schedule

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What's Known on this Subject

Many books misrepresenting the science of vaccines or vaccine safety have been published. None has been as influential as that published by Dr Robert Sears, *The Vaccine Book: Making the Right Decision for Your Child*.

What This Study Adds

This article reviews the flaws in Dr Sears' logic, as well as misinformation contained in his book that likely will lead parents to make the wrong decisions for their children.

ABSTRACT

In October 2007, Dr Robert Sears, in response to growing parental concerns about the safety of vaccines, published *The Vaccine Book: Making the Right Decision for Your Child*. Sears' book is enormously popular, having sold >40 000 copies. At the back of the book, Sears includes "Dr Bob's Alternative Vaccine Schedule," a formula by which parents can delay, withhold, separate, or space out vaccines. Pediatricians now confront many parents who insist that their children receive vaccines according to Sears' schedule, rather than that recommended by the American Academy of Pediatrics, the Centers for Disease Control and Prevention, and the American Academy of Family Physicians. This article examines the reasons for the popularity of Sears' book, deconstructs the logic and rationale behind its recommendations, and describes how Sears' misrepresentation of vaccine science misinforms parents trying to make the right decisions for their children. *Pediatrics* 2009;123:e164–e169

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Key Words
vaccines, schedule, adverse reactions

Abbreviations
CDC—Centers for Disease Control and Prevention
VAERS—Vaccine Adverse Event Reporting System
MMR—measles-mumps-rubella

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MANY PARENTS ARE hesitant about vaccinating their children. Vaccine hesitancy can be explained in part by a lack of trust in those who make vaccine recommendations; a suspicion of profit motive driven by pharmaceutical companies; misinformation on the Internet; failure to appreciate the seriousness of vaccine-preventable diseases, given their low rates; and constant stories in the media claiming that vaccines cause a variety of illnesses, ranging from allergies to autism. Most recently, with the addition of several new vaccines to the infant schedule, some parents have become concerned that children receive too many vaccines too early. Given that young infants currently receive 14 different vaccines, requiring as many as 5 shots at a single visit and 26 inoculations by 2 years of age, the concern that children might be overwhelmed by too many vaccines is understandable.

To address parents' concerns about vaccines, Dr Robert Sears, son of noted pediatrician and author Dr William Sears, wrote *The Vaccine Book: Making the Right Decision for Your Child*.[1] Sears' book, published in October 2007 as part of the Sears Parenting Library, has already sold >40 000 copies and has moved into the top 100 on the Amazon.com bestseller list. The popularity of Sears' book centers in part on 2 schedules, called alternative and selective, that offer parents a way to avoid giving their children several vaccines at one time.

Sears' book is unique. Unlike typical antivaccine books, he offers a middle ground, allowing parents to act on their fears without completely abandoning vaccines. Unfortunately, Sears sounds many antivaccine messages.

THE MESSAGE

Doctors Do Not Understand Vaccines

In his preface, Sears writes, "Doctors, myself included, learn a lot about diseases in medical school, but we learn very little about vaccines. . . . We don't review the research ourselves. We never learn what goes into making vaccines or how their safety is studied. . . . So, when patients want a little more information about shots, all we can really say as doctors is that the diseases are bad and the shots are good." Implicit in Sears' premise is the idea that doctors do not know much about vaccines and that if parents educate themselves they will know more than their doctors. For some parents, this admission can be quite reassuring, allowing them to negate their doctor's advice and take control of a worrisome situation.

Although Sears is correct that doctors do not often review all of the studies on vaccine science, safety, and efficacy, he ignores the expert committees that do, specifically the Advisory Committee on Immunization Practices, which advises the Centers for Disease Control and Prevention (CDC), and the Committee on Infectious Diseases, which advises the American Academy of Pediatrics. Collectively, these advisory committees and their parent agencies have the expertise in virology, microbiology, statistics, epidemiology, and pathogenesis necessary to review the studies that inform their recommendations. Their advice to doctors has served us well; during the past century, vaccines have helped to increase the lifespan of individuals in the United States by ~30 years, with an excellent record of safety.

Public Health Agencies and Pharmaceutical Companies Are Not Trustworthy

Sears casts doubt on the reliability and motives of the CDC and pharmaceutical companies. For example, he writes, "Twenty years ago a group of doctors from the CDC, several US medical centers, and two pharmaceutical companies (GlaxoSmithKline and Merck) undertook the task of determining just how common the hep B [hepatitis B] infection was in infants and children. If they found that hep B was very common in kids, it would make sense to begin vaccination of all newborns. . . . The consensus of the researchers was that approximately 30 000 infants and children were being infected with this virus each year." After taking a closer look at the data, Sears thought that only "about 360 cases [were] reported in kids from birth through age nine each year." Sears' implication is clear, that is, to provide a rationale for newborn hepatitis B vaccine, the CDC, in league with pharmaceutical companies, misrepresented the data.

It is not difficult in today's society to appeal to the notion of corporate or government malfeasance. But Sears' estimate of the impact of hepatitis B infections is not supported by the facts. Before the hepatitis B vaccine became part of the routine schedule for children, every year ~16 000 children <10 years of age were infected with hepatitis B virus after nonsexual, person-to-person contact.[2] Given that reported cases might not include subclinical infections, this estimate is probably low.

Vaccine Mandates Should Be Eliminated

Sears thinks that vaccines should be optional. "Only twenty states allow parents to decline some or all vaccines at public school registration on the basis of personal beliefs," writes Sears. "Parents who decline vaccination in [some] states can have their children taken away from them." Sears fails to mention that enforcement of vaccine mandates, which were initiated because of measles outbreaks that swept across the United States in the middle 1970s, has dramatically reduced hospitalizations and deaths resulting from vaccine-preventable diseases[3,4] or that states with philosophical exemptions have higher rates of vaccine-preventable diseases (such as pertussis), compared with states without such exemptions.[5] His claim that unvaccinated children have been removed from the home is alarming and false, only inflaming an already frightened public.

Vaccine-Preventable Diseases Are Not That Bad

In his chapter on pneumococcal infection, Sears tells the following story. "A six-month-old unvaccinated infant had a pneumococcal ear infection that spread to the skull bones behind the ear. She required surgery and IV [intravenous] antibiotics. Afterward, I asked the parents if they regretted their decision not to vaccinate. They said no. They were both well-educated professionals, had done a lot of reading on this issue, and still felt comfortable with their decision." Sears implies that vaccine-preventable diseases, although occasionally serious, are not really that bad. Before the conjugate pneumococcal vaccine became part of the routine schedule in 2000, however, pneumococci caused ~17 000 cases of invasive disease every year in children <5 years of age, resulting in 700 cases of meningitis and 200 deaths.[6] The parents in Sears' story were fortunate that their child did not suffer sepsis, severe pneumonia, or fatal or debilitating meningitis.

Hide in the Herd

Perhaps the most disingenuous comment in the book is directed at parents who are afraid of the measles-mumps-rubella (MMR) vaccine. "I also warn [parents] not to share their fears with their neighbors," writes Sears, "because if too many people avoid the MMR, we'll likely see the diseases increase significantly." In other words, hide in the herd, but do not tell the herd you're hiding; otherwise, outbreaks will ensue. Sears' advice was prescient. Recent outbreaks of measles in 15 states, caused by an erosion of herd immunity in communities where parents had chosen not to vaccinate their children, were the largest in the United States since 1996.[7]

Natural Infection Is Better Than Vaccination

Sears describes the value of chickenpox parties. "Some parents . . . may purposely get their child exposed to get the disease over with," he writes. "If you've ever been invited to a 'chickenpox party,' you'll know what I'm referring to. Having the disease in most cases provides lifelong immunity (better immunity than the shot provides), so there is practically no worry about catching the disease as an adult." Sears' concern that immunity to chickenpox will fade, only shifting the burden of disease from children to adults, fails to take into account decades of experience with other live viral vaccines. Although measles, mumps, and rubella infections are often more serious in adults, widespread immunization of children has not shifted the burden of disease; rather, it has reduced dramatically or eliminated these infections. Furthermore, although Sears is correct in stating that natural immunity is generally better than vaccine-induced immunity, the high price of natural immunity, that is, occasionally severe and fatal disease, is a risk not worth taking.

Vaccination Has Eliminated Infectious Diseases at the Price of Causing Chronic Diseases

Sears writes, "When I reviewed numerous studies, I did find some that show a possible link between a vaccine and a chronic disease. Examples include the Hib [*Haemophilus influenzae* type b] vaccine and diabetes, the hep B vaccine and multiple sclerosis and rheumatoid arthritis, and the MMR vaccine and eczema." Sears fails to point his readers to the clear body of evidence that has exonerated vaccines as a cause of these disorders (reviewed in ref 8).

Vaccine Safety Testing Is Insufficient

Sears writes, "A new medication goes through many years of trials in a select group of people to make sure it is safe. . . . Vaccines, on the other hand, don't receive the same type of in-depth short-term testing or long-term safety research." On the contrary, vaccines are tested in larger numbers of children for longer periods of time than drugs. For example, the human papillomavirus vaccine was tested in 30 000 women,[9] the conjugate pneumococcal vaccine in 40 000 children,[10] and each of the current rotavirus vaccines in ~70 000 children before licensure.[11,12] No medication receives this level of scrutiny. Furthermore, safety mechanisms such as the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink Project are model systems for detecting rare adverse events after licensure. Drug surveillance would benefit from mimicking these vaccine catchment systems.

Public Health Officials Make Recommendations for the Public and Not for Individuals

Sears writes, "Obviously, the more kids who are vaccinated, the better our country is protected and the less likely it is that any child will die from a disease. Some parents, however, aren't willing to risk the very rare side effects of vaccines, so they choose to skip the shots. Their children benefit from herd immunity . . . without risking the vaccines themselves. Is this selfish? Perhaps. But as parents you have to decide. . . . Can we fault parents for putting their own child's health ahead of the other kids' around him?" Sears' argument represents a fundamental flaw in logic. For example, Sears states that the polio vaccine, which prevents a disease that has not occurred in the United States since 1979, is given to protect the population and not the individual. "[Polio] doesn't occur in our country," he writes, "so the risk is zero for all age groups." Although it is true that polio has been eliminated from the United States, it has not been eliminated from the world. The disease is still prevalent in India, Africa, Southeast Asia, and the Middle East. Because international travel is common and because only 1 of every 200 people infected with poliovirus exhibits symptoms, it is likely that people who are unknowingly shedding poliovirus come into the United States every year. An unimmunized child would be particularly susceptible if an outbreak occurred. Furthermore, the unimmunized child might later travel to a country where polio is endemic. Therefore, every individual benefits from receiving polio vaccine.

THE PROBLEM

Decision-Making

Sears wants parents to use the information he has provided to make their own decisions about whether to vaccinate their children. "I have offered you all the information you need to make this decision," he writes, "but I have held back from actually telling you what to do. I want you to formulate your own decision without letting my opinion sway you one way or the other." Unfortunately, Sears, who wants parents to make informed decisions, has written a book that will largely misinform them.

Distinguishing Good Science From Bad Science

At the end of every chapter describing individual vaccines, Sears includes sections titled "Reasons to get the vaccine" and "Reasons some people choose not to get the vaccine." In the latter sections, Sears often takes the position that, if parents think that a vaccine is problematic, then the vaccine is problematic. He believes that parents' fears should be indulged by offering alternative schedules, not countered by scientific studies, and he fails to explain that good science is the only way to determine whether a vaccine causes a particular adverse event. Instead, Sears alludes to evidence on both sides of any issue, failing to distinguish studies on the basis of their quality, internal consistency, or reproducibility and failing to distinguish those that are accepted by the scientific community from those that are not.

Risks From Vaccines

In chapters describing individual vaccines, Sears lists side effects found in product inserts and VAERS reports. Weighing the risks and benefits of the conjugate pneumococcal vaccine, he writes, "In the first two years of Prevnar's use in the United States, about 32 million doses were given, and about 4100 adverse reactions were reported to VAERS. Most reactions were fairly mild, but about 15 percent (around 600) were considered serious. This means that for every 53 000 doses, one serious reaction occurred." Like many parents who are concerned about vaccines, Sears thinks that reports to VAERS represent an accurate profile of a vaccine's side effects. However, VAERS is a passive surveillance system and cannot be used to determine the true incidence of adverse events, which can be determined only by using control groups (not provided by VAERS). For this reason, VAERS reports often represent coincidental and not causal associations. Furthermore, the source of VAERS reports can be misleading. For example, many of the recent VAERS reports of autism after receipt of vaccines came not from parents, doctors, nurses, or nurse practitioners but from personal-injury lawyers.[13] Finally, pharmaceutical company lawyers often list in product inserts all adverse events that occurred after receipt of vaccines even if those events occurred at rates similar to those found among placebo recipients.

Risks From Vaccine-Preventable Diseases

Sears often counters data on the national incidence of specific infectious diseases with personal experience. For

example, in the section on pneumococcal disease, he writes, "I've seen only one serious case of [pneumococcal] infection in my office in my ten years of practice." Regarding meningococcal disease, he writes, "I saw one case during my medical training, and I haven't seen it since." Because Sears works in a private practice and not a hospital, he is unlikely to see serious infectious diseases commonly. His individual experience should be enriched by his knowledge of published studies, however, and not used to negate them. This see-no-evil approach only misinforms his readers.

Animal Products

Sears explains that some vaccines are made by using fetal bovine serum, raising the specter of mad cow disease. "All animal and human tissues are carefully screened for all known infectious diseases," he writes. "Some vaccine critics are still worried, however, that there may be other viruses or infectious agents (called 'prions') . . . that are much smaller than viruses and that we don't yet know how to screen for." Sears fails to mention that prions propagate in the nervous system and not the bloodstream, that they do not grow in the mammalian cells used to produce attenuated viral vaccines, that they have never been found to contaminate fetal bovine serum, that mad cow disease is not a human health problem in the United States, and that studies found no increased risk of mad cow disease in children who did or did not receive vaccines in the United Kingdom, where mad cow disease was a problem (reviewed in ref 14). Rather, in keeping with his theme that parental fears trump scientific studies, he concludes, "If exposure to animal tissues worries you, you may want to choose the brand that doesn't use cow extract."

Thimerosal

Sears does not take a clear stand on this issue, writing, "Do I think mercury is harmful? Yes. Do I think the amount in the old vaccines caused harm? I'm not 100% convinced one way or the other." It is hard to imagine a better conceived, better designed study on the subtle effects of mercury poisoning than that performed by Bill Thompson and colleagues at the CDC and published in 2007.[15] The study carefully identified the quantity of mercury exposure from thimerosal before birth (from RhoGam; Ortho Diagnostics, Raritan, NJ) and after birth (from vaccines) for >1000 children. Researchers then subjected the children to >40 neurologic, psychological, and developmental tests and found no significant differences for those who received greater or lesser quantities of mercury. By choosing not to evaluate the quality of the scientific findings on this issue, Sears again fails to educate his readers.

Aluminum

Sears' main argument for spacing out vaccines is to avoid giving infants too much aluminum at one time, writing, "When a baby gets the first big round of shots at two months, the total dose of aluminum can vary from 295 micrograms . . . to a whopping 1225 micrograms if the highest aluminum brands are used and a hep B vaccine is also given. . . . These doses are repeated at four and six months." Extrapolating studies of patients undergoing hemodialysis and severely premature infants to healthy newborns, Sears claims that these quantities might be unsafe. However, Sears fails to put aluminum exposure in context. By 6 months of age, infants typically ingest ~6700 μg of aluminum in breast milk, 37 800 μg in infant formula, or 116 600 μg in soy-based formula.[16] Furthermore, Sears fails to describe scientific studies that led the National Vaccine Program Office to conclude that the amount of aluminum contained in vaccines did not warrant changing the vaccine schedule.[17]

Other Vaccine Ingredients

Sears claims that the MMR vaccine contains human albumin purified from human blood. "The human and cow blood products used in manufacturing may also concern some parents," he writes. However, the MMR vaccine contains genetically engineered human serum albumin, a product that is not derived from human blood, as a stabilizer.

MMR Vaccine and Autism

Sears writes, "Some doctors and researchers who suspect the MMR vaccine may play a role in autism also feel it is safer to give the three injections separately, spaced out one year apart. I can't find enough research to determine if this precaution is justified, but in theory it does make sense." For this reason, Sears recommends that the measles, mumps, and rubella components of MMR be administered separately. Sears fails to mention the many epidemiological studies that showed that the MMR vaccine did not increase the risk for autism[18–24] or to note that the theory that measles-containing vaccine causes intestinal inflammation has been thoroughly debunked.[25–27] Worse, Sears takes the discredited notion that measles vaccine causes intestinal disease one step further, recommending that "the MMR vaccine not be given when a child is suffering from diarrhea or has taken antibiotics in the past few weeks. This vaccine may cause more reactions when the intestines aren't at peak health."

THE LOGIC

Coincidence Versus Causality

Sears' general theories of science and medicine are often poorly reasoned or illogical. Sears writes, "Sometimes infants and children develop medical problems . . . within days or weeks of a vaccination. Although it can be highly suspected that the vaccine was the cause, it can't be proven. I'm sure the truth of the matter is somewhere in between causality and coincidence." Epidemiological studies, which are the single best way to determine whether a vaccine is associated with an adverse event, have shown consistently that vaccines cause certain problems, such as measles-containing vaccine causing thrombocytopenia[28] and diphtheria-tetanus toxoids-pertussis vaccine causing seizures.[29] Some studies have failed consistently to find an association, such as

thimerosal in vaccines causing autism.[30,31] In all of these cases, it can be said that a truth has emerged. There is no middle ground between coincidence and causality; a vaccine either causes a problem or it does not.

Scientific Proofs

Sears has a poor grasp of the scientific method. "Some studies have been published in recent years that have failed to show statistical proof of a relationship between vaccines and autism," he writes. "However, by the same token, it is also difficult to prove that there is not a connection." Using the scientific method, investigators form the null hypothesis. Good epidemiological studies are powered to reject or not to reject the null hypothesis. However, the scientific method does not allow investigators to accept the null hypothesis. Said another way, scientists can never prove never. The most that scientists can show is that 2 events are not associated statistically; scientists cannot prove that the events can never be associated statistically. In stating that it is "difficult to prove that there is not a connection," Sears is suggesting the impossible.

Context

Sears argues that elements such as mercury are neurotoxins and the presence of mercury in thimerosal makes some vaccines (such as multidose preparations of inactivated influenza vaccines) dangerous. However, Sears never discusses the fact that mercury is present on the earth's surface and that, like aluminum, children ingest mercury in breast milk and infant formula at levels that often exceed those contained in vaccines.[32] Sears also fails to explain that small quantities of heavy metals such as cadmium, beryllium, lead, and thallium, which can be toxic in large quantities, are present in everyone who lives on our planet. By creating the notion of zero tolerance, Sears fails to educate his readers that the dose makes the poison, that it is the amount of a potential toxin and not its mere presence that counts.

Understanding Risk

Sears does not recommend the meningococcal vaccine for teenagers because of the possible risk of Guillain-Barré syndrome. Indeed, the most recent estimates are that the conjugate meningococcal vaccine might cause Guillain-Barré syndrome for ~1 per 1 million recipients.[33] However, the risk of meningococcal disease for a child who is not vaccinated is ~10-fold greater than the possible risk of Guillain-Barré syndrome for a child who is vaccinated. Furthermore, the high rates of death and permanent sequelae caused by meningococci make the choice not to be vaccinated an illogical one. By failing to weigh the relative risks of the disease and vaccine side effects accurately, Sears again misinforms his readers.

THE HARM

For parents who are worried about vaccines, Sears offers 2 alternative schedules. One, titled "Dr Bob's Selective Vaccine Schedule," is for parents who want to decline or to delay vaccines. Children whose parents choose this schedule might not be receiving the measles, mumps, rubella, varicella, and hepatitis A vaccines and will not be receiving the polio and influenza vaccines or a booster dose of pertussis vaccine.

The other schedule, titled "Dr Bob's Alternative Vaccine Schedule," is written for parents who worry that children are receiving too many vaccines too early. Children whose parents choose this schedule will not be receiving the influenza vaccine until 5 years of age (which is unfortunate, given that tens of thousands of children <4 years of age are hospitalized with complications resulting from influenza every year),[34] will not be receiving the hepatitis B vaccine until 2.5 years of age, will not be receiving measles vaccine until 3 years of age, and, to space out vaccines so that children do not receive >2 shots at 1 visit, will be visiting the doctor for vaccines at 2, 3, 4, 5, 6, 7, 9, 12, 15, 18, 21, and 24 months and 2, 2.5, 3, 3.5, 4, 5, and 6 years of age. Increasing the number of vaccines, the number of office visits, and the ages at which vaccines are administered will likely decrease immunization rates. In addition to the logistic problem of requiring so many office visits, Sears' recommendation might have another negative consequence; recent outbreaks of measles showed that several children acquired the disease while waiting in their pediatricians' offices.[7]

At the heart of the problem with Sears' schedules is the fact that, at the very least, they will increase the time during which children are susceptible to vaccine-preventable diseases. If more parents insist on Sears' vaccine schedules, then fewer children will be protected, with the inevitable consequence of continued or worsening outbreaks of vaccine-preventable diseases. In an effort to protect children from harm, Sears' book will likely put more in harm's way.

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