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Protecting Public Trust in Immunization

Louis Z. Cooper, MD^a, Heidi J. Larson, PhD^{b,c}, Samuel L. Katz, MD^d

^aProfessor Emeritus, Department of Pediatrics, College of Physicians & Surgeons, Columbia University, New York, New York; ^bInternational Development, Clark University, Worcester, Massachusetts; ^cHarvard Center for Population and Development Studies, Cambridge, Massachusetts; ^dProfessor Emeritus, Department of Pediatrics, Duke University, Durham, North Carolina

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ABSTRACT

Public trust in the safety and efficacy of vaccines is one key to the remarkable success of immunization programs within the United States and globally. Allegations of harm from vaccination have raised parental, political, and clinical anxiety to a level that now threatens the ability of children to receive timely, full immunization. Multiple factors have contributed to current concerns, including the interdependent issues of an evolving communications environment and shortfalls in structure and resources that constrain research on immunization safety (immunization-safety science). Prompt attention by public health leadership to spreading concern about the safety of immunization is essential for protecting deserved public trust in immunization. *Pediatrics* 2008;122:149–153

VACCINATION AGAINST CHILDHOOD diseases is one of the greatest medical success stories of the last half century. Worldwide, tens of millions of lives have been saved. In the United States, immunization rates are at all-time high levels, and vaccine-preventable diseases (with few exceptions) are at all-time lows. Nevertheless, allegations of harm from vaccines have become so loud and widespread that they pose a threat to immunization programs and to trust in recommendations from our public health authorities and the medical community. Here we offer reflections on factors that have contributed to this situation and some suggestions that may help to strengthen public trust and decrease the polarity that is sapping precious health resources.

Every time a mother holds her healthy infant to be immunized, she is demonstrating great faith in the potential benefit and safety of the vaccine and trust in the clinician who recommended it. Over past years, clinicians and public health leaders have taken for granted the magnitude of that act of trust. We also have basked in the praise that comes with being a participant in the success of immunization in dramatically reducing morbidity and mortality in childhood and changing the practice of pediatrics. This success has come from considerable and focused investment (financial and scientific) in the development of vaccines; the biological effectiveness of vaccines; sound public policy and implementation in delivering vaccines to target audiences; and a history of high levels of public trust in vaccine safety and efficacy. This trust is an expression of a special social contract that is one key to the success of immunization programs.

“Vaccines are victims of their own success” is the shorthand now used to reflect the reality that, in the absence of vaccine-preventable disease, many parents fear vaccines more than the diseases known to them only vaguely. Although they strongly advocate for vaccines recommended by the US Public Health Service and the American Academy of Pediatrics, the majority of practicing pediatricians in the United States are young enough to have no personal experience with most vaccine-preventable diseases.

Before the era of modern vaccines, which began with polio vaccine in 1955, the widely used smallpox vaccine and the less frequently used rabies vaccine carried risks of relatively frequent and severe adverse reactions. However, at the time these vaccines were introduced, smallpox and rabies were tangible disease threats that were more feared by the public than the risks of the vaccine. Thus, resistance to immunization was quite limited.

Although those early vaccines are no longer in use, no one claims “zero risk” for the vaccines against 16 diseases that are currently recommended to protect children in the United States. Here and in other countries where immunization has been most effective, widely publicized and often dramatically presented allegations of adverse events after immunization have raised anxiety levels among parents of young children. An increasing number of parents express more fear of the vaccine than of the diseases they are designed to prevent.

At the clinical level, pediatricians now spend much more time putting parental fears in perspective. Although record or near-record high immunization rates confirm their success, there is no measure of how that extra time has

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Key Words

immunization, vaccination, safety, public health practice, public participation, parent beliefs, adverse effects, immunization-safety science

Abbreviations

CDC—Centers for Disease Control and Prevention
 FDA—Food and Drug Administration
 DHHS—Department of Health and Human Services
 NIH—National Institutes of Health
 ISB—Immunization Safety Branch
 NIP—National Immunization Program
 NCIRD—National Center for Immunization and Respiratory Diseases
 VFC—Vaccines for Children Program
 PHS—Public Health Service
 NVPO—National Vaccine Program Office
 NVAC—National Vaccine Advisory Committee

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Address correspondence to Louis Z. Cooper, MD, 80 Central Park West, New York, NY 10023-5206. E-mail: loucooper@att.net

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detracted from them addressing other important issues during the limited time allotted (averaging 18 minutes) for a pediatric health supervision visit.

Refusal rates for state-mandated vaccines are also an indicator of weakening public trust in vaccines. In Washington, the refusal rate has reached 5%, and although lower, rates have doubled in other states such as Missouri and Maine. Clustering of high rates of exemptions from vaccine in some communities has resulted in small outbreaks of vaccine-preventable diseases.

In another signal of public questioning, 7 states have banned the use of thimerosal as a preservative in vaccines. Included are such large states as California and New York. Twenty other states have considered similar restrictions. This willingness of state legislatures to intrude against consensus, mainstream medical, and public health recommendations is concerning.

Drivers of controversy that have led to vaccine refusals and bans on thimerosal include:

- incomplete science;
- faulty or dishonest “science”;
- political motivation;
- financial motivation; and
- philosophic and religious objections to immunization or some constituent used in vaccine preparation.

Given the long history of vaccines, what is different now?

- There has been a dramatic increase in the number of vaccines available and recommended for routine use.
- There is an increased number of vaccines now mandated by state laws. Although the vast majority of parents comply, mandates are inherently coercive and can feed distrust.
- Vaccine-preventable diseases are relatively absent from the environment and the memories of young parents and clinicians.
- Consumerism has risen, with people wanting to understand health issues and assume responsibility for their own health decisions (the end of medical paternalism) and physicians wanting patients to become partners in their care.
- Information technology has increased access to information and misinformation about immunization. Unfortunately, misinformation has equal access to the Internet, and the volume of this non-science-based material exceeds that from reliable sources. Rumor, disinformation, and misinformation can be spread globally in minutes. As cell phones become ubiquitous, news can spread rapidly around the world in record time.
- The Internet has facilitated social networking, which empowers and reinforces the zeal of even relatively small numbers of people with similar views.
- Print, broadcast, and electronic media are driven by business decisions and a 24/7 news cycle. Controversy

and bad news are known to attract more readers, viewers, and listeners than good news. Allegations of vaccine harm garner disproportionate attention. The concept of airing all sides of issues or providing “fair and balanced coverage” often means giving equal time to “outlier views” alongside scientific views.

- The general climate of distrust has been increased by exposures of dishonesty in the business/corporate world, politics and government, news media, and traditional professions such as accounting, academia, organized religion, law, and medicine.

Nowhere is distrust more apparent and understandable than among parents who believe their child has been injured by immunization. They can feel betrayed, having followed the advice of trusted sources and then “seeing with their own eyes” and believing sincerely that their child was harmed, regardless of whether scientific evidence supports their beliefs.

In fact, more than 2 decades ago, the National Childhood Vaccine Injury Act of 1986 was passed in response to pressure from parents concerning their strong belief that the diphtheria-pertussis-tetanus vaccine was harming their children and demand for redress of their grievances; liability concerns that were threatening a fragile vaccine industry; and pediatricians who were ready to drop immunization for fear of malpractice claims. The act created a no-fault federal mechanism for compensation of children injured by immunization by establishing a special vaccine court within the Federal Court of Claims. The program successfully prevented vaccine makers from abandoning the US market, kept practicing pediatricians from stopping immunization, and, since 1988, has awarded \$1.8 billion in compensation for vaccine-associated injury. However, the program remains flawed in the eyes of those who have been denied compensation. Although some denials have been on procedural grounds, most denials have been based on the absence of scientific evidence to support a causal relationship between the vaccine given and injury to the child. Clearly, this is not because of lack of funds, because a special vaccine trust fund receives \$0.75 from an excise tax added to the cost of each vaccine, and the fund had a balance of \$2.6 billion at the end of 2007. Emotions are critically high now as the vaccine court is hearing an unprecedented set of cases called the Omnibus Autism Proceeding, a grouping together of 4800 cases in which parents claim that the measles-mumps-rubella vaccine and/or thimerosal-containing vaccines triggered autism or autism spectrum disorder in their children. The outcome of these cases will depend on the court’s understanding of the scientific evidence underlying the claims.

Given these new dynamics and drivers that have led to a more questioning public around the safety and efficacy of vaccines, what can be done to strengthen public trust in immunization? Investment in 2 key areas is critical to strengthening public trust. One area that needs increased investment is immunization-safety science; the other area that needs both increased financial investment and significant rethinking by the “vaccine

community" is its communication strategy. These are absolutely interdependent, because effective communication must rely on clear information that is based on adequate immunization-safety science.

What is immunization-safety science? Or, more accurately, what are the sciences necessary for protecting public trust in the safety of vaccines? Most of the biological, social, and communication sciences have roles. Some of these sciences are more central and obvious than others, such as allergy/immunology, epidemiology, and infectious diseases, but anthropology, ethics and political science also have important roles given the multiplicity of questions. Research on the short- and longer-term risks and benefits of combinations and timing of multiple vaccines requires a different profile of disciplines than does the question of "what is the value of mandates in public immunization programs?" Newer technologies, such as vaccinogenomics and nanotechnology, have not yet played a role in immunization safety. As an increasing body of research is failing to demonstrate causal relationships between autism and thimerosal-containing vaccines or the measles-mumps-rubella vaccine, allegations that it is the total number, combination, and/or timing of the US childhood immunization schedule that is harming children are mounting. The "harmonized schedule" agreed on by the Centers for Disease Control and Prevention (CDC), the American Academy of Family Physicians, and American Academy of Pediatrics is faulted (without data) by some as inflexibly forcing a one-size-fits-all policy that ignores genetic and environmental differences.

Shortfalls in immunization-safety science and communication were expressed from diverse perspectives during the CDC's Blue Ribbon Panel meeting in June 2004. Consensus was reached about certain essential characteristics of a trust-protecting immunization-safety program for the United States. These characteristics include transparency, accountability, adequate long-range funding, and minimization of conflicts of interest. This panel's charge did not include a request for suggestions on how to alter the existing structures and practices for evaluating the safety of immunization. Experience in the interval since that panel's report leads us to the following suggestions for strengthening public trust. We believe the suggestions are worthy of consideration by our national and local public health, industry, medical, consumer, and political leaders.

- Invest more in public awareness and genuine public engagement around immunization issues. Recognize the number and heterogeneity of publics to be served and the diversity and legitimacy of their questions and concerns.
- Educate the public on the elaborate, already existing US system for research and testing of vaccines, including the responsibilities of the vaccine industry and, particularly, the independent and interdependent functions of industry, the US Food and Drug Administration (FDA), the CDC, the Health Resources and Services Administration, and all their advisory bodies for prelicensure and postlicensure evaluation.

- Educate the public on the function, membership, and selection process for members of key advisory bodies.
- Increase the number and diversity of citizen members on advisory bodies without reducing scientific expertise.
- Give the public sufficient information and adequate time to understand the rationale for any new vaccines before embarking on immunization campaigns, which can be done without delaying protection.
- Engage local communities and parent groups as advocates of new vaccines.
- Avoid the hyperbolic marketing practices of overselling.
- Improve the communication skills of public and private health leaders to present information in perspective, including benefits, risks, and gaps in knowledge. Avoid obfuscation, admit gaps in knowledge, and be available and candid in answering the questions asked, building comfort even when the circumstances are uncomfortable. Take the time to explain changes in recommendations/policy. Such explanations are essential for reducing charges of waffling, indecision, and hidden agendas.
- Invest in research on what is truly driving parents' questions and concerns and what may be needed to earn/keep their trust in vaccines.
- Decrease reliance on state mandates and in no case push for mandates before evaluating the results of voluntary immunization programs.

WHAT ADDITIONAL STEPS CAN BE TAKEN TO EXPAND IMMUNIZATION-SAFETY SCIENCE AND ITS VISIBILITY AND TO STRENGTHEN PUBLIC TRUST?

We must not forget the remarkable record of immunization-safety science in detecting and characterizing the risks associated with specific vaccines and the policy changes implemented by the safety findings. Specific examples include characterization of and policy changes around vaccine-associated paralytic polio, Guillain-Barre syndrome after swine flu immunization, and intussusception associated with an early version of a vaccine against rotavirus infection (which was withdrawn in 1999). These examples of safety science at work have not shielded immunization programs from allegations that other harm caused by vaccines is being overlooked or denied and that not enough research is being performed.

In fact, there is no more dramatic documentation of the shortfalls in research on immunization safety than the findings of a series of Institute of Medicine review committees. At the request of the Department of Health and Human Services (DHHS), these expert review committees were established to evaluate specific hypotheses about harm from vaccines. Over the past 15 years, more than half of the allegations reviewed by the committees have concluded that "evidence is inadequate to accept or reject a causal relationship."

GIVEN THIS EXPLICIT ACKNOWLEDGMENT OF THE GAPS IN IMMUNIZATION-SAFETY SCIENCE, WHAT STEPS NEED TO BE TAKEN?

Immunization-safety science requires leadership, infrastructure, facilities and human resources, and appropriate long-range planning and funding different from, but appropriately comparable with, the programs that have contributed to the great success of immunization programs. Clear lines of authority and responsibility exist within existing private and public entities for vaccine development and distribution. These lines focus financial resources that energize the vaccine endeavor and are perpetuated by systems that reward these efforts. For the private sector, vaccines are a profitable investment. Public programs reap direct political and financial rewards from successful immunization programs. For some vaccines, cost/benefit ratios are remarkable. (The CDC fiscal-year 2008 budget justification credits the childhood vaccine series of 7 vaccines with a \$16.50 saving for every \$1 spent.) For other vaccines, the moral rewards of lives saved are equally compelling. No such simple system, with self-perpetuating resources, exists to energize the science of immunization safety.

The remarkable growth of National Institutes of Health (NIH) and CDC resources for vaccine development and distribution has not translated into growth in funds to support immunization-safety sciences in any public program. Although research pertinent to immunization safety is often an ancillary or secondary benefit of research within the NIH and other public agencies, the only agency that dedicates specific funding is the CDC. An immunization safety office now reports to the CDC's chief science officer. Until 2005, that unit, then identified as the Immunization Safety Branch (ISB), was nested within 1 of the 3 divisions of the National Immunization Program (NIP) at the CDC. Because the NIP's major assignment is distribution of vaccines and monitoring of vaccine-preventable diseases with major funding from the Vaccines for Children Program (VFC) and Public Health Service (PHS) 317 program, the ISB was moved out of the NIP (now the National Center for Immunization and Respiratory Diseases [NCIRD]) in an effort to reduce allegations of potential conflict of interest. Regardless of bureaucratic placement, the mismatch in resources is clear. The NCIRD is funded in the \$3 billion range, whereas the ISB, now the Immunization Safety Office, has been constrained by a budget essentially stalled at less than \$20 million. This funding restricts programs of merit within the CDC, including the Clinical Immunization Safety Assessment Network, the Vaccine Safety Datalink program, and the Vaccine Adverse Events Reporting System, known as the VAERS and shared with the FDA. At the NIH, with a \$29 billion budget that dwarfs even the funds from the VFC, the other demands for its resources have left no sense of priority for immunization-safety research. The success rate for funding of new grants (21%) has dropped by one third between 2007 and 2002. The Jordan Report, the NIH's periodic review of immunization science, mentions safety issues only in passing. Certainly, knowledge relevant to immunization-safety science is a by-

product of other research within the 27 institutes and centers of the NIH but does not surface as a priority in any of their goals. The FDA's mandate is focused by its statutory obligations around the licensing of vaccines with minimum resources for postlicensing research.

Private-sector science around vaccine safety understandably has been limited to that required for licensure, limited postlicensing surveillance, and defense of allegations of harm from specific vaccines. Safety science funded by industry also is handicapped by perceptions of conflict of interest.

Given these constraints, immunization-safety science has not generated academic excitement or an effective advocacy constituency for its share of attention and funding. Development of a career ladder to attract and keep investigators committed to the field in government and academia has been hampered by this lack of funding.

The good news is that existing federal laws and infrastructure within the DHHS (ie, in the CDC, FDA, National Vaccine Program Office [NVPO], NIH, and Health Resources and Services Administration) and, to a lesser extent, the Department of Defense and the Veteran's Administration can provide a sound foundation for responsible and relatively prompt expansion of research on the safety of immunization. The National Childhood Vaccine Injury Act of 1986 created the NVPO and National Vaccine Advisory Committee (NVAC) chaired by the Assistant Secretary of Health. As defined in its charter, the NVAC "shall:

1. study and recommend ways to encourage the availability of an adequate supply of safe and effective vaccination products in the States,
2. recommend research priorities and other measures the Director of the NVP should take to enhance the safety and efficacy of vaccines,
3. advise the Director of the NVP in the implementation of sections 2102, 2103, and 2104 of the PHS Act,
4. identify annually for the Director of the NVP the most important areas of government and non-government cooperation that should be considered in implementing sections 2102, 2103, and 2104 of the PHS Act."

Membership of the NVAC includes 15 public members, 2 vaccine industry representatives, 10 ex-officio, nonvoting representatives of all relevant federal agencies, and many nonvoting liaison representatives from other nongovernmental agencies, Canada, and Mexico.

Unfortunately, although the mandate for the NVPO and NVAC concerning safety is clear, the NVPO director (the assistant secretary of health) has no authority and very limited budget to support research on vaccine safety across DHHS agencies. A comprehensive national vaccine plan was last published in 1994. The NVPO staff is small, and the selection process for NVAC public membership has not been perceived as representing diverse publics well. The NVP has little clout and no enforcement capacity toward implementing "important areas of government and nongovernment cooperation."

Contributing to the DHHS' failure to present a coherent immunization-safety strategy has been the issue of from where they should get their funds. Although the DHHS budget is significant, public expectations and mandated responsibilities of key operating agencies exceed their resources. The NIH, the foundation for biomedical science in the United States, currently can fund only a small percentage of its grant applications. Investigator-initiated research, the well-spring of American scientific creativity, is funded at a rate that is discouragingly low. In short, immunization-safety science has not been effective in competing for a share of resources commensurate with the health importance of the immunization program.

Meaningful expansion of resources devoted to immunization-safety research could be cobbled together from existing DHHS budgets without measurable negative impact on its agencies. On the other hand, given congressional intent regarding safety when it created the National Childhood Vaccine Injury Act, the success of that program, its fiscal solvency, the virtually imperceptible magnitude of the existing excise tax on purchased vaccine, and its expanding income directly related to increasing numbers and doses of vaccine, the Vaccine Trust Fund arguably could be a source of funding.

Relatively few changes could help to strengthen public trust in the safety of national immunization programs. The NVP/NVAC and CDC are aware that increasing concerns about safety are a real threat to immunization's unparal-

leled success, but that awareness has not translated into action at the levels of government that have the authority and responsibility to make a difference.

Where do changes have to begin? Ultimately, responsibility and authority for creating and implementing an appropriate immunization-safety research and communication program rests with the president and the secretary of Health and Human Services. Prevention, especially immunization, has been a consistent priority of all recent secretaries of the DHHS. Because the secretary supervises all the DHHS agencies that must play a role in immunization-safety science, he must play a role toward creation of a robust program that protects deserved public trust in immunization. Although the DHHS can accomplish what needs to be done, congressional cooperation can make the task easier. If the administration fails to act, Congress could take the lead by amending existing legislation. The longer the United States delays, the greater the risk that harmful vaccine-preventable diseases will reemerge. Such costs would dwarf the cost of a responsible immunization-safety science program.

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PARENTS ADVISED TO MONITOR TEEN USE OF INSULIN PUMPS

“Chicago—Insulin pumps are used by tens of thousands of teenagers worldwide with Type 1 diabetes, but they can be risky and have been linked to injuries and even deaths, according to a review by federal regulators. Parents should be vigilant in watching their children's use of the pumps, researchers from the Food and Drug Administration wrote. They didn't advise against using the devices, but they called for more study to address safety concerns in teens and even younger children. The review of use by young people over a decade found 13 deaths and more than 1500 injuries connected with the pumps. At times, the devices malfunctioned, but other times, teens were careless or took risks, the study said. Some teens didn't know how to use the pumps correctly, dropped them or didn't take good care of them. There were two possible suicide attempts by teens who gave themselves too much insulin, according to the analysis. ‘The FDA takes pediatric deaths seriously,’ said Judith Cope of the FDA, lead author of the analysis. ‘Parental oversight and involvement are important. Certainly teenagers don't always consider the consequences,’ Dr. Cope said.”

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