

VICTIMS OF OUR OWN SUCCESS

*Will Immunization
Remain the Paradigm of
Effective Prevention?*

ISSUE BRIEF NO. 4

BASED
ON A
GRANTMAKERS
IN HEALTH
ROUNDTABLE

WASHINGTON, DC

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Foreword

As part of its continuing mission to serve trustees and staff of health foundations and corporate giving programs, Grantmakers In Health (GIH) convened a select group of grantmakers and national experts who have made a major commitment to childhood immunization. The roundtable explored various factors influencing public acceptance of childhood immunization, with discussions ultimately centering on the importance of ensuring and conveying accurate information to the public and policymakers. Current and potential roles for health philanthropy were also discussed.

This report brings together key points from the day's discussion with factual information on childhood immunization drawn from a background paper prepared for the meeting. When available, recent findings, facts, and figures have been incorporated. Mary Backley of GIH's staff planned the program in collaboration with colleagues from The Robert Wood Johnson Foundation. Katherine Treanor, M.S.W., program associate, prepared the report, with contributions from fellow GIH staff members, Anne Schwartz, Ph.D., and Leslie Whitlinger, to the final product.

Special thanks are due to those who participated in the discussion but especially to presenters and discussants: Louis Cooper, M.D., Professor of Pediatrics, Columbia University School of Medicine; Kathryn Edwards, M.D., Professor of Pediatrics, Vanderbilt University School of Medicine; Bruce Gellin, M.D., M.P.H., Executive Director, National Network for Immunization Information and Adjunct Assistant Professor of Preventive Medicine, Vanderbilt University School of Medicine; Samuel Katz, M.D., Emeritus Professor of Pediatrics, Duke University School of Medicine; Walter Orenstein, M.D., Assistant

Surgeon General, and Director of the National Immunization Program, Centers for Disease Control and Prevention; Paul Tarini, Communications Officer, The Robert Wood Johnson Foundation; and Eric Zook, Ph.D., Research Director, Porter Novelli.

Additionally, GIH gratefully acknowledges The Robert Wood Johnson Foundation for providing partial support for this meeting and the many valuable contributions of Dr. Gellin to both the program and report.

About GIH

Grantmakers In Health (GIH) is a nonprofit, educational organization dedicated to helping foundations and corporate giving programs improve the nation's health. Its mission is to foster communication and collaboration among grantmakers and others, and to help strengthen the grantmaking community's knowledge, skills, and effectiveness. Formally launched in 1982, GIH is known today as the professional home for health grantmakers, and a resource for grantmakers and others seeking expertise and information on the field of health philanthropy.

GIH generates and disseminates information about health issues and grantmaking strategies that work in health by offering issue-focused forums, workshops, and large annual meetings; publications; continuing education and training; technical assistance; consultation on programmatic and operational issues; and by conducting studies of health philanthropy. Additionally, the organization brokers professional relationships and connects health grantmakers with each other as well as with grantmakers in other fields whose work has important implications for health. It also develops targeted programs and activities, and provides customized services on request to individual funders. Core programs include:

- Resource Center on Health Philanthropy. The Resource Center monitors the activities of health grantmakers and synthesizes lessons

learned from their work. At its heart are staff with backgrounds in philanthropy and health whose expertise can help grantmakers get the information they need and an electronic database that assists them in this effort.

- The Support Center for Health Foundations. Established in 1997 to respond to the needs of the growing number of foundations formed from conversions of nonprofit hospitals and health plans, the Support Center now provides hands-on training, strategic guidance, and customized programs on foundation operations to organizations at any stage of development.
- Building Bridges with Policymakers. GIH helps grantmakers understand the importance of policy to their work and the roles they can play in informing and shaping public policy. It also works to enhance policymakers' understanding of health philanthropy and identifies opportunities for collaboration between philanthropy and government.

GIH is a 501(c)(3) organization, receiving core and program support from more than 175 funders annually.

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Introduction

Immunization is one of the greatest public health achievements of modern times. By controlling many once-common diseases, vaccines have saved millions of lives and, in the United States today, effectively prevent 10 childhood infections. The 1999 rates of childhood immunization in the United States are the highest ever recorded resulting in the lowest incidence of vaccine-preventable diseases in the nation's history (HHS 2000). In fact, the overall immunization rate for preschool children was 80 percent in 1999, a dramatic increase over 1992's rate of 55 percent.

Despite this success, however, the Institute of Medicine (IOM) recently warned that new challenges and reduced resources are weakening the nation's immunization system, increasing the likelihood of disease outbreaks. As part of its ongoing work on this issue, the IOM's June 2000 report to the United States Congress stated, "a look past the high immunization rates reveals a system facing new responsibilities and shrinking or uncertain resources, which leave it ill-equipped to meet future needs." Federal grants to support the immunization infrastructure have been reduced by more than half, resulting in less effective data collection, assessment of immunization rates, and strategic planning efforts (IOM 2000). Additionally, some states have cut spending and reduced the number of sites at which children can get immunized.

Compounding the problem of reduced resources are public concerns, both real and hypothetical, about the potential side effects of various vaccines. The safety and efficacy of some vaccines have been called into question in recent years, and the possibility of links between vaccines and specific conditions – including autism, cerebral palsy, diabetes, and sudden infant death syndrome (SIDS) – has been suggested. Although

the majority of the scientific community agrees that vaccine-related risks are quite small and the benefits far outweigh potential risks, such questions and concerns have attracted the attention of national and state legislators, as well as the media. For example, the hepatitis B vaccine – a vaccine that prevents a severe viral infection of the liver – has been the subject of several negative news reports, including a January 1999 segment on ABC's *20/20: Who's Calling the Shots?* In addition, on May 18, 1999, a congressional subcommittee held a hearing entitled *Hepatitis B Vaccine: Is the Vaccine Helping or Hurting Public Health?*

The measles, mumps and rubella (MMR) vaccine has also been the focus of public inquiry. On October 3, 1999, *CNN/Time* ran an emotionally charged piece, *A Question of Harm*, alleging that the MMR vaccine was linked to the development of autism. Although most autism experts agree that this neurodevelopmental disorder can be traced to an early developmental period, the potential link to immunization was also explored in a U.S. House of Representatives Government Reform and Oversight Committee hearing in April 2000. The proceedings were broadcast on C-SPAN and over the Internet (*Autism: Present Challenges, Future Needs – Why the Increased Rates?* April 3, 2000). The July 31, 2000, issue of *Newsweek* also raised this subject in its cover story, *Understanding Autism*.

In view of this potential erosion of both public trust and public health, Grantmakers In Health (GIH) convened a roundtable discussion, *Victims of Our Own Success: The Immunization Debate as the Paradigm of Effective Prevention*, in August 1999. The objective was to explore ways to convey the full spectrum of immunization's benefits and risks to policymakers, clinicians, and parents, all of whom are faced with decisions that are critical to the health of children and the public at

TOP TEN CHILDHOOD
DISEASES PREVENTED
BY VACCINES

Diphtheria

*Haemophilus influenzae
type b (Hib)*

Hepatitis B

Measles

Mumps

Pertussis (whooping cough)

Polio

Rubella (German measles)

Tetanus (lockjaw)

Varicella (chicken pox)

CDC, 2000

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“Thanks in large part to these high immunization rates, we have seen a breathtaking decline in suffering and death from most vaccine-preventable diseases...”

large. During the meeting, participants heard presentations from grantmakers, public health officials, pediatricians, infectious disease specialists, and public policy experts, and engaged in an exchange of ideas, experiences, and information. Discussions centered on the value of immunization and the challenges involved in relaying timely, accurate information to the people who need it in an era of instant communications, increased media attention, and growing reliance on the Internet.

The importance of communication was considered within the larger context of:

- the role of immunization in protecting community health,
- factors influencing public support of immunization,
- recent research into perceptions and attitudes surrounding immunization,
- the issue of vaccine safety: real and perceived,
- the need for a national strategy to address immunization challenges,
- current efforts to promote immunization, and
- steps that foundations are taking to strengthen immunization programs and, especially, to restore public confidence in immunization.

This report presents information on these issues, including comments and remarks made during the meeting. Descriptions of current activities undertaken by health foundations to address the areas mentioned above, as well as recommendations for the future, conclude the report.

A Matter of Public Safety

Modern childhood vaccines are approximately 90 percent to 95 percent effective. In practice, this means that for every 20 children who are vaccinated, only one or two may fail to develop a sufficient immune response should they encounter the virus or bacteria at school, at a playground, at a shopping mall, or at day care.

In addition to safeguarding individuals, immunizations also have a clear public benefit. Community immunity – the level of protection within U.S. communities, as established by immunologists and epidemiologists – is a key determinant in keeping infectious disease in check: The greater the proportion of immunized individuals in a community, the less the chance that disease will spread (CDC April 11, 2000b). The level of community immunity is particularly important for infants who are susceptible to many of the diseases covered, but may be too young to be immunized or to have received the full set of immunizations that will provide the protection they need.

To illustrate, in the late 1960s and early 1970s, before widespread use of the measles vaccine, millions of children came down with measles each year. The rate of vaccination at this time for at-risk populations in most communities was only 60 percent to 70 percent – not high enough to provide sufficient community immunity. In response, several states established immunization requirements for entry into school and day care programs, and experienced significant drops in their incidence rates for measles. Accordingly, other states quickly followed suit with similar results. By 1998, only 89 cases of measles were reported in the U.S., with no measles-

For 1998, the U.S. Centers for Disease Control and Prevention reported:

- no cases of polio caused by wild polio virus,
- one case of diphtheria,
- six cases of birth defects from rubella in infants born to unimmunized migrant worker mothers,
- 54 cases of invasive Hib disease (meningitis, pneumonia, and sepsis) in children less than 5 years of age, and
- 89 cases of measles, all believed to be related to importations from other countries.

associated deaths. This level of community immunity is a direct result of the school exclusion statutes that now exist in all states.

As long as the great majority of children receive their vaccines, community immunity protects the unvaccinated and those in whom immunizations have failed or worn off. But if the number of people in a community who are not protected by immunization grows, the level of community protection will drop, creating a scenario where the recurrence of vaccine-preventable diseases is far more likely.

Some children, however, either are not or cannot be immunized. A small percentage of the population is allergic to vaccine components or cannot be vaccinated because of other medical conditions. Geographic and economic barriers can also reduce access to immunizations (IOM 2000). In addition, 48 states and the District of Columbia allow exemptions for religious reasons, and 14 states allow exemption for philosophical or personal reasons (Flanders 2000). These exemptions can have serious consequences not only for the individuals who are not vaccinated but also for their communities.¹ One study found that children who were exempted from immunization were 35 times

more likely to become infected with measles than those who were vaccinated (Salmon 1999).

Of greater importance, a disease that infects exempted children can spread to the community at large (Salmon 1999). A decline in community immunity lessens the protective benefits of vaccines and may allow for an infectious disease to spread. Recently, two infants in California's San Francisco Bay area died of pertussis. The infants were too young to be immunized, and their protection depended on the level of immunization in their community, which had fallen (Cooper 1999). In the United Kingdom, concern about the alleged MMR-autism link has already produced a decline in measles vaccine administration. In fact, there have been more than 1,200 cases of measles reported in Ireland alone, and several deaths among those who declined the vaccine.

Drops in immunization rates have had similar effects on pertussis control in Sweden, Japan, the United Kingdom, the Russian Federation, Ireland, the former West Germany, and Australia. In each of these countries, a resurgence of disease followed a decline in public confidence in immunization programs fueled by concerns about vaccine safety. In Japan, for

...Vaccines work – they are cost-effective tools to prevent disease. Without them, epidemics of vaccine-preventable diseases could easily return, resulting in increased illness, disability, and death. Our task is to reach all the children who still remain unvaccinated and at risk.”

DONNA E. SHALALA,
HHS SECRETARY,
U.S. DEPARTMENT OF
HEALTH AND HUMAN
SERVICES
JULY 6, 2000

¹ All states allow exemption from vaccination for medical reasons.

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*“ We have become the victims
of our own success...
It is the ultimate irony that
as we celebrate the prevention
of epidemics of diseases that
just a few generations ago
sent fears through the
community – meningitis,
polio, diphtheria, congenital
rubella, measles – we must
also acknowledge the growing
misperception that vaccines
cause more harm than good.”*

DR. LOUIS SULLIVAN,
FORMER HHS SECRETARY,
1998 NATIONAL
IMMUNIZATION
CONFERENCE

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example, cases of pertussis were extremely rare, and there were no pertussis-related deaths in 1974. But after questions surrounding vaccine risk emerged – along with suggestions that vaccination was now unnecessary – a national debate ensued and the pertussis vaccine was no longer recommended. As a result, the use of the pertussis vaccine declined from 80 percent of infants to only 10 percent. Only five years later, Japan experienced an epidemic of pertussis that affected more than 13,000 children and resulted in 41 deaths. In Great Britain, a similar drop in pertussis vaccination in 1974 was followed by an epidemic of more than 100,000 pertussis cases and 36 deaths by 1978 (Gangarosa 1998).

Despite the success of immunization in protecting the public from infectious disease and the consequences of failure to immunize, public support is shifting for a variety of reasons, causing concern among public health officials and others involved in protecting the nation’s health.

Public Support of Immunization

What causes the public to turn its back on immunization? The reasons are varied and complex, and include complacency, misperceptions, lack of public education, and the effects of scientific discoveries and public policy.

Complacency

The disappearance of many once-common infectious diseases may reduce public motivation to follow immunization recommendations. In addition, with many infectious diseases effectively controlled, the rare adverse event or side effect may be spotlighted, lowering public confidence in a specific vaccine and contributing to a general decline in some or all immunizations. A drop in immunization levels may then lower the level of community immunity, setting the stage for a disease to spread if it is reintroduced to a community (Chen 1998).

Misconceptions

Myths and misunderstandings about vaccines exist, often stemming from lack of knowledge, uncertainty about where to seek information, and fear of adverse side effects. Other commonly held concerns include:

- questions about the continuing need for vaccines when the diseases they protect against have been virtually eliminated in the United States,
- whether giving a child multiple vaccinations for different diseases at the same time overloads the child’s immune system, and
- “hot lots” of vaccines that have been associated with more adverse events and deaths than others (CDC April 5, 2000b).

Additionally, conflicting information about vaccines is sometimes amplified through the news media which finds these stories appealing because of their controversial, alarming, and emotional nature. While such coverage may be for the public's benefit, it can contribute to public misunderstanding or confusion if it is not scientifically accurate, balanced, or presented within context.

Lack of Public Awareness

Health education about immunization has traditionally been focused on promoting vaccine coverage, overcoming barriers to vaccination, maintaining accurate immunization records, and addressing outbreaks. Very little information, however, has been provided on the safety of vaccines. While physicians are an important source of immunization information, many clinicians, especially in busy pediatric and family practices, have little time to prepare for and respond to patient questions about vaccines, leaving a definite knowledge gap.

Scientific Discoveries

As medical research and technological advances produce new vaccines, in addition to refining older ones, the issues surrounding immunization will become increasingly complex. Research currently under way could someday lead to vaccines for HIV, malaria, and tuberculosis. Other work could well result in the development of immunologic protection against conditions such as asthma, multiple sclerosis, and diabetes.

Breakthroughs in research and changes in epidemiologic trends will necessitate continuing revisions to immunization recommendations and schedules, as well. Several recent developments have spurred changes in U.S. immunization practices:

- In June 1999, the U.S. Centers for Disease Control and Prevention (CDC) decided that – with the virtual elimination of wild polio in the U.S. – use of the live (oral) polio vaccine is no longer necessary, given the rare risk of paralytic poliomyelitis associated with that vaccine. Instead, only the inactivated (injected) polio vaccine is now recommended.
- In July 1999, vaccine makers were asked to phase out use of thimerosal, a mercury-based preservative. The U.S. Public Health Service and the American Academy of Pediatrics jointly issued a statement explaining the risk of mercury exposure during early neurological development and recommending that first doses of hepatitis B vaccine for infants be delayed temporarily until an adequate supply of mercury-free or mercury-reduced vaccines becomes available.
- A review of data from the federal Vaccine Adverse Event Reporting System (VAERS) and a postlicensure study indicated that administration of a new rotavirus vaccine appeared to precede intussusception, a type of bowel obstruction in infants. This information prompted the CDC to change its prior recommendation, and, as a result, the Advisory Committee on Immunization Practices (ACIP) – a group of independent experts appointed by the U.S. Department of Health and Human Services (HHS) – no longer recommends the recently licensed rotavirus vaccine for infants (CDC October 22, 1999).

Impact of Public Policy

Lastly, the strategies and laws guiding implementation of immunization programs are determined at the federal, state, and local levels, sometimes resulting in uneven funding streams and policy decisions. For example, Medicaid policy changes and implementation of the State Children's Health Insurance Program (SCHIP)

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The formal process of assessing causality of an adverse event and an exposure (eg, vaccine) is a complex process that can be considered in terms of the answers to three questions:

Can it? Did it? Will it?

DR. ROBERT T. CHEN
JULY 1998

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VACCINE SAFETY

Both public and private entities play important roles in vaccine safety. Government agencies involved in vaccine development, use, and monitoring include the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the CDC, and, to a more limited extent, the Department of Defense and U.S. Agency for International Development. Working in conjunction with these government entities are private organizations such as academic research centers, health care professional associations, and vaccine manufacturers.

The following is a brief overview of the pathway and current system of checks and balances for vaccine safety:

Vaccine Approval and Licensure

The FDA retains the bulk of responsibility for ensuring vaccine safety during development, clinical trials, and use. The approval process is strict and can take more than 10 years. Prior to licensure, the FDA requires vaccines to go through three sets of clinical trials. The agency also requires both the vaccine itself and the production plant in which it is made to be licensed.

Although FDA approval means that clinicians may use a vaccine, health professionals typically wait for the recommendation process to be completed. During this process, several expert committees, including the ACIP, review the scientific evidence about each vaccine and determine whether it should be recommended for use. Depending on the vaccine in question and the population for which it is intended, other expert committees – such as panels convened by the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Physicians/American Society of Internal Medicine – may also review vaccine safety and efficacy.

Postapproval Monitoring

After initial approval, vaccines continue to be monitored. To begin, manufacturers are required to submit samples from each vaccine lot to the FDA prior to a vaccine's release (CDC April 5, 2000a). They must also share with the agency vaccine test results for safety, potency, and purity.

In addition to the FDA's requirements, adverse events that may be linked to vaccines are closely monitored. Passed by Congress in 1986, The National Childhood Vaccine Injury Act strives to improve monitoring of vaccine-related adverse events and provides a compensation mechanism for individuals or families harmed by vaccines. The key components of this legislation are summarized in the following (CDC April 5, 2000a).

- *Vaccine Adverse Events Reporting System (VAERS)*: Operated jointly by the FDA and the CDC since 1990, VAERS is a postmarketing safety surveillance system. VAERS accepts vaccine-related reports from private physicians, state and local public health clinics, health care professionals, vaccine manufacturers, vaccine recipients, and parents or legal guardians. The system, however, was not designed to evaluate the validity of these reports or collect supplemental information. VAERS analyzes the data as part of an “early warning” system and may generate a hypothesis about the relationship between a vaccine and an illness or adverse event. Hypotheses generated by VAERS data must be subjected to rigorous scientific investigation before they can be supported. Between 10,000 and 12,000 reports are filed annually with VAERS.
- *Vaccine Safety Datalink (VSD)*: Operated by the CDC, the VSD links databases from four health maintenance organizations containing information on more than 500,000 children ages zero to six, both vaccinated and not vaccinated. These data, representing 2 percent of the population, are then compared with incidence rates in the presence of immunization to help determine whether there is a causal link between a specific vaccine and an adverse event. If the data suggest a causal role, researchers conduct ad hoc studies to develop more definitive information.

VSD allows for large epidemiological studies on vaccine-adverse events by actively and systematically reviewing data on a known population sample. This project is currently examining potential associations between vaccines and 34 serious medical conditions.

- *The National Vaccine Injury Compensation Program (NVICP)*: A no-fault alternative to the tort system, NVICP seeks to resolve claims for adverse events associated with required childhood vaccinations. The vaccines currently covered under the program include DTP, MMR, polio, hepatitis B, Haemophilus influenza type b, varicella, and rotavirus.

Administered by HHS and the Department of Justice and supported by a surcharge on each vaccine covered under the no-fault program, NVICP has received more than 5,000 claims, and has paid out more than \$1 billion in compensation awards since its inception in October 1988. Eligibility for compensation is determined in one of three ways:

- The petitioner must show that the injury is covered under the Vaccine Injury Table, a legal mechanism for defining complex medical conditions and allowing a statutory presumption of causation;
- The petitioner must prove that the vaccine caused the condition; or
- The petitioner must prove that the vaccine significantly aggravated a preexisting condition (CDC April 5, 2000a).

This simplified process benefits claimants because it requires much less proof than is necessary to succeed in a traditional court case. It is also less adversarial.

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In the U.S., vaccines have been so successful preventing disease that the number of vaccine adverse events reported annually to the Vaccine Adverse Events Reporting System has exceeded the number of reported childhood vaccine-preventable illnesses.

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CDC, APRIL 5, 2000C

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Public tolerance of adverse reactions related to products given to healthy people, especially healthy babies, is substantially lower than to products administered to people who are already sick.

DR. ROBERT T. CHEN
JULY 1998

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have shifted responsibility for the provision of vaccines for disadvantaged populations from public health clinics to private providers, creating gaps in access for some individuals relying on public health programs (IOM 2000).

Furthermore, as improvements to existing vaccines and development of new ones continue, immunization recommendations and schedules may be reevaluated. While on the federal front, the Advisory Committee on Immunization Practices provides recommendations to the CDC on immunization policies, it is up to the states to decide what vaccines to require for school entry, for health care workers, and others.

At the state level, immunization is an area of significant legislative activity. During 1998, proposals to change existing laws on immunization requirements and exemptions were introduced in 13 states, often driven by anecdotal concerns about vaccine safety. In Ohio, one legislator introduced a proposal after a family in his district expressed concerns about the hepatitis B vaccine. In Louisiana, another legislator, concerned about any potential link between the MMR vaccine and autism, introduced a bill to significantly alter immunization requirements. The pediatric and infectious disease community, working with child health advocacy groups, helped to educate legislators and legislative staff about the issue, and thereby prevented a disruption in immunization programs within those states (Cooper 1999).

Perceptions and Attitudes Surrounding Immunization

Adding to this set of complex factors is recent research which indicates that – despite the concerns mentioned previously – most parents, policymakers, and clinicians still believe in the overall value of immunization.

In 1999, the National Network for Immunization Information (NNii) – a partnership of the Infectious Diseases Society of America, the Pediatric Infectious Diseases Society, the American Academy of Pediatrics, and the American Nurses Association – undertook a national survey with support from The Robert Wood Johnson Foundation. The objective was to examine perceptions and knowledge about immunizations and vaccine-preventable diseases among parents, legislators, and physicians.

NNii conducted 15 focus groups comprised of parents of young children in five cities; following ABC's *20/20* episode on the hepatitis B vaccine, four additional focus groups were convened to assess the impact of the segment. Additionally, two focus groups of health care providers offered insight into the challenges they face, and their information needs. A telephone survey of legislative staff serving on health committees in state legislatures helped to assess the range of immunization-related issues that have recently been discussed in 44 state legislatures around the country. Finally, a nationally representative telephone survey of 1,600 parents of children under the age of six was conducted to inform the project about future directions. Full survey results are included in the November 2000 issue of *Pediatrics*,

“Do Parents Understand Immunizations? A National Survey,” by Bruce Gellin, M.D., M.P.H, and colleagues.

The following information presents key findings from both survey and focus groups.

Parents

- *Parents support immunization, but their level of knowledge is low.* Generally, parents regard immunizations as important, effective, and safe. They believe that immunization protects their children and their communities from disease, and that child immunization is part of responsible parenting. Parents, however, know very little about the diseases being prevented or about the vaccines themselves. Most parents had difficulty distinguishing one vaccine from another, and they demonstrated little knowledge about potential side effects. Focus group participants, however, asked many questions about the risks and long-term effects of vaccines, particularly those in focus groups conducted after ABC’s 20/20 episode aired.
- *Parents support vaccine requirements for school admission, but they tend not to think of these requirements in terms of government mandates.* Parents view immunization as an uncomplicated decision, with 83 percent of those surveyed saying they believe that government vaccine requirements are beneficial and protect children. Focus group discussions, however, revealed a degree of complacency among parents regarding immunization requirements.
- *Parents trust their pediatricians for information about immunizations.* Eighty-four percent of survey respondents rated their pediatricians as their top information source on immunizations. But focus group discussants expressed varying levels of satisfaction with their pediatricians in terms of how such information was provided. Similarly, many

physician discussants said they were hesitant to broach the subject of potential vaccine-related side effects or adverse reactions.

Legislators

- *Legislators at all levels are actively involved in this issue.* Immunization was a legislative issue in 30 percent of states whose legislators responded to the survey. Of those, 24 percent were considering proposals to expand vaccine requirements; 12 percent were examining funding issues related to immunization; 10 percent were responding to or effecting changes in immunization schedules; and 10 percent were considering changes in their exemptions.
- *Legislators want balanced, reliable information on vaccines.* The survey showed that state lawmakers are open to information about immunization, and that they want to know more about the pros and cons of specific vaccines and about immunization practices and schedules. One in four indicated that they would also like to know more about relevant cost issues. Within their own states, legislators said they were most likely to turn to state health departments for information on immunization; organizations such as the CDC, the American Academy of Pediatrics, and the American Association of Family Physicians were also viewed as valuable sources of information.
- *Legislative support for immunization mandates is strong.* Only 6 percent of legislators said that parents should be allowed to send their children to school or day care if they have not received their immunizations.

Physicians

- *Physicians need assistance answering some questions surrounding immunization, particularly as they emerge via the news media.* Although most physicians have their own

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"The suffering or death of even one child from a vaccine-preventable disease is an unnecessary tragedy. If parents have questions about vaccinations, they should talk with their health provider or call the National Immunization Hotline..."

DR. WALTER A. ORENSTEIN
DIRECTOR, NATIONAL
IMMUNIZATION PROGRAM,
U.S. DEPARTMENT OF
HEALTH AND HUMAN
SERVICES
JULY 6, 2000

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tried-and-true methods for answering parents' questions or providing them with information on immunization, they reported that negative media reports are sometimes difficult to respond to.

- *Physician education on immunization issues should start early.* Medical school students and physicians in training should understand recent and emerging immunization issues. Educational outreach for practicing physicians was also identified as an important issue.
- *Nurses are an important part of the equation.* Although parents may get basic immunization information from their physicians, nurses are generally the people who administer the vaccines. Nurses also have considerable interaction with parents. Accordingly, it is important for nurses to be kept current on immunization issues as well.

Promoting Immunization

The NNii survey findings reveal important implications for effective public communication on the benefits and risks of immunization. Although the findings support public belief in immunization, they also show that the public may be influenced by negative information about vaccine-related risks and side effects. In addition, although parents trust their pediatricians for information on immunization, many are seeking a more robust discussion with health care providers on this issue.

Child health advocates, public health agencies, and health foundations are thus challenged to develop educational interventions that provide parents and practitioners with accurate and timely information about safety.

Activities of Government and Voluntary Organizations

In recognition of the importance of immunization to individual and public health, many governmental and nonprofit organizations have launched efforts to increase immunization coverage and provide information about vaccines. Selected educational and outreach activities of several organizations are showcased here.

- *The CDC's National Immunization Program* is engaged in a number of communication activities. The program publishes and disseminates Vaccine Information Statements, brief summaries designed for nonclinicians that explain the benefits and risks of specific vaccines. Physicians are legally required to provide parents with these statements before administering any vaccine to a child. It also operates a telephone hotline that provides immunization information in both English

CALLING THE SHOTS: IMMUNIZATION FINANCE POLICIES & PRACTICES

In 1998, the U.S. Senate Appropriations Committee and the CDC asked the Institute of Medicine (IOM) to examine the roles and responsibilities of state and federal government in supporting immunization programs and services. The resulting IOM report, *Calling the Shots: Immunization Finance Policies & Practices*, included recommendations for a national strategy to address the increasing challenges facing our immunization system. Guiding the IOM's strategy were a set of six fundamental roles for the nation's immunization system, including:

- purchasing vaccines,
- public access to vaccines,
- control and prevention of infectious disease,
- surveillance of immunization coverage,
- sustained and improved coverage, and
- effective use of primary care and other public health resources to achieve national immunization goals (IOM 2000).

The IOM's (2000) Committee on Immunization Finance Policies and Practices concluded that "vaccines are a powerful technology to prevent disease, but the nation's health care system is not fully realizing their potential. . . .Constant vigilance is required to protect populations against vaccine-preventable diseases, and the country must do better." The IOM's strategy presents a long-term approach to improving our immunization system, addressing such key issues as funding, monitoring, and outreach. The elements of this strategy include:

- an increased investment in the immunization infrastructure of \$1.5 billion over five years, totaling \$300 million annually from state and federal government;
- an enhanced federal-state partnership to support immunization efforts, including allocating federal grants more effectively and requiring state contributions to strengthen local involvement in immunizations;
- clarification of the system's function as a platform for specific immunization programs;
- a greater public health role for the private sector;
- new measurement tools to improve surveillance of immunization rates, and inclusion of a population focus in performance assessment tools; and
- broadening the perspective on immunization to include adults, adolescents, and the elderly, in addition to infants and children (Guyer 2000).

and Spanish. Additionally, the program maintains a Web site, produces a number of other publications, and participates in collaborative efforts with organizations and coalitions to disseminate accurate information about vaccines (Orenstein 1999).

- *The National Network for Immunization Information (NNii)* serves as a resource for information on vaccination and vaccination-related issues by assisting parents, health care professionals, and the media sort through the wealth of information currently available, distinguish what is scientifically valid, and reach decisions. Funded by The Robert Wood Johnson Foundation, NNii’s projects include determining the most effective ways to communicate about immunization; assessing key stakeholders’ knowledge about immunizations; providing materials that clearly and comprehensibly convey information about immunization; and working with

other organizations to ensure broad and timely distribution of accurate immunization information. As discussed previously, the Network recently conducted research on attitudes toward immunization among the public, health care professionals, and state legislators. In addition, NNii is preparing a patient communication resource kit designed to improve the immunization dialogue between health care providers and patients. This resource kit provides extensive background information on vaccines, answers frequently asked questions such as how vaccine recommendations are made and why we vaccinate, and provides answers to questions on each currently used vaccine. Finally, the NNii has established partnerships with the American Academy of Pediatrics and the American Nurses Association to assist their members in communicating effectively about immunizations.

RECOMMENDED CHILDHOOD IMMUNIZATION SCHEDULE, UNITED STATES
JANUARY – DECEMBER 2000

VACCINE	AGE											
	BIRTH	1 MONTH	2 MOS.	4 MOS.	6 MOS.	12 MOS.	15 MOS.	18 MOS.	24 MOS.	4-6 YEARS	11-12 YEARS	14-16 YEARS
HEPATITIS B (HEP B)	HEP B	HEP B HEP B	HEP B HEP B	HEP B	HEP B	HEP B	HEP B	HEP B			HEP B	
DIPHTHERIA, TETANUS, PERTUSSIS (DTaP)			DTaP	DTaP	DTaP		DTaP	DTaP		DTaP	Td	Td
H. INFLUENZA type b (Hib)			Hib	Hib	Hib	Hib	Hib					
POLIO (IPV)			IPV	IPV	IPV	IPV	IPV	IPV		IPV		
MEASLES, MUMPS, RUBELLA (MMR)						MMR	MMR			MMR	MMR	
VARICELLA (VAR)						VAR	VAR	VAR			VAR	
HEPATITIS A (HEP A)									HEP A in selected areas			

Vaccines are listed under routinely recommended ages. Green shaded bars indicate range of recommended ages for immunization. Any dose not given at the recommended age should be given as a "catch-up" immunization at any subsequent visit when indicated and feasible. Blue shaded bars indicate vaccines to be given if previously recommended doses were missed or given earlier than the minimum recommended age.

Approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

- *The American Academy of Pediatrics* keeps its members informed about immunization issues and publishes handouts for parents. In addition, the Academy's state chapters work with other groups at the state level to educate lawmakers, the public, and the news media. The Academy's trademark *Red Book: Report of the Committee on Infectious Diseases* is considered the definitive reference source on immunizations for most pediatricians.
- Other groups involved with improving immunization rates and disseminating information about immunization programs and policies include: *The American College Health Association*, *The American College of Obstetricians and Gynecologists*, *The American Public Health Association*, *Every Child by 2*, *Healthy Mothers and Babies*, *The Immunization Action Coalition*, *The National Medical Association*, and *Rotary International*.

In addition, coalitions for victims of vaccine-preventable diseases and their families, such as Parents of Kids with Infectious Diseases (PKIDS) and the Hepatitis Foundation International, actively communicate on issues related to vaccines.

The Philanthropic Approach

Foundations are also supporting immunization efforts in many ways, including providing support for immunization registries, working in collaboration with government agencies to improve immunization rates, and funding programs that include immunizations as part of a more comprehensive package of health care services for the medically underserved. As more foundations focus on population-based health, health promotion, and disease prevention, they are coming to recognize immunization as an area where grantmaking can contribute signifi-

cantly to the public health. The following examples illustrate the variety of approaches and strategies different organizations employ:

- *The Blue Cross Blue Shield of Michigan Foundation* supports the Caring Program for Children, which provides free, basic health care, including immunization, to uninsured Michigan children.
- *The California Endowment* awarded a two-year, \$419,000 grant to develop a five-county, community-based immunization project. The goal is to achieve a 90 percent immunization rate for two-year-olds.
- *The Colorado Trust* has funded a five-year, \$1.8 million project to develop and implement strategies for ensuring that all Colorado children are fully immunized against infectious diseases. Late in 1996, the Trust convened and funded a statewide taskforce to examine immunization rates and come up with recommendations to improve them. Subsequently, the Colorado Children's Immunization Coalition was launched to implement the taskforce's strategies. In 1998, the Trust awarded \$515,980 to improve immunization rates in five Colorado communities through physicians and their staffs.
- *The Columbus Foundation* has funded a comprehensive health care and developmental screening program for children. Expanded in 1998, this door-to-door immunization project provides vaccines, screening and preventive services.
- *The Cumberland Pediatric Foundation* focuses its efforts on keeping both the medical community and the general public well informed on the increasingly complex issues surrounding immunization. The Foundation alerts pediatricians to new developments and breaking news stories on immunization and

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National surveys indicate that 9 percent fewer poor children complete the full series of the most critical vaccines than other children. If distinct pockets of low vaccination coverage, particularly in poor communities, remain undetected, they will provide a reservoir for future disease outbreaks.

IOM, JUNE 15, 2000

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other pediatric issues via both e-mail and a fax-based rapid information network. It has also organized information forums with pediatricians, vaccine manufacturers, and the local news media to help disseminate balanced and accurate information on immunization issues.

- *The Bill and Melinda Gates Foundation* funds immunization programs both nationally and internationally. Within the United States, the Foundation has funded projects committed to speeding the delivery of several new vaccines that protect children against respiratory, diarrheal, and liver disease. For example, in August 2000, the Foundation awarded grants of \$20 million each to the University of Maryland School of Medicine and the Johns Hopkins School of Public Health and Hygiene to develop a new type of measles vaccine that would protect infants younger than nine months old.

Internationally, the Foundation's gift of \$750 million to the Global Fund for Vaccines and Immunization will help ensure that life-saving vaccines are accessible to children in developing countries.

- *The Healthcare Foundation of New Jersey* has awarded a \$92,200 grant to the New Jersey Department of Health and Senior Services to develop a computerized immunization tracking system for children who live in the South Ward of Newark.
- *The Robert Wood Johnson Foundation* launched the All Kids Count (AKC) program in 1991, following a measles epidemic in which 120 people, mostly infants, died. AKC is a national network of demonstration projects to develop and implement community-based immunization registries for infants and toddlers, which performs a number of valuable services. For parents,

AKC consolidates into one reliable list all the vaccines a child has received; provides a free copy of a child's immunization history for school, day care, or camp entry requirements; helps ensure a child's immunizations are up-to-date; and provides reminders of immunizations due or missed. For communities, immunization registries help control vaccine-preventable diseases, sustain immunization rates or increase rates in pockets of need, and help identify high-risk or under-immunized populations.

- *The John S. and James L. Knight Foundation* awarded \$1.7 million in grants to organizations in 26 cities to establish or improve public awareness and parent education activities promoting childhood immunization. At the end of the two-year grant period, the grantees had educated more than 6,000 health care professionals and reached more than 119,000 parents. Since then, the Foundation has approved six transition grants to help projects at critical junctures strengthen their programs.
- *The Kate B. Reynolds Charitable Trust* provided a \$75,000 grant to the Caswell County Health Department to improve coverage of child immunizations, as well as breast and cervical cancer screening for the medically underserved.
- *The Rose Community Foundation* has provided funding for a county health center located in a preschool that offers a range of child health services, including immunizations, simple lab work, and dental and mental health care.

- *The Skillman Foundation* is funding a program to link physicians and other medical providers to the Southeastern Michigan immunization registry, as a means to promote and monitor immunization coverage for children up to three years old. Previously, the Foundation provided support for the planning and development of the registry.

Maintaining the Public Trust: A Prescription for Change

As shown by NNii's research findings, parents and other members of the public tend to take the value of immunization for granted. This acceptance is indicative of public trust – the foundation for all successful immunization programs. Continued research efforts and communication activities are two approaches that health grantmakers can take to maintain and reinforce public trust in immunization.

The scientific and epidemiological areas where more research is needed include:

- surveillance to detect adverse events;
- studies to determine whether a vaccine has a causative role in an adverse event or whether the timing between immunization and an adverse event is coincidental;
- research of risk factors associated with adverse events to determine who is at risk, how risks can be mitigated, and whether contraindications for certain vaccines are needed; and
- development of guidelines for clinical management of adverse events (Orenstein 1999).

Communication efforts should be multifaceted, targeting different audiences with different strategies, and providing accurate, timely information. Some broad communication strategies include:

Conducting audience research. As the findings demonstrate, it is important to understand what key audiences know and think about issues related to immunization and what types of information they need. Parents, health care workers, lawmakers, journalists, health plans, and patient groups are all potential audiences.

Audience research can also help track and measure the success of other communication efforts.

Developing educational materials. Materials should be tailored for diverse audiences, including clinicians, the news media, legislators and policymakers, parents, and patients. Possible products include printed materials, videos, conference exhibit booths, hotlines, Web sites, and e-mail newsletters or notifications.

Developing media expertise at the local level. Many grassroots organizations are working to improve community immunization coverage. Media training can assist these groups to communicate more effectively with different audiences about vaccine benefits, risks, and safety (Gellin 1999).

Keeping legislators informed. Legislators need accurate, timely information to guide their policy decisions regarding immunization. Educational materials for lawmakers should be concise and supported by peer-reviewed scientific evidence. In addition, advocates of immunization should listen carefully to the concerns of those who are seeking more information. Frequently, they are people whose lives have been affected by real or perceived vaccine-related side effects and who have compelling stories to tell. Effective responses to their concerns must be supported by both science and an understanding of the emotions involved.

Partnering with professional and advocacy groups. National organizations such as the American Liver Foundation, the American Diabetes Association, and the National Multiple Sclerosis Society can help create rapid-information networks on immunization issues, respond to media reports, and supply witnesses and testimony for legislative hearings. Other

advocacy groups, such as PKIDs, can effectively communicate the importance of immunization at a personal and emotional level (Kane 1999).

Working with the news media. Developing strong relationships with members of the media can help assure balanced and better-informed coverage of immunization issues. Journalists need credible sources of information who can inform them on issues related to immunology and vaccine development, and who can provide them with background materials, contacts, and expert sources.

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