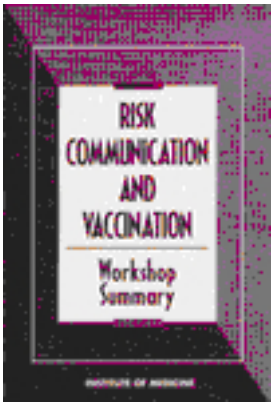

Risk Communication and Vaccination: Workshop Summary

Geoffrey Evans, Ann Bostrom, Richard B. Johnston, Barbara Loe Fisher, and Michael A. Stoto, Editors

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Risk Communication and Vaccination

Summary of a Workshop

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Vaccine Safety Forum
Board on Health Promotion and Disease Prevention
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This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religious since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatlichemuseen in Berlin.

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Preface

The Institute of Medicine's (IOM's) Vaccine Safety Forum was established in 1995 to examine critical issues relevant to the safety of vaccines used in the United States and to discuss methods for improving the safety of vaccines and vaccination programs. Government agencies, vaccine manufacturers, health professionals, and vaccine consumers share a responsibility for vaccine safety. Members of the forum thus include individuals representing parent or consumer groups with an interest in immunization, individuals representing vaccine manufacturers, physicians, representatives from federal agencies responsible for regulating vaccines and implementing vaccine policies, and academic researchers with expertise in vaccine-related issues.

The Vaccine Safety Forum's activities are a continuation of discussions undertaken by other IOM committees over the past 5 years. Previous IOM work on the subject resulted in the volumes *Adverse Effects of Pertussis and Rubella Vaccines* (1991), *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality* (1994a), *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* (1994b), and *Research Strategies for Assessing Adverse Events Associated with Vaccines: A Workshop Summary* (1994c). The first workshop of the Vaccine Safety Forum resulted in the publication *Options for Poliomyelitis Vaccination in the United States: Workshop Summary* (1996). The second and third workshops dealt with detecting and responding to adverse events following vaccination and research to identify risks for adverse events following vaccination, respectively. A summary of these two workshops is in press.

On May 13, 1996, the forum convened a workshop on risk communication and vaccination. Workshop speakers and participants discussed key concepts in risk communication, unique aspects of communicating risks about vaccines, and

current practices in vaccine risk communication. The focus was on the risk of adverse effects of vaccines, but the risks of the disease the vaccines protect against, and of vaccine failure, were also discussed. This document represents a summary of that workshop.

The workshop began with an overview of risk communication in general and communicating risks about vaccines more specifically. The overview was followed by presentations about issues of ethics, medical decisionmaking, and informed consent. Next a panel of "stakeholders," people with a professional or personal interest in communicating information about vaccine risk, spoke about their roles, expectations, and perceptions of the risk communication process. Members of this panel represented consumers, government, health care providers, vaccine manufacturers, media, and legal profession. The afternoon session began with individuals from government, industry, and consumer groups speaking about and giving examples of their current vaccine risk communication activities. A panel discussion among risk communication researchers followed. These individuals were intentionally chosen as having expertise in risk communication without necessarily having deep knowledge of the issues related to vaccines and vaccination. Their purpose was to react to what had been discussed previously in the workshop and to help participants fit vaccine risk communication into the context of risk communication theory and practice in general. The final panel of the day brought back the stakeholders from the morning session for a discussion of potential improvements in the way that vaccine risk communication is carried out. Open discussion among all participants was encouraged after each of the afternoon panels. An agenda and list of participants can be found at the end of the workshop summary.

The purpose of a forum at IOM is to foster dialogue and discussion across sectors and institutions. Forum activities offer a mechanism for convening individuals from a variety of government, academic, industry, and citizen groups in connection with a particular theme. Such activities provide a structured opportunity for regular and open communication among representatives of these groups. The objective, however, is to illuminate issues, not to resolve them. Unlike study committees of IOM, forums cannot provide advice or recommendations to any government agency or other organization. Similarly, workshop summaries or other products resulting from forum activities are precluded from reaching conclusions or recommendations but, instead, are intended to reflect the variety of opinions expressed by the participants. The comments in this report represent the views of the workshop participants, as indicated in footnotes for each section and generically in the text. The identification of a speaker as a "vaccine manufacturer's representative" or a "CDC representative" is not intended to suggest that any particular organization holds the same views.

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EXECUTIVE SUMMARY

Health risk communication has traditionally consisted of messages designed to encourage behavior that reduces individual and societal risk (e.g., smoking cessation and seat-belt use). Increasingly, risk communication, including health risk communication, is seen as an interactive process of an exchange of information and opinion among individuals, groups, and institutions (National Research Council, 1989). To be effective, risk communications must address the experiences, beliefs, values, and attitudes of message recipients as well as providers. Understanding how risks are perceived and the inherent biases of both message providers and recipients are key to good risk communication.

Although health risk communication has been an active research area for several decades, the science and practice of vaccine risk communication are not yet well developed. Many of the problems with risk communication in general, however, apply to vaccine risks. In particular, the rarity of vaccine-preventable diseases in the vaccine era makes it more difficult to communicate the risks of these diseases. Recent studies illustrate specific factors influencing how vaccine risks and benefits are perceived by and acted on by consumers and vaccine providers. Individual's immunization decisions are influenced by decisions that others make. People might prefer to do what a majority of others do or may take advantage of the protection afforded by high immunization rates and not be vaccinated; they may also be influenced to vaccinate by the fact that vaccination would protect others. Other factors include perceptions of disease risk and the ability to control those risks, and preferences for the risks of diseases per se over

risks of the vaccine against them. Studies have also addressed issues of mandatory vaccination, informed consent, individual rights versus societal welfare, and people's trust in information providers.

Information on vaccine benefits and risks is currently limited in availability and scope. Information available to consumers today includes the vaccine information statements issued by the Centers for Disease Control and Prevention (CDC), material from other federal agencies such as the Food and Drug Administration (FDA) and National Institutes of Health (NIH), manufacturers' package inserts that accompany vaccines, oral communications from health care providers, and information provided by a variety of nonprofit and consumer organizations.

Three major themes emerged during the workshop. **First, risk communication is a dynamic process in which many participate, and these individuals are influenced by a wide range of circumstances, interests, and information needs.** Effective risk communication depends on the providers' and recipients' understanding more than simply the risks and benefits; background experiences and values also influence the process (Zeckhauser, 1973). Good risk communication recognizes a diversity of form and context needs in the general population. Both the method and content of risk communication should reflect the goals of the communication, which could include advocacy, education, and development of a decisionmaking partnership (in any combination).

Second, the goal that all parties share regarding vaccine risk communication should be informed decisionmaking. Consent for vaccination is truly "informed" when the members of the public know the risks and benefits and make voluntary decisions. The discussion of mandatory vaccination at the workshop suggested that it may interfere with informed consent and may damage trust and deter effective communication, and thus needs to be carefully weighed against its benefits.

Finally, there is often uncertainty about estimates of the risk associated with vaccination. Risk communication is more effective when this uncertainty is stated and when the risks are quantified as much as science permits. Trust is a key component of the exchange of information at every level, and overconfidence about risk estimates that are later shown to be incorrect contributes to a breakdown of trust among public health officials, vaccine manufacturers, and the public. Continued research to improve the understanding of vaccine risks is critical to maximizing mutual understanding and trust.

Workshop participants suggested a number of ways to improve vaccine risk communications, including: tailoring it to audience needs, abilities, and interests; improving the format and structure of printed material; presenting more balanced information; adding references and bibliographies to communications; and providing estimates of the likelihood of risks when known, while stating the

uncertainty of other risks about which less is known. In particular, some workshop participants suggested that provision for exemptions for mandatory immunizations in all states on philosophical grounds would improve vaccine risk communication efforts and would not seriously undermine efforts to raise coverage levels.

INTRODUCTION AND BACKGROUND

Health risk communication has traditionally consisted of messages designed to encourage behavior that reduces individual and societal risks (e.g., smoking cessation and seat-belt use). Increasingly, risk communication, including health risk communication, is seen as an interactive process of the exchange of information and opinion among individuals, groups, and institutions (National Research Council, 1989). Risk communication has a 20-year history as a field of study (Fischhoff, 1995), arising initially out of controversies over environmental issues between, for example, residents of a community and a company building a potentially polluting plant nearby. Although health risk communication has been an active area of research and practice for several decades, the science and practice of vaccine risk communication are not yet well developed. Much of the complexity is due to a situation, as with any intervention in preventive medicine, in which healthy individuals are exposed to a medication or medical test in the interest of unknown future benefits. The purpose of the workshop summarized in this report was to allow for discussion among experts in risk communication theory and practice in general and those concerned with vaccine risk communication issues.

According to the 1989 NRC report *Improving Risk Communication*, risk communication "can be considered successful only to the extent that it, first, improves or increases the base of accurate information used by decision makers, be they government officials, industry managers, or individual citizens and, second, satisfies those involved that they are adequately informed within the limits of available knowledge" (National Research Council, 1989, p. 8). The benefits of good risk communication include improved decisionmaking, both individually and collectively, and the development of productive working relationships among diverse interest groups.[1]

Risk communication can serve one or more of the following purposes: (1) advocacy, to persuade people to take a particular action; (2) education, to give people enough information so that they can make their own decisions effectively;

[1] *Understanding Risk: Informing Decisions in a Democratic Society* (National Research Council, 1996) was published after the workshop, but it is also relevant for these discussions.

or (3) promotion of a decisionmaking partnership, to involve people actively in risk management and decisionmaking, including structuring the problem and selecting management options (National Research Council, 1989). The method and content of any particular instance of risk communication depend on the goals of the communicator. For example, an organization whose goal is to promote immunization may tend in its public communication efforts to emphasize the benefits and minimize the risks associated with that intervention. On the other hand, an organization whose goal is to alert the public to the risks of an intervention such as vaccination may tend to emphasize the risks and minimize the benefits of the intervention.

Studies of effectiveness for both behavioral and informational goals suggest that to be effective a communication must evoke a sense of personal relevance in the recipient, and that the recipient can do something to reduce or control the risk.

RISK PERCEPTION AND DECISIONMAKING[2]

There are many influences on how people perceive and respond to risks. Several participants noted that individuals' values, beliefs, and attitudes as well as the wider social or cultural values or dispositions strongly influence how risks are perceived or accepted. A better understanding of risks, consequently, will not lead to a uniform response to them. As an expert in risk communication noted, information alone does not resolve controversy. Good risk communication depends on understanding more than quantitative risks and benefits; background experiences and values also influence the process. For example, people who have a general mistrust of government or big business may be less likely to accept the vaccine risk estimates published by government health agencies or vaccine manufacturers.

Decisions about health risks were described by one speaker as being made not only on a rational basis but also on emotional, psychological, religious, spiritual, philosophical, and intuitive bases. This "cultural rationality" recognizes a richer range of influences on decisionmaking than does the narrower concept of rationality commonly used by experts in the field, according to a speaker who studies risk communication.

Studies show that voluntary, natural, and controllable risks are generally more accepted than risks that are imposed, not within an individual's control, or due to human-made causes. Risks that are familiar are also usually more accepted than

[2] This section is based on information presented by Ann Bostrom, Jacqueline Meszaros, Douglas MacLean, and Cristine Russell, as well as discussion among other participants.

those that are unfamiliar or hypothetical (Slovic et al., 1979; Lichtenstein et al., 1978; Fischhoff et al., 1978). Morgan (1993) uses observability and controllability as the two dimensions that characterize a hazard's "dreadfulness" and the degree to which it is understood (see Figure 1).

HEURISTICS AND BIASES

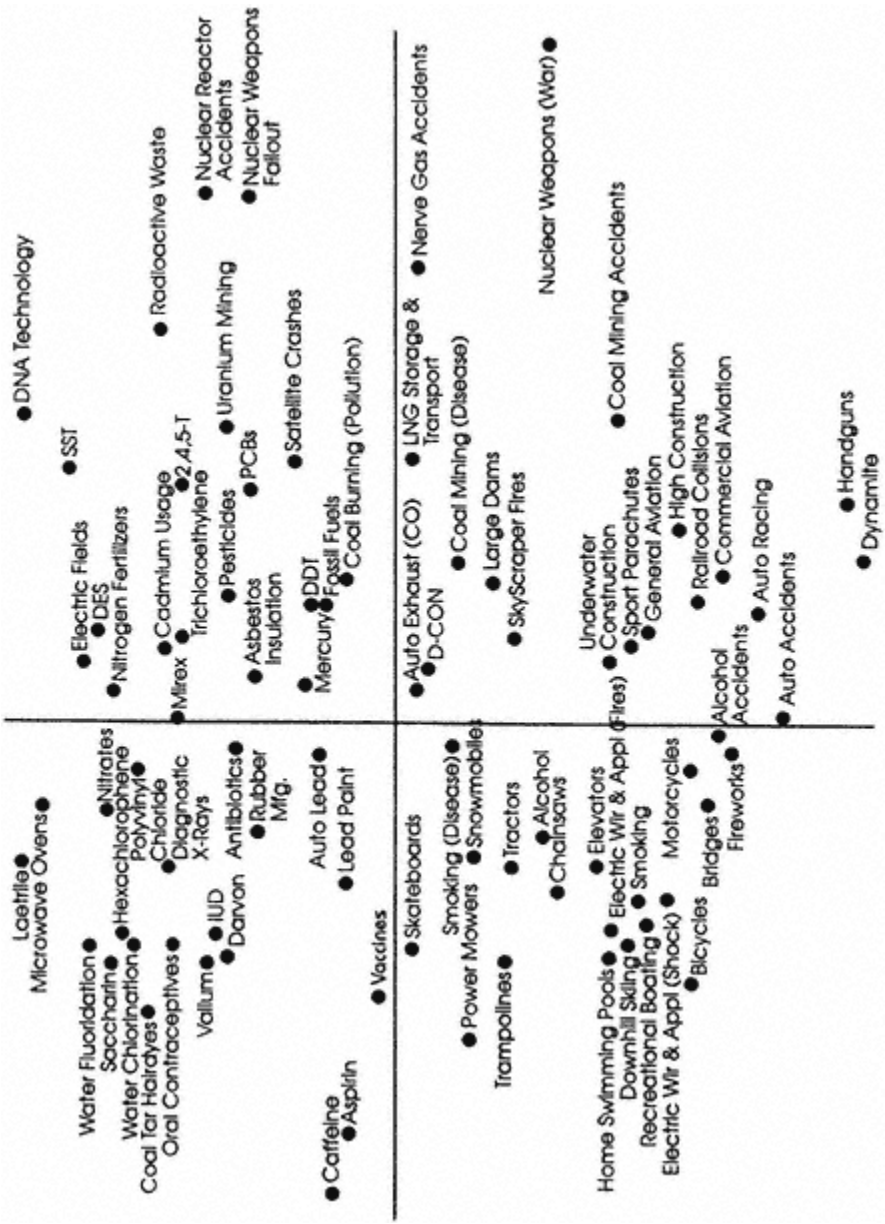
Cognitive shortcuts or rules of thumb known as *heuristics* affect peoples' quantitative estimates of risk. Risk scientists have shown that there are regular and predictable patterns in the ways that these operate. Use of these heuristics can result in biases in quantitative estimates of risk.

Anchoring refers to a lack of feel for absolute frequency and a tendency for people to estimate frequencies for a new event on the basis of the frequencies presented for other events. For example, if a person is told that 1,000 people a year die from electrocution and then is asked to estimate how many people die from influenza, his or her number is likely to be lower than if the person is first told that 45,000 people a year die in automobile accidents (Kahneman and Tversky, 1972). The tendency is to "anchor" on the first number and not adjust far enough from it. Consequently, how and what probability estimates of risk are presented and in what order they are presented may affect how risks are perceived because of anchoring effects.

Compression is the overestimation of small frequency risks and the underestimation of large frequency risks (Fischhoff et al., 1993). If this applied to vaccine risks, people would behave as if the risk of rare adverse effects from vaccines were higher than reported.

Availability means that events that are easily remembered or imagined are more accessible or "available" to people, so that their frequencies are overestimated (Tversky and Kahneman, 1973). If, for example, a particular risk has recently or often been reported in the popular press, people may well overestimate its frequency. A science writer commented that people pay more attention to dramatic, new, or unknown risks or risks conveyed within the context of a personal story. Most people will give proportionally more weight to a dramatic risk of dying from an airplane crash, for example, than to the risk of dying from lung cancer due to smoking, even though the latter is more likely. Drama, symbolism and identifiable victims, particularly children or celebrities, the science writer said, also make a risk more memorable.

When risks are given as *verbal probabilities* (e.g., likely, unlikely, rare, and common), interpretation depends on the context (Budescu and Wallsten, 1985; Wallsten et al., 1986). The phrase "likely to catch a cold" will be interpreted differently from "likely to become infected with HIV," for example.



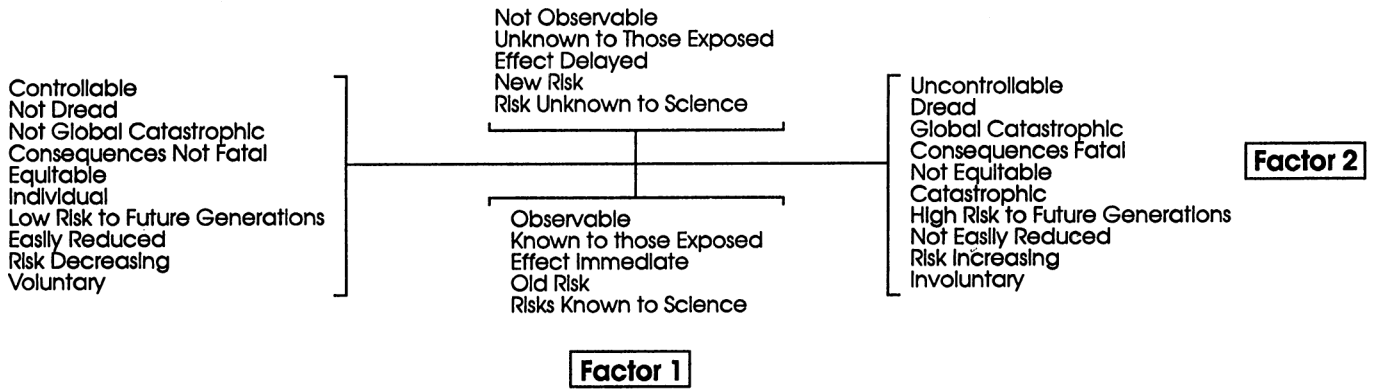


Figure 1
Illustration of observability and controllability for some common health hazards. Hazards can be characterized according to their degree of "dreadfulness" or controllability (horizontal axis) and the degree to which they are understood or are observable (the vertical axis). Source: Reprinted, with permission, from Slovic, P. Perception of Risk. Science 236:282. Copyright 1987 by the American Association for the Advancement of Science.

Exposure refers to the fact that people tend to underestimate the cumulative effect of multiple exposures to a risk (Linville et al., 1983). In many instances of risk, the concern is about exposure over time, not necessarily from a single exposure alone. Communication of cumulative risk can be helpful in these instances. Cigarette smoking is an example of an exposure in which cumulative risk is important.

Comparisons. Risk is multidimensional, but when a communicator makes a risk comparison on the basis of one or two dimensions, people may assume that many dimensions are being compared and draw conclusions based on the broader comparison rather than that which was intended. For instance, experts may say that the risk of an environmental exposure is inconsequential because on average it is low, but ordinary people might call for action because they fear that the risk falls disproportionally, and thus unfairly, on vulnerable groups.

Omission bias is the tendency to believe that an error of omission is less serious than an error of commission. That is, people tend to be more averse to a risk incurred by taking an action than one incurred by taking no action. For example, a University of Pennsylvania study found that nonvaccinators (parents who chose not to vaccinate their children) were more likely to accept deaths caused by a disease (that is, omitting vaccination) than deaths caused by vaccination (an act of commission) (Meszaros et al., 1996).

Framing, the way in which information is presented or the context into which it is placed, affects how risk communication messages are received. Studies show that a different framing of the same options can induce people to change their preferences among options (Tversky and Kahneman, 1973; Lichtenstein and Slovic, 1971). This is known as a *preference reversal*. For example, the data on lung cancer treatment suggest that surgical treatment has a higher initial mortality rate but radiation has a higher 5 year mortality rate. In one illustration, 10 percent of surgery patients die during treatment, 32 percent will have died one year after surgery, and 66 will have died by five years. For radiation, 23 percent die by one year and 78 die by five years. When people are given these mortality statistics, they tend to be evenly split between preferring radiation and preferring surgery. When the same statistics are given as life expectancies (6.1 years for surgery and 4.7 years for radiation) there is an overwhelming preference for surgery (McNeil et al., 1982).

How information is framed can also affect whether people allow an omission bias to be a prime motivator of a decision not to vaccinate. One study of university students found that when the issue of responsibility was removed, subjects were more likely to opt for vaccination. Responsibility was removed by reframing the question as "if you were the child, what decision would you like to see made" (Baron, 1992).

Other research shows that people tend to have a preference for *eliminating risk* and for *maintaining the status quo* (Thaler, 1980; Samuelson and Zeckhauser, 1988). Consequently, people often have an aversion to increasing the probability of one type of risk to reduce that of another, even by the same amount. They may even prefer a riskier situation over a less risky situation if the former maintains the status quo (Fischhoff et al., 1981).

INFLUENCES ON AND BIASES OF EXPERTS

Experts in a particular area may (or may not) be less likely to exhibit, in their own field of expertise, the specific heuristic rules and biases discussed above. Experts also have their own biases. Their values, beliefs, and attitudes influence the form and content of the risk and benefit information that they present. In addition, organizational biases (such as whether experts are affiliated with a government agency promoting vaccination, a vaccine manufacturer, or a consumer organization concerned with vaccine safety) can also influence how experts view an issue.

Because of their particular professional training, their mental models and approaches to problem solving can differ fundamentally from those of nonexperts (Chi et al., 1981). For example, in their search to draw conclusions or solve problems, they may sometimes rely inappropriately on limited data, impose order on random events, fit ambiguous evidence into their own predispositions, omit components of risk such as human errors, and be overconfident in the reliability of analyses (Fischhoff et al., 1982; Fischhoff and Merz, 1995; Freudenberg and Pastor, 1992).

INFLUENCES ON THE ACCEPTABILITY OF VACCINE RISKS[3]

Individual's immunization decisions are influenced by decisions that others make. Recent studies illustrate specific factors influencing how vaccine risks and benefits are perceived by and acted on by consumers and vaccine providers. People might prefer to do what a majority of others do (bandwagoning) or may take advantage of the protection afforded by high immunization rates and not be

[3] This section is based on information presented by Ann Bostrom, Martin Wasserman, David Walsh, Douglas MacLean, Peter Meyers, Ann Fisher, Jacqueline Meszaros, Jon Merz, Rosemarie McLaren, Fran Phillips, Peggy O'Mara, and Barbara Loe Fisher, as well as discussion among participants.

vaccinated (free-riding); they may also be influenced to vaccinate by the fact that vaccination would protect others (altruism). Other factors include perceptions of disease risk and the ability to control those risks, and preferences for the risks of diseases per se over risks of the vaccine against them. Studies have also addressed issues of mandatory vaccination, informed consent, individual rights versus societal welfare, and people's trust in information providers.

THE LOGIC OF VACCINATION DECISIONS: BANDWAGONING, FREE-RIDING, AND ALTRUISM

A major influence on the acceptance of vaccine risks is whether people employ what is known in the risk communication field as bandwagoning, free-riding, or altruistic logic. *Bandwagoning* refers to the tendency for individuals to choose the decision of the majority as an indication of what might be a wise action for themselves, without fully evaluating their options. A study at the University of Pennsylvania found, for example, that when parents who vaccinate their children were given a hypothetical situation in which 100 percent of other children were vaccinated for a particular disease, 95 percent said that they would also vaccinate even though their children would be at no risk of catching the disease (Meszaros et al., 1996).

The tendency to bandwagon is countered by *free-riding* logic. People who follow this logic feel that they do not have to expose themselves to the risks of vaccination because they are protected from disease by the vaccination of the majority of other people (a phenomenon known as herd immunity). Nonvaccinators in the University of Pennsylvania study were more likely to use free-riding logic than were vaccinators. People who use *altruistic logic*, in contrast, are willing to take on personal risks if a large number of people will benefit by their doing so. Overall, bandwagoning appears to be much more common than either altruism or free-riding (Hershey et al., 1994).

PERCEPTION OF DISEASE RISKS

Perception of the *risk of contracting* a disease influences willingness to accept the risk of a vaccination. For example, a common misconception among parents in one Washington, D.C. survey is that vaccine-preventable diseases have been virtually eliminated in the United States, thus ending the need to immunize children (McLaren, unpublished data presented at the workshop). The success of vaccination programs in reducing the incidence of vaccine-preventable diseases in the United States makes it more difficult to communicate the risk of those diseases.

The perceived *severity* of a disease also affects acceptance of vaccines, as a comparison of two recent disease outbreaks in Canada shows (Pless, unpublished data presented at the workshop). During an outbreak of a particularly deadly type of meningitis, the members of the public readily chose mass immunization to protect themselves from the disease. In contrast, during a measles outbreak, people were less accepting of an immunization campaign because they did not perceive measles as a serious disease. In fact, a child with a case of measles is less likely to die than a child with meningitis, yet because it is so prevalent, measles kills a larger number of children worldwide each year. Before there was a vaccine, measles outbreaks caused many severe complications and deaths, even in developed countries.

Several speakers noted that the perception of *control* over whether one's children become infected by vaccine-preventable diseases affects the acceptance of vaccine risks. For instance, Maszaros and colleagues found that nonvaccinators believed they could have much more influence in preventing their children from catching whooping cough if their children were not vaccinated than did vaccinators (Meszaros et al., 1996). Nonvaccinators also thought that it was less likely that their child would be disabled or killed by the disease in the absence of vaccination than to suffer the same fate due to receipt of the vaccine. These results suggest a common effect seen in risk communication: that people do not believe expert probability estimates because they think that they have control in ways that experts may not have anticipated. In the Washington, D.C., survey mentioned previously, responses to the question of why parents did not vaccinate their children included a belief in self-healing and folk remedies (McLaren, unpublished data presented at the workshop).

ETHICAL AND POLICY ISSUES

Acceptance of the risks associated with vaccination depends, in part, on the weight that a person gives to *societal good versus individual rights*. Although childhood vaccines may prevent much death and disability from disease while causing relatively few deaths or disabilities from adverse effects, some participants felt that it is not appropriate to compare the value of lives lost due to adverse reactions to a vaccine to the value of lives lost due to the natural disease. A consumer advocate stated that Americans should never be forced by the government to engage in any medical procedure which carries the risk of injury or death, including vaccination, without informed consent. Citizens should have the right to be fully informed about the benefits and risk of vaccines and make independent decisions about which risks to take, including the right to select the preventive health care that is appropriate for their families, she said.

In contrast, others believe that governments have the right and responsibility to override individual autonomy if there is a compelling public health interest. An epidemiologist commented that the logic of public health laws, requiring quarantine for instance, suggest that although an individual might choose not to be vaccinated and to take the risk of being infected by a communicable disease, he or she does not have the right to make that choice if it promotes the infection of other individuals. Some groups claiming religious and philosophical objections to vaccination respond to this by voluntary quarantine, for the sake of their own children as well as others. Walsh, a political philosopher, concluded that "compulsory childhood vaccination is not on strong philosophical grounds." It can be ethical, Walsh says, to require public health measures such as quarantine and mandatory vaccination, but only when the survival of the community itself is at stake. It is debatable whether the communicable diseases for which there are vaccines actually threaten community survival, he said.

Mandatory vaccination laws require children to receive several specific vaccines before being allowed to enter public school (and, in some cases, day care as well). Every state makes provision for exemptions to mandatory vaccination on medical grounds; all but three states allow exemptions on religious grounds; but only 16 states allow exemptions on philosophical grounds (CDC, 1995). Several speakers were highly critical of mandatory vaccination policies and, particularly, the lack of exemptions on philosophical grounds in many states.

Some participants stressed that a lack of exemptions for mandatory vaccination on philosophical grounds can seriously impair risk communication about vaccines. Mandatory vaccination influences not only how vaccine risks and benefits are received by the public but also the content and form of risk communication about vaccines. A practicing physician and academician noted that if vaccination were not required by law, there would be a need for better communication about the risks and benefits of vaccines.

Participants discussed the effect on vaccine coverage of allowing greater access to exemptions on philosophical grounds within a mandatory vaccination program, with several speakers commenting that the overall effect might be relatively small. For example, speakers who promote immunization for public health departments and private organizations commented that few parents whose children are unvaccinated cite philosophical reasons for the lack of vaccination. Instead, most have inadequate access to health care, are unaware of recommendations for early childhood vaccination, or have not made vaccination a priority. In some cases, their physicians may not have suggested immunization when the child sought treatment for other reasons. Mandatory vaccination policies require such parents to consider vaccination and make a decision, said a participant who formerly administered the immunization program for the city of Philadelphia. He described that city's experience after making measles vaccination mandatory

for public school attendance. Immunization levels for measles rose from between 80 and 85 percent to more than 95 percent, even though exemptions to vaccination on philosophical grounds were permitted. An epidemiologist, noting that a vaccination program can be effective even when immunization rates are less than 100 percent (Fine and Clarkson, 1986), a phenomenon known as herd immunity, suggested that even if a slight decrease in coverage occurred efforts in the United States would not necessarily be seriously hampered. Another epidemiologist noted that immunization rates in the United States, unlike other countries, did not fall in response to increased media attention to the safety of pertussis vaccine in the 1970s and 1980s, and that this might not have been the case if philosophical exemptions had been widely available.

A number of speakers questioned whether mandatory vaccination is consonant with a patient's right to informed consent. *Informed consent* is a legal and ethical doctrine adopted by the medical profession and courts in the 1950s. It is defined as occurring when information about the risks and benefits of a medical procedure "is disclosed by a physician to a competent person, and that person understands the information and voluntarily makes a decision to accept or refuse the recommended medical procedure" (Meisel et at., 1977). As some participants noted, consent is truly "informed" when an individual knows the risks and benefits and makes a voluntary decision.

An ethicist noted that informed consent can radically change the meaning of a transaction. As an extreme example, he said, the primary difference between assault with a deadly weapon and surgery or between servitude and employment may well be informed consent. Informed consent not only offers an avenue for communicating the risks and benefits of vaccination but also can influence how readily people accept the risks associated with vaccination. A media representative commented that people who are exposed to risk information take more responsibility for health care decisions and thus are less likely to blame others when the unexpected happens.

Informed consent with the aim of promoting a decision that someone believes is best for the individual can backfire in the vaccine arena, noted one speaker, an expert on risk communication. "The choice not to immunize may be optimal to the individual if there is herd immunity," she said, "but in the aggregate, this choice could lead to failure of that herd immunity." In addition, immunization can be beneficial to individuals other than those vaccinated (if, for instance, the disease could be more severe for the others) even without herd immunity. This perspective suggests that informed consent for individuals may not always lead to the greatest good for the community but sometimes can contribute to a "tragedy of the commons," in which the common good (herd immunity, in this instance) is affected if too many people make the decision not to immunize (Hardin, 1968).

UNCERTAINTY AND TRUST

The degree of trust that recipients place in the communicators of information about vaccine risks and benefits, as well as the ability of the communicators to convey any existing uncertainty about adverse events, also influences decisions made about vaccination. For example, the University of Pennsylvania study found that nonvaccinators exhibited significantly more skepticism about medical information in general and about vaccines and their effectiveness in particular (Meszaros et al., 1996).

A lawyer stated that there is a fundamental conflict of interest in vaccine risk communication because health officials and health care providers, in the interest of public health, generally see their roles as encouraging immunization. Their natural tendency, consequently, will be to emphasize the benefits of immunization and in their communications minimize the risks about vaccines. At the same time, they have the responsibility to provide their patients accurate and unbiased information on the nature and extent of the risks involved with vaccination. Ultimately, the public might be better served if public health officials, health care providers, and the population they serve all worked towards the development of a trusting relationship, in which public health officials were seen as having responsibility for ensuring the health of the population, including balancing disease and vaccine risks (IOM, 1996b).

A consumer advocate said that vaccine manufacturers, providers, and policymakers knew that there were risks associated with vaccine use when vaccines were first marketed but did not adequately communicate those risks to the public. Nor was it communicated that there was some uncertainty and disagreement about what was known, she said. "This failure to communicate what medical science does and does not know about vaccine risks was quite simply perceived as a fundamental betrayal of trust by those who were being asked to take the risks," she said. When government and industry's media campaigns to achieve a high vaccination rate downplayed vaccine risks, there was further erosion of trust. Overzealous enforcement of mandatory vaccination laws, she said, also fosters a lack of trust.

A vaccine manufacturer's representative noted that part of the problem with trying to convey risks following vaccinations to the general public is that frequently the true risks are not known. There are a range of views as to which adverse events should be discussed in written statements and other communications about vaccines. The position at one end of the continuum is to describe only those risks that are shown by conventional scientific standards to be causally associated with the vaccine. The position at the other end is to claim safety only with regard to adverse events that can be shown *not* to be associated with the vaccine and then to describe equally all other putative adverse events. The

goals of risk communication are probably not well-served by either of these extreme positions. A statistician and public health policy analyst suggested that overconfidence about risk estimates that are later shown to be incorrect contributes to a breakdown of trust between public health officials, vaccine manufacturers, and the public.

A political scientist noted that many scientific studies on vaccine adverse events yield only a recommendation for further study. "The inquiry of science is never ultimately finished," he said. Public policy, therefore, is always made in the absence of final information. "Politics is about decisionmaking in the absence of complete information," he said.

CURRENT COMMUNICATIONS EFFORTS[4]

In the United States, the main sources of information about vaccine risks or benefits are vaccine information statements issued by CDC, manufacturers' package inserts that accompany vaccines, oral communications from health care providers, and publicity provided by a variety of nonprofit organizations.[5]

GOVERNMENTAL EFFORTS

Vaccine Information Statements

Vaccine information Statements (VISs) are produced by the technical, educational, and legal staff of CDC, with input from specialists in education and low-literacy reading, physicians, and parents. Public and private providers are required by law (P.L. 99–660) to give VISs each time that a vaccine is administered. These statements, written at a fifth- to seventh-grade reading level, attempt to describe concisely the benefits and risks of vaccines. They also include a description of the National Vaccine Injury Compensation Program, information about the federal Vaccine Adverse Event Reporting System (VAERS), and other relevant information. Each VIS is one sheet of paper. VISs are available in 13 languages. (See Appendix B for an example of a VIS.)

[4] This section is based on information presented by Robert Sharrar, Carlton Meschievitz, Jill Hackell, Sanford Kimmel, Sharon Humiston, Barbara Loe Fisher, Rosemarie McLaren, and Ion Anderton, as well as discussion among other participants.

[5] The workshop discussion focused on communicating with parents of young children, the recipients of many vaccines, but the issues apply to adults receiving vaccines as well.

VISs were not intended to substitute for provider knowledge or for parent-provider communication, but rather to make such communication easier, according to a physician who coordinated the development of the VISs. Studies show that some knowledge is gained from reading VISs in an ideal setting, in which the research interviewer minds the child and the parent reads at his or her leisure. "However, even under these optimal circumstances, immediate and long-term recall is far from impressive," she said. One study showed that only 54 percent of parents coming to a clinic with an infant or toddler knew that there were two types of polio vaccine, a statement that appears in a large, bold heading on the front of the polio VIS (Humiston et al., 1996).

The target audience for VISs is a diverse group with a wide range of interests and abilities. The statements have been criticized by some as having too high a reading level. The statement about the polio vaccine, for example, requires a reading level beyond the capability of 57 percent of an inner-city Philadelphia clinic population (Melman, et al., 1995). In contrast, some criticize the VISs for not providing enough information. For parents who wish to know more than is provided in a VIS, a notation on each states, "If you want to learn more, ask your doctor or nurse. She/he can give you the vaccine package insert or suggest other sources of information."

MANUFACTURERS' EFFORTS

Package Insert

The primary tool for communicating the risks and benefits of a vaccine to health care providers is the manufacturer's vaccine package insert. This insert includes statements on efficacy, contraindications, warnings, precautions, and adverse events associated with use of the vaccine. The information in the package insert comes from clinical trials conducted with the vaccine, postmarketing studies, spontaneous adverse events reported to the manufacturer, and adverse events reported to VAERS and in relevant medical journals. Package inserts are regulated by the FDA, which determines the type of information that must be included and reviews and approves each package insert prior to marketing and whenever changes are made. Factual statements in a package insert must be supported by data from clinical studies and references to scientific literature.

The contraindications section of the insert discusses situations or conditions, such as known or suspected severe egg allergy, for which a vaccine should not be used because the risks apparently outweigh the benefits. The warnings section describes serious adverse events and potential safety hazards, as well as limitations in the use of the product and steps that should be taken if these limitations occur.

For example, giving an intramuscular injection to a child with a coagulation disorder would generally be excluded, but, in the face of an epidemic, it might be considered. The precautions section includes special care to be given for the safe and effective use of the product. For example, epinephrine should be available to counter any unexpected anaphylactic reactions that occur at the time of injection.

The adverse events section lists undesirable effects associated with the use of the products that may occur as part of the action of the product. The section includes estimates of the risk of common local and systemic reactions, as well as (wherever possible) estimates of the risk of rare or unusual reactions such as vaccine-associated polio after vaccination with the oral polio vaccine or Guillain-Barré syndrome after vaccination with the tetanus vaccine. According to a pharmaceutical company representative, litigation concerns dictate that this section also must list events that are not generally thought by scientists to be caused by the vaccine. Sudden infant death syndrome (SIDS) after vaccination with the diphtheria and tetanus toxoids and pertussis vaccine (DTP), for instance, for which several studies and an Institute of Medicine (IOM) report have found that there is evidence of no causal association (Institute of Medicine, 1991), is still mentioned. This legal necessity undercuts the ability of these statements to communicate clearly the risks of vaccines.

Advertising

Advertising and other promotional materials generated by a vaccine manufacturer about its products are also heavily regulated by FDA, which requires that the materials provide a fair balance of safety and effectiveness information, make specific claims, and be supported by properly referenced data. Manufacturers must submit advertising for FDA review and approval prior to use for products that are not yet licensed, products for which licensure is pending, and products within the first 120 days after licensure.

Parent Information Brochures

Vaccine manufacturers also publish informational brochures for parents; these brochures usually do not specify a product brand name. According to a vaccine manufacturer's representative, these brochures provide information about the disease, state that a vaccine exists to protect against the disease, that there may be side effects from the vaccine, that not all people should receive the vaccine, and that vaccine usage should be discussed with a physician. The brochures are intended by the manufacturers to facilitate communication about vaccines between

patient or parents and provider. Some other participants suggested that the brochures are a form of advocacy for vaccine use, in addition to providing such information.

NONPROFIT ORGANIZATIONS

A number of nonprofit organizations communicate vaccine benefits and risks to the public. Organizations that promote immunization include the Children's Defense Fund, the Children's Action Network, Kiwanis International, and the American Academy of Pediatrics. A consumer advocate indicated that most of these organization are funded by corporations or by the U.S. government and most do not discuss the risks associated with immunizations in their promotional materials. Organizations whose goal is to inform consumers about vaccine risks include the National Vaccine Information Center, Parents for Freedom of Choice, and Vaccine Information and Awareness. Many of these organizations are funded by individual donations and put their emphasis on the risk side of the equation.

PROVIDER-PARENT INTERACTIONS

Communication between health care providers and parents or patients is often limited, noted a practicing pediatrician, because the time that doctors have to spend with patients during an office visit is restricted. When communicating vaccine risks and benefits, consequently, practitioners often rely on materials such as the VISs, educational videos, or information provided by ancillary personnel. The speaker said he often gives parents the VISs at the first well-child visit, before the child is scheduled to receive any immunizations. This allows parents time to review the information in the statements and generate any questions before their next visit, during which the immunizations are administered. Although he does discuss some potential adverse events, the speaker acknowledged that he tends to emphasize the decreased risk of disease provided by the vaccine, often giving examples of the morbidity and mortality associated with the diseases against which the vaccines are protective.

IMPROVING VACCINE RISK COMMUNICATIONS[6]

Several speakers and participants suggested ways to improve communication about vaccine risks and benefits, including tailoring messages to audience needs, biases, abilities, and interests; improving the appearance or organization of written materials; presenting information in a nonbiased manner; referencing statements; providing estimates of the likelihood of the better-defined risks; and stating the uncertainty of other risks.

To be effective, risk communication about vaccines needs to take into account what people already know or believe about the risks and benefits associated with immunization, said several participants. A risk communication expert proposed a progressive research strategy to improve vaccine risk communication. The first step involves conducting nonstructured interviews of individuals who represent the audience to which communications are directed. These interviews are an effective means of elaborating the most pressing concerns or beliefs of the interviewees. Subsequent questionnaire surveys based on interview results could quantify the prevalence of certain beliefs. Risk communication messages could be developed based, in part, on the results of the interviews and questionnaires and then tested, possibly with focus groups. Such evaluation could assess whether the information was easily understood and accepted and whether it is likely to foster a behavior change.

Several speakers suggested that, as with all risk communication, vaccine risk communications need to be well organized and accessible. A risk communication expert said that studies show that such devices as summaries and clearly marked section headings promote comprehension and retention of the information presented (Atman et al., 1994). One speaker, a member of the consumer-oriented press, suggested designing the VISs in a visually appealing, contemporary, and upbeat fashion. A pediatrician involved in the development of the VISs noted that a researcher at Louisiana State University who produced a simple, colorful vaccine brochure with explanatory drawings found that parents learned as much from her brochure as they did from the VIS (Davis et al., 1996).

It was also suggested that vaccine risk communicators consider the varied information needs of the audience. Some recipients of risk communication material prefer short, simple messages that explain the risks and benefits of vaccines in nontechnical language;

[6] This section is based on information presented by Ann Bostrom, Sharon Humiston, Ann Fisher, Martin Wasserman, Peggy O'Mara, and Rosemarie McLaren, as well as discussion among other participants.

others want as much scientific information as is available. Currently, the primary sources of consumer information on vaccines are the VISs (criticized by some as being too simplistic and not inclusive enough) and the vaccine package inserts, which may have too much technical information for some people to understand and process effectively. To bridge the gap, it was suggested that vaccine risk communicators consider preparing intermediate messages about vaccine risks and benefits that have more detailed information than the VISs but that are less technical than the package inserts. The package inserts might also be reorganized so as to be more accessible to consumers.

Another possibility is an interactive or computerized information system, in which users can access the level of information that is appropriate for their needs and abilities. Such a system was developed by researchers at Ohio State University and the Mayo Clinic (Raman et al., 1996). The system was arranged in a hierarchical fashion with five levels of increasingly complex information, all written at an eighth-grade reading level. The system was tested in a middle-class medical practice, and although 13 percent of the parents declined to participate, there was great variability in the level of information requested by those parents who did participate. Those who agreed to use the system expressed a high degree of satisfaction with it (Ramen et al., 1996).

Several speakers and audience participants suggested that vaccine risk communications include references to the scientific literature, so that readers who question the information presented or who wish to know more can examine the original source for each statement. It was also suggested that all the evidence regarding a specific topic be presented, including information that does not support the position of the person or organization conveying the information.

As discussed previously, many participants noted that there is often uncertainty about estimates of the risks of vaccines. This uncertainty reflects the generally low risks of serious adverse consequences; if the risks were high, the product would not have been licensed. To promote effective risk communication, several speakers and participants felt that risk messages should acknowledge the uncertainty about the existence and magnitude of many of the potential risks associated with vaccines, with the inclusion of estimates of the incidence of the better-defined risks to the extent possible. A risk communications expert added that "in almost every policy forum that I can think of, the ultimate conclusion has been that it is essential for good public policy to communicate uncertainty, even if it is difficult." She suggested that vaccine risk communications include statements regarding what assumptions were made to define risk estimates and whether there is consensus among various groups of experts and the public about the accuracy or uncertainty of the estimates provided.

Other participants suggested that it be emphasized in vaccine risk communications that research is under way to improve understanding of those risks. A CDC representative suggested that much of the problem is inherent in the gaps in knowledge identified in previous IOM reports (1991, 1994a, 1994c), and

that unless these gaps are filled with research on vaccine safety, we will continue to have problems communicating uncertain risks.

Two suggestions were offered to avoid organizational bias and a conflict in the roles that some federal agencies and providers are asked to play. The first was that individuals providing information about the risks and benefits of vaccines be more open to other points of view, including seeking information from the National Vaccine Information Center. The second was that, in order to decouple the mission to prevent infectious disease through vaccination with the need to inform people of the risks of vaccines, an independent organization without a dual role should be the official source of the risk-benefit information.

SUMMARY

Three major themes emerged during the workshop. First, risk communication is a dynamic process in which many participate, and these individuals are influenced by a wide range of circumstances, interests, and information needs. Effective risk communication depends on the providers' and recipients' understanding more than simply the risks and benefits; background experiences and values also influence the process. Good risk communication recognizes a diversity of form and context needs in the general population. Both the method and content of risk communication should reflect the goals of the communication, which could include advocacy, education, and development of a decisionmaking partnership (in any combination).

Second, the goal that all parties share regarding vaccine risk communication should be informed decisionmaking. Consent for vaccination is truly "informed when the members of the public know the risks and benefits and make voluntary decisions. The discussion of mandatory vaccination at the workshop suggested that it may interfere with informed consent and may damage trust and deter effective communication, and thus needs to be carefully weighed against its benefits. Other reasons for risk communication regarding vaccines are that (1) people appreciate receiving the information; it is a fundamental form of respect for persons, and shows that they are treated more equally in the decisionmaking process; (2) early recognition and treatment of side effects may reduce their consequences; and (3) identifying individual factors, such as immune deficiency, might influence the decision to vaccinate.

Finally, there is often uncertainty about estimates of the risks associated with vaccination. Risk communication is more effective when this uncertainty is stated and when the risks are quantified as much as science permits. Trust is a key component of the exchange of information at every level, and overconfidence about risk estimates that are later shown to be incorrect contributes to a breakdown

of trust among public health officials, vaccine manufacturers, and the public. Continued research to improve the understanding of vaccine risks is critical to maximizing mutual understanding and trust.

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Workshop Agenda

INSTITUTE OF MEDICINE
VACCINE SAFETY FORUM
Workshop on Risk Communication and Vaccination
May 13, 1996

8:00 a.m.	**Risk Communication Overview** Introduction: *Geoffrey Evans*, Vaccine Injury Compensation Program Overview of Risk Communication and Vaccine Risk Communication: *Ann Bostrom*, Georgia Institute of Technology
9:00 a.m.	**Issues of Ethics, Medical Decisionmaking, and Informed Consent** *David Walsh*, Catholic University of America; *Douglas MacLean*, University of Maryland
9:45 a.m.	**BREAK**
10:00 a.m.	**Stakeholders: Roles, Expectations, Perceptions** Media: *Cristine Russell*, Health Correspondent; *Peggy O'Mara, Mothering Magazine* Consumer: *Barbara Loe Fisher*, National Vaccine Information Center, *Rosemarie McLaren*, Children's Defense Fund Government: *Martin Wasserman*, Maryland Department of Health and Mental Hygiene Provider: *Sanford Kimmel*, Medical College of Ohio

	Industry: *Jill Hackell*, Lederle-Praxis Biologicals; *Carlton Meschievitz* , Pasteur Mérieux Connaught
	Legal: *Peter Meyers*, George Washington University
12:00 p.m.	**LUNCH**
1:00 p.m.	**Current Information on Vaccine Risk Communication Activities** Government: *John Anderton*, Centers for Disease Control and Prevention
	Vaccine Information Statements: *Sharon Humiston*, University of Rochester
	Industry: *Robert Sharrar*, Merck Research Laboratories
	Consumer: *Barbara Loe Fisher*, National Vaccine Information Center
2:40 p.m.	**BREAK**
3:00 p.m.	**PANEL I: Risk Communicators** Moderator: *Ann Bostrom*
	Ann Fisher, Pennsylvania State University; *Douglas MacLean*, University of Maryland; *Jon Merz*, University of Pennsylvania; *Jacqueline Meszaros* , Temple University
	Open Discussion
4:00 p.m.	**PANEL II: Stakeholders** Moderator: *Ann Bostrom*, *Barbara Loe Fisher*, National Vaccine Information Center; *Jill Hackell* , Lederle-Praxis Biologicals; *Sanford Kimmel*, Medical College of Ohio; *Peter Meyers*, George Washington University; *Peggy O'Mara, Mothering Magazine; Frances Phillips*, Department of Health, Ann Arundel County, Maryland; Judith Randal, Science Journalist; Cristine Russell, Health Correspondent

Open Discussion

5:30 p.m. **Closing Comments:** *Richard B. Johnston*, Chair, Vaccine Safety Forum

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Appendix

Example of Vaccine Information Statements

DIPHTHERIA, TETANUS, AND PERTUSSIS VACCINE (DTP)

What you need to know before your child gets the vaccine

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention

ABOUT THE DISEASES

Diphtheria, tetanus (lockjaw), and pertussis (whooping cough) are serious diseases. Diphtheria and pertussis spread when germs pass from an infected person to the nose or throat of others. Tetanus is caused by a germ that enters the body through a cut or wound.

Diphtheria causes:	Tetanus causes:	Pertussis causes:
a thick coating in the nose, throat, or airway	serious, painful spasms of all muscles	coughing and choking for several weeks (makes it hard for infants to eat, drink, or breathe)
It can lead to: - breathing problems - heart failure - paralysis - death	**It can lead to:** - "locking" of the jaw so the patient cannot open his or her mouth or swallow - death	**It can lead to:** - pneumonia - seizures (jerking and staring spells) - brain damage - death

ABOUT THE VACCINES

Benefits of the vaccines

Vaccination is the best way to protect against diphtheria, tetanus, and pertussis. Because most children get the vaccines, there are now many fewer cases of these diseases. There would be many more cases if we stopped vaccinating children.

DTP schedule

Most children should have a total of 5 DTP vaccines. They should have DTP at:

- ✔ 2 months of age
- ✔ 4 months of age
- ✔ 6 months of age
- ✔ 12–18 months of age
- ✔ 4–6 years of age

Other vaccines may be given at the same time as DTP.

Related vaccines

DTaP (Diphtheria Tetanus acellular Pertussis)

- Like DTP, it prevents diphtheria, tetanus, and pertussis.
- It is only given for the 4th and 5th doses.
- It is less likely to cause the mild problems we see after DTP and is probably less likely to cause some of the moderate problems.

DT (Diphtheria Tetanus)

- Unlike DTP, it does not prevent pertussis. For this reason, it is usually not recommended.

Who should get DTP vaccine?

Most doctors recommend that almost all young children get DTP or DTaP vaccine. Some children should get DT. With all vaccines, there are some cautions.

Tell your doctor or nurse if the child getting the vaccine:

- ever had a serious allergic reaction or other problem after getting DTP, DTaP, or DT
- now has moderate or severe illness
- has ever had a seizure
- has a parent, brother, or sister who has had seizures
- has a brain problem that is getting worse

If you are not sure, ask your doctor or nurse.

What are the risks from these vaccines?

As with any medicine, there are very small risks that serious problems, even death, could occur after getting a vaccine.

The risks from the vaccine are much smaller than the risks from the diseases if people stopped using vaccine.

Below is a list of problems that may occur after getting the vaccine. *If your child ever had one of the moderate or severe problems listed below or any other serious problem after DTP, DTaP, or DT,* discuss it with your doctor or nurse before this vaccination.

Mild problems

If these problems occur, they usually start within hours to a day or two after vaccination. They usually last up to 1–2 days:

- soreness, redness, or swelling where the shot was given
- fever
- fussiness, drowsiness, less appetite

Acetaminophen or ibuprofen (non-aspirin) may be used to prevent or reduce fever and soreness. This is especially important for children who have had seizures or have a parent, brother, or sister who has had seizures.

Moderate problems

Once for every 100–1,000 doses:

- on-going crying for 3 hours or more
- fever of 105° or higher
- an unusual, high-pitched cry

Once for every 1,750 doses:

- a seizure (jerking and staring spell) usually caused by fever
- "shock-collapse" (becomes pale, limp, and less alert)

Severe problems

These problems happen **very rarely:**

- serious allergic reaction after DT or DTP
- a long seizure
- decreased consciousness or coma. Some of these children may have lasting brain damage. There is disagreement about whether or not DTP causes the lasting brain damage. If it does, it is very rare.

What to do if there is a serious reaction:

- ☞ Call a doctor or get the person to a doctor right away.
- ☞ Write down what happened and the date and time it happened.
- ☞ Ask your doctor, nurse, or health department to file a Vaccine Adverse Event Report form or call:
  (800) 822-7967 (toll-free)

The **National Vaccine Injury Compensation Program** gives compensation (payment) for persons thought to be injured by vaccines. For details call:
(800) 338-2382 (toll-free)

If you want to learn more, ask your doctor or nurse. She/he can give you the vaccine package insert or suggest other sources of information.

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