

## Effectively managing public concerns about immunization safety<sup>1</sup>

The benefits of immunizing against the vaccine-preventable diseases far outweigh the minimal risks of vaccination. In order to maintain or improve the strength of every national immunization program, workers at each level of the public health community—from local health workers to health department officers—should be educated about the issues surrounding vaccination, and they should be prepared to respond to public concerns. The quick response to public anxieties regarding vaccines and the rapid, honest communication of explanations and actions can help ensure the integrity of immunization programs throughout the Americas. That is according to “Guidelines for Managing Immunization Safety Concerns,” a document prepared by the Division of Vaccines and Immunization of the Pan American Health Organization (PAHO).

Although immunization has been an important public health accomplishment over the past 200 years, it is not without controversy. Vaccine safety issues have been undergoing visible public debate, especially over the last 20 years. At times, immunization programs worldwide have been jeopardized by public reactions to the debate. Although vaccines are not completely effective at all times, they are one of the safest interventions in the medical armamentarium.

The world has already witnessed the dangers and effects of stopping vaccination. In the United Kingdom during the 1970s, public concern regarding the safety of pertussis vaccines led to a rapid decline in immunization coverage rates. Prior to that, coverage had been over 80%, with an average of 2 000 to 8 000 cases reported annually. After the coverage rates decreased to 30%, the number of pertussis cases soared to over 100 000. After two large epidemics and some education about the disease and the vaccine, the public slowly regained confidence in the vaccine and the immunization programs. As a result, vaccination coverage reached 95% in the mid-1990s, with the lowest recorded number of pertussis cases in the history of the country.

Every immunization program should ensure the safety of vaccines and should be prepared to deal with any public concerns about vaccination safety. Some of the events may be known effects that were observed during prelicensing clinical trials or during experimental stages of vaccine development. In addition, many medical events that are reported as allegedly vaccine-related are background illnesses that are transmitted through the

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<sup>1</sup> Based on: Pan American Health Organization, Division of Vaccines and Immunization. Guidelines for managing immunization safety concerns. Washington, D.C.: PAHO; 2002. Available from: [http://www.paho.org/English/HVP/HVI/hvp\\_immunsafety.pdf](http://www.paho.org/English/HVP/HVI/hvp_immunsafety.pdf) [Internet site]. Accessed 23 August 2002.

community regardless of vaccination. The first few years of a child's life are the most vulnerable years with regard to illness, and it is also the time period when other diseases begin to manifest themselves, such as developmental disorders and hearing difficulties. These early years are also when vaccines are administered. It is not difficult for the "coincidental" vaccination to be misinterpreted as causal. For many of these events, it is nearly impossible to find out the true cause, even with the most detailed investigation. Any medical event perceived by the public, by parents, by the recipient, or by health workers to be allegedly vaccine related should be examined on the local level. If the time period and symptoms support a suspicion of its being vaccine related, a more formal standardized investigation should be initiated.

Upon completion of the investigation, these events should be classified into one of the four following categories: 1) program related, 2) vaccine related, 3) not related, or 4) unknown (an inconclusive investigation). The purpose of detecting, investigating, and analyzing these events is to take action based on the conclusions reached by this process. These actions may include: reassurance of parents, caregivers, and other adults; communication with the public and with other health care workers; treatment; correction of program errors such as in vaccine handling, storage, administration, and syringe issues; discussions with manufacturers regarding vaccine quality and effectiveness; recall of the vaccine; and further research. These kinds of measures reinforce confidence in the immunization program, but only if there is open and honest communication with the public.

Communication with the public and other health workers during critical periods of wavering public confidence is vital to the success of any immunization program. When rumors or allegations are circulating in the community, they should be addressed immediately. Immunization program personnel should be trained to prepare media statements about circulating stories or known ongoing investigations. These explanations for the public can be an effective way to proactively manage the issue. Two-way, open communication should also take place, with community leaders being involved and lines of communication established with the news media.

Another highly effective tool is education. Parents and adults need to be fully informed about what to expect after vaccination such as possible side effects. Adults also need to learn about what may happen if vaccinations are refused, including the effects of diseases.

As technology improves, so does the quality and effectiveness of the vaccines used. Vaccines

today are much safer than they were 40 years ago. Nevertheless, with new vaccines arriving on the market every year and with an increase in information dissemination via the Internet and other media, public concerns regarding the safety and benefits of vaccines continue to grow.

## VACCINE QUALITY AND SAFETY

All vaccines procured through the World Health Organization (WHO) for national immunization programs must meet WHO requirements. The suppliers for the vaccines must go through the WHO prequalifying process, which involves an examination of the vaccine characteristics, of adherence to "good manufacturing practice" (GMP) standards during vaccine production, and of the activities of the national control authority (NCA) that oversees vaccines. WHO considers a vaccine to be of known good quality provided that the NCA controls the quality of the vaccine according to six critical functions defined by WHO. These six are: 1) a published set of licensing requirements, 2) review of clinical data collected during surveillance of vaccine field performance, 3) a system of lot release, 4) laboratory testing, 5) regular inspections for compliance with GMP standards, and 6) evaluation of clinical performance.

The safety and efficacy of vaccines are demonstrated during the clinical trials conducted before licensing. These trials undergo different phases that evaluate the efficacy and safety of the vaccine and that fulfill conditions required for registration. Follow-up studies of vaccines after licensing occur when the vaccine is applied to the population.

Many reported events that have allegedly been related to vaccines indicate a problem with vaccine administration. These problems may include contamination, improper injections, cold-chain problems, and dosage or dilutant mistakes. The problems can be easily fixed with proper training, handling, and storage techniques. It is imperative that every local-level health worker be aware of these potential problems and recognize them when they occur, so that rapid corrective measures can be taken.

## INVESTIGATING EVENTS ATTRIBUTED TO VACCINATION

Assessing whether or not an alleged reaction truly resulted from vaccine administration and subsequent immunization is difficult, especially in young children. Many alleged side effects of vaccines occur with some frequency in this age group, and separating the time connection of vaccine ad-

ministration from the natural occurrence of the event is nearly impossible. Also, the number of side effects seen is directly related to the number of doses administered. That is, if a vaccination campaign is underway, it is expected that the number of side effects will also increase, but that the rate (the number of side effects in relation to the number of doses) should remain the same. So, it is important to remember that the occurrence of a post-vaccination event does not in any way prove that the vaccine caused any signs or symptoms of the event.

For currently used vaccines, any alleged reaction to a vaccine should be examined on the local level, and if it meets the criteria described below, an investigation into the event should begin.

The investigation has several purposes: 1) to confirm or rule out the reported event, 2) to identify other possible causes, 3) to determine whether the event is isolated, and 4) as needed, to inform the parties involved.

### Steps in the investigation

As soon as any event is alleged to be vaccine related, the health care worker should inform the parents or guardians about the safety of immunization, reassure them, and explain that coincidental events can occur.

Any serious event, rumors, or events occurring in clusters require an investigation. Until the investigation is complete, it will be impossible to determine the cause or causes of the event. These causes could be program related, vaccine related, not related to vaccination, or unknown. In some situations, outside evidence will be needed to identify the cause.

Among the possible program-related causes are: dosage level, method of administration, sterilization of needle and syringe, improper handling of used needles, vaccines reconstituted with the wrong dilutant, an improper amount of dilutant, improper preparation of vaccines, drugs substituted for vaccines or dilutants, contaminated vaccine or dilutant, improperly stored vaccines, and using vaccines after their expiration date.

If there are several cases, various factors should be checked: 1) Did the same health worker administer the vaccine?, 2) Are unimmunized persons in the same age group and same geographical area showing the same symptoms?, 3) Are other people immunized with the same lot of vaccine in the same geographical area showing the same symptoms?, and 4) Are there other people immunized with the same vaccine lot at the same facilities on the same day who are not showing the same symptoms?

Vaccine-related causes are highly unusual, so it is very important to investigate each case. However, it is expected that only a low incidence of vaccine-related events will be confirmed.

When clinical events not related to vaccination coincide with vaccination, it means that the event could have occurred even if the person had not been immunized. The best evidence to support the argument that this may have been a coincidental event is for the same event to have occurred in a population that was not immunized.

### Information required in the investigation report

The investigation report should include a number of pieces of information. Among these are: the reasons for the diagnosis and possible causes, the number of persons found to have the same problem, the suspected antigen, symptoms and signs that are common to all patients, the names of the health workers who vaccinated the population in question, and whether health workers who were involved used the same vaccine lot. Also needed in the investigation report are: how many of the unimmunized persons in the same age group and same community or health center in the area in question presented the same symptoms; the time between vaccination and onset of symptoms; the immunization practices of health workers involved, including handling, storage, transportation, and administration of vaccines; and any laboratory findings.

### Conducting the investigation

The investigation should be conducted within the first 24 hours. Basic variables to be collected include: demographic data such as age, sex, and place of residence; recent case history (symptoms and signs, when they appeared, duration, clinical examination, treatment, outcome, and diagnosis); the type, date of appearance, duration, and treatment of the clinical event; the history of pathology and clinical history of the patient (previous reactions to vaccines, drug allergies, preexisting neurological disorders, and current medications); and the type of vaccine used and the date of the last dose.

The vaccination used needs to be identified in terms of: lot number, manufacturing and expiration dates, manufacturing laboratory, shipment and transportation data, the physical appearance of the vaccine, and the results of quality control procedures of the vaccine.

The operational aspects of the program also need to be reviewed. Among the features to be considered are: the storage of the vaccine; the handling

and transportation of the vaccine; use of diluents, reconstitution of the vaccines, and forms of administration; proper dosage; and the availability of needles and syringes and appropriate practices.

### **Actions to be taken**

**The event is definitely not related to vaccination.** If the event is not related to vaccination, the concerned parties should be informed of the results of the investigation. Information may go to the parents; to town, state, and regulatory authorities; to health authorities; to professional associations; or to the entire country. When appropriate, the mass media should also be involved.

Even though the event was not related to vaccination, it may require appropriate medical follow-up, in which case a referral should be made.

**The event is related to the program.** With a program-related event, just as with an event not related to vaccination, the various concerned parties should be informed of the results of the investigation. In addition, corrective actions should be implemented immediately. These actions could cover logistical, training, or supervisory aspects.

**The event is vaccine related.** If the event occurred within an expected frequency for a particular vaccine, then the concerned parties should be notified of the results of the investigation.

The concerned parties should also be informed when the event was unexpected or occurred at an unexpected frequency. In addition, responsible authorities should take the following actions: stop vaccinating with the implicated vaccine, coordinate with the national control authority to reassess the quality of the vaccine and to contact the manufacturer as appropriate, recall the vaccine when appropriate, and report the investigation results to the Pan American Health Organization for international information dissemination.

**The investigation is inconclusive.** Again, concerned parties should be informed of the results of the investigation even when that investigation is inconclusive.

In any of these four situations, the Pan American Health Organization is available for consultation to help the country's national immunization program to investigate and analyze the results.

### **COMMUNICATION ABOUT IMMUNIZATION SAFETY CONCERNS**

Countries should work to improve communications with the community and with health care

workers. Messages should be disseminated quickly, and they should address the concerns of the public. Key information about any investigation into a vaccine concern should be relayed to the public and other health care workers with honesty, completeness, and accuracy.

A dedicated spokesperson within the health department should have special training for preparing media releases and developing public statements to aid in rumor control. This person should also be available to assist local health workers in formulating plans regarding any alleged vaccine-related issues that may arise.

### **EDUCATION ABOUT IMMUNIZATION SAFETY**

Education materials should be available for health care workers to use during their encounters with children and their parents or guardians. These materials should provide information regarding known side effects and the frequency at which they occur.

In addition, health care workers need to know about events caused by program-related errors. Every health care worker should undergo training to learn how to avoid making program-related errors, which could lead to an increase in side effects attributable to vaccination. During critical time periods, such as vaccination campaigns and ongoing investigations, health care workers should have information readily available to learn the facts about immunization, and they should disseminate accurate and truthful information to parents, guardians, and other adults.

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### **SINOPSIS**

#### **Cómo abordar eficazmente los temores del público sobre la seguridad de las vacunaciones**

*Los beneficios de la vacunación frente a las enfermedades prevenibles de este modo son muy superiores a sus mínimos riesgos. Con el fin de mantener o fortalecer los programas nacionales de vacunación, los trabajadores de todos los niveles de la salud pública deberían recibir formación sobre los temas relacionados con la vacunación y estar preparados para responder a las dudas planteadas por el público. Una respuesta rápida y franca a los temores del público acerca de las vacunas podría garantizar la integridad de los programas de vacunación en todo el continente americano, según el documento "Directrices para enfrentarse a los temores sobre la seguridad de las vacunaciones" (Guidelines for Managing Immunization Safety Concerns), elaborado por la División de Vacunas e Inmunización de la Organización Panamericana de la Salud (OPS) y resumido aquí.*

Todo acontecimiento médico que se considere posiblemente relacionado con una vacuna debe ser investigado en el ámbito local. Si su distribución temporal y los síntomas respaldan la sospecha de que pueda estar relacionado con una vacuna, se debe iniciar una investigación más formal y, una vez finalizada, el acontecimiento debe ser clasificado en una de las cuatro categorías siguientes: 1) relacionado con el programa, 2) relacionado con la vacuna, 3) no relacionado, o 4) desconocido (investigación no concluyente).

Dependiendo de la categoría a la que haya sido asignado el acontecimiento, las acciones posteriores pueden consistir en

tranquilizar a los padres, a los cuidadores y a otros adultos; comunicarse con el público y con otros trabajadores de la salud; instaurar tratamiento; corregir los errores del programa, como pueden ser la manipulación de la vacuna, su almacenamiento, su administración o los problemas relacionados con la jeringuilla; comentar con los fabricantes problemas relacionados con la calidad y eficacia de la vacuna; retirar la vacuna del mercado, o iniciar nuevas investigaciones.

### Course, "Health Sector Reform and Sustainable Financing"

*Dates:* 13–31 January 2003

*Location:* Harvard School of Public Health  
Boston, Massachusetts, United States of America

The Harvard School of Public Health and the World Bank Institute will offer a three-week course entitled "Health Sector Reform and Sustainable Financing" in Boston 13–31 January 2003. The course introduces a practical and comprehensive framework for understanding health systems and their performance and a structured approach to developing health system reform policies to improve that performance. Specific course modules examine the theoretical and empirical basis for reform strategies in such diverse areas as health financing, payment systems, organizational change, regulation, and population and provider behavior. The course makes extensive use of case materials from countries in all regions of the world and at all levels of economic development. The principal goal of the course is to provide intensive, state-of-the-art knowledge and training on options for health sector development, including lessons learned and best practices from country experience.

The course is targeted to mid-career senior-level decisionmakers and managers who are actively involved in planning or directing government-initiated health sector reforms, compulsory social health insurance programs, private-voluntary or private-sector initiatives, and developing-country training programs in health sector reform and sustainable financing. The cost of the course is US\$ 4 700, which covers tuition and course materials. In addition, participants must pay for their own airfare, hotel stay, and meals.

The course organizers encourage "country teams" of three or four members to apply for the course. For country teams that send four or more participants, the course organizers will provide a tuition waiver for one of the participants.

To be considered for participation in the course, interested persons must send in a completed application form, a recent CV, and a short personal statement describing why the course would be of benefit. The deadline to apply is 15 November 2002. The course organizers will make a decision on each application within two weeks of receiving it.

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