Developing a national system for dealing with adverse events following immunization

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Although vaccines are among the safest of pharmaceuticals, the occasional severe adverse event or cluster of adverse events associated with their use may rapidly become a serious threat to public health. It is essential that national monitoring and reporting systems for vaccine safety are efficient and adequately coordinated with those that conventionally deal with non-vaccine pharmaceuticals. Equally important is the need for an enlightened and informed national system to be in place to deal with public concerns and rapid evaluation of the risk to public safety when adverse events occur. Described in this article is the outcome of efforts by the WHO Global Training Network to describe a simple national system for dealing with vaccine safety and with emergencies as they arise. The goals of a training programme designed to help develop such a system are also outlined.

Keywords: adverse drug reaction reporting systems, organization and administration; immunization programmes; national health programmes; programme development, methods; vaccines, adverse effects.

Voir page 175 le résumé en français. En la página 176 figura un resumen en español.

Introduction

The Global Training Network (GTN) is a WHO initiative to improve the quality of vaccines and their use. It was developed in 1996 as a means of providing educational resources to vaccine control and production staff throughout the world. GTN currently consists of 14 training centres that offer instruction in priority areas using approved syllabuses and standardized documentation materials.

GTN differs from previous training activities in vaccine quality because it is a coordinated programme; provides training in a small number of curricula defined by needs; uses standardized curricula and training materials approved by experts; screens applicants carefully, requiring an institutional training plan; sets priorities among countries that will benefit to maximize impact; and expects a return on the investment by contributions to quality from trainee institutions.

Instruction through GTN is offered through formal courses, placements and workshops. Courses may consist of lectures, laboratory or practical work, case studies, site visits and examinations. Placements are usually one-on-one and tailored to meet the needs of the individual participants. Workshops can offer specific subjects either as follow-up to formal coursework or at the request of a country or region.

GTN provides training to national regulatory authorities (NRAs), national control laboratories and vaccine producers (that meet the minimum criteria) in good manufacturing practices, laboratory quality systems, quality control testing, production of diphtheria–tetanus–pertussis vaccines (for control staff), licensing and animal husbandry. A recent addition is a new curriculum designed for countries that procure vaccines; it provides intensive training in the regulatory functions necessary for vaccine procurement, including the licensing of vaccines through the use of information provided by well-developed regulatory authorities, lot release of vaccines, and the monitoring of adverse events following immunization (AEFIs). The course on AEFIs, which has been developed to strengthen national systems dealing with these events, is specifically designed for staff of NRAs and immunization and surveillance programmes working together in the area of vaccine safety, and is described further in this article.

Although vaccines used in national immunization programmes (NIPs) generally have a favourable risk–benefit profile, the effects of AEFIs are potentially devastating to local and international immunization programmes (*1*).[a] A single serious event or cluster of events may result in rapid erosion of public confidence in vaccinations and a sudden fall in immunization rates. Moreover, an undetected problem in vaccine quality or a programmatic error can be dangerous to the public (*2*).

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[a] See also the WHO website: Vaccine safety. Information for health care providers, at http://www.who.int/gpv-safety/prof/infheal.htm

Ensuring the credibility of NIPs has become increasingly challenging with changes in the scientific, social, legal and communication environments pertaining to health. To address AEFIs effectively, the key persons in immunization safety need to work together in a systematic and effective manner. GTN has commissioned the Department of Pharmacology, University of Cape Town, to develop and conduct a training programme for personnel from immunization programmes, regulatory authorities and ministries of health to enable them to detect, assess and appropriately deal with serious and potentially dangerous AEFIs.

Key aspects of the training programme are presented below, but excluding those for the 5-day training course, which is still in its infancy. A model for communication and action among those responsible is set out which addresses the challenges in dealing expeditiously with AEFIs.

Special issues pertaining to vaccines

It is necessary to identify the differences between vaccines and other medicines in terms of their efficacy, safety, quality, promotion, procurement, storage and distribution in order to understand the need for a modified approach to monitoring the safety of vaccines and immunization programmes.

Vaccines are administered as a preventive measure to large numbers of healthy individuals and particularly to children. As immunization coverage increases and the burden of vaccine-preventable disease falls, the benefits of vaccines become less of a concern and the public tolerance of adverse events is correspondingly reduced. Most immunization programmes aim to control and ultimately eradicate vaccine-preventable disease. Such achievements are only perceived at the public health level; they are less tangible to the vaccinees and their carers.

Several vaccines are produced by a few manufacturers only and used on a large scale. Use of the product concerned may be promoted by the state, and this is interpreted as reflecting a vested government interest. The relationships between manufacturers and NIPs tend to be more collaborative than those between drug regulators and other pharmaceutical manufacturers. An AEFI may lead to public concern, and this may have serious implications for public health if it is not dealt with adequately. Such issues need to be considered when immunization programmes are established.

Maintenance of the cold chain is essential for ensuring that any vaccine is of good quality and thus safe and effective. Lack of efficacy of certain batches of vaccines is difficult to detect, particularly when disease burden is low and herd immunity high. Lot-by-lot surveillance is necessary to monitor the safety of each new batch. Collaboration between the surveillance programme and the national control laboratory responsible for vaccine batch testing is required for appropriate handling of batch-related problems. The use of AEFI report forms can encourage or facilitate the reporting of certain adverse events, such as local injection site abscesses, which usually occur in clusters as a result of a programmatic error. Reportable events include all serious events; clusters of AEFIs and any event that causes or may cause public concern. This differs from the spontaneous monitoring of non-vaccine pharmaceuticals where, historically, more focus has been placed on individual case reports rather than clusters or suspected rate changes.

Assessment of a causal association between administration of a vaccine and occurrence of an adverse event can be difficult. The pharmacology of vaccines tends not to be well understood. Diseases ascribed to vaccine administration are not uncommon in the populations being vaccinated. Patients and health care workers often attribute blame to a vaccine if there is a temporal association between the adverse event and vaccine administration, without considering other possible causes. Programmatic and coincidental events need to be distinguished from vaccine-related adverse events and from adverse events due to adjuvants, suspending agents, stabilizers and residues of growth medium.

The challenges in assessing causality in vaccine-induced diseases have been addressed by many national programmes through the creation of a special group or advisory committee of clinicians and experts, whose brief is to conduct case investigations and analysis (*3*).

The need for systems for managing public vaccine scares is most obvious during immunization campaigns, when there is heightened awareness of AEFIs owing to an apparent rise in reports. Many doses are given over a short period of time creating increased awareness among health care workers and the public of potential dangers. The publicity that these programmes attract may aggravate the deleterious impact of rumours of adverse events. Programme errors such as unsafe injection practices may increase during this period of intense activity, resulting in an increased risk of AEFIs. The need for surveillance and crisis management is crucial during these periods.

Thus, it is important that a response system should be in place, with the following characteristics:

- a rapid notification system of essential information about any AEFI;
- rapid and effective evaluation of AEFI information;
- rapid and effective response to AEFIs;
- a means of measuring the outcome or efficacy of action;
- adequate education and training of key personnel.

These characteristics justify a special monitoring system for vaccines, operating in collaboration with, or under the auspices of, the national monitoring system for drugs. It is recommended that the vaccine AEFI reporting system be based within the NIP, with good liaison mechanisms with the NRA

and its drug safety monitoring unit. This is already the case in some countries; however, in others, resource constraints or other factors may require that the vaccine AEFI reporting system be an integral part of the national drug safety monitoring programme. When this is the case, it is important that the staff are aware of the issues that differentiate vaccines from other products, and respond to AEFI reports appropriately; close liaison with the NIP is essential.

It is inappropriate for vaccine safety surveillance to be carried out concurrently by the NRA and the national immunization programme, since there is a risk of confusion, duplication, and possible conflict between the organizations. This has been the experience in some countries and is a situation that should be avoided.

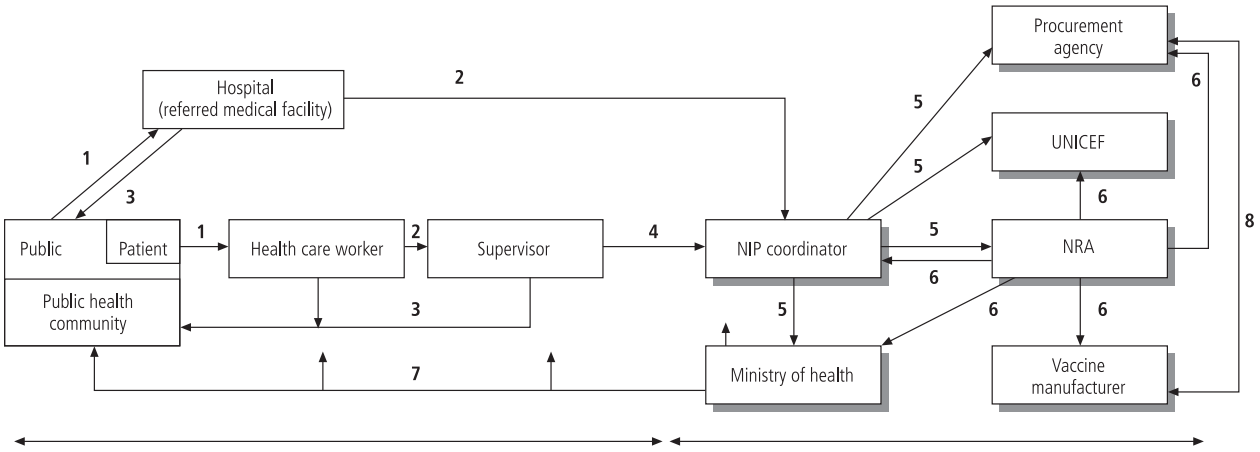
A model for dealing with AEFIs

A model for dealing with AEFIs has been developed (Fig. 1). Any operational model dealing with vaccine safety needs to be simple in its functioning, and generally applicable. This model will be analysed, critically reviewed and adapted by participants in the training programme for subsequent implementation in their own countries.

To achieve the ideal situation shown, potential pitfalls and problems need to be identified. Any system to monitor AEFIs should involve responsible health personnel acting in a coordinated and well-delineated manner. Duplication or omission of functions and responsibilities can be devastating to an immunization programme. There needs to be agreement on the defined functions by the AEFI programme within the NIP, the NRA, the ministry of health, vaccine manufacturers and other identified personnel.

The model provides an inclusive system encompassing the chain of events from the moment a single AEFI or cluster of AEFIs becomes apparent to the final implementation of a plan of action at national and possibly international level. Only certain AEFIs require all relevant personnel to be consulted. The model assumes a triage system that distinguishes special from routine situations. A typically non-significant, or routine situation would be a case of mild fever or redness and swelling at the injection site. However, should these AEFIs occur with unusual frequency, by vaccine, by type of reaction, or by locality/facility, further investigation and reporting would be warranted. In addition, deaths, hospitalizations or any

Fig. 1. **The reporting process for adverse events following immunization (AEFIs)**



Functions

Health care worker	Supervisor	NIP coordinator	NRA
Recognizes AEFIs Reports AEFIs	Stimulates reports Investigates Filters Provides feedback Manages data Proposes classification	Receives reports Transmits reports Triages Works with environment Manages data Ensures response	Receives reports Transmits reports Shares database Evaluates reports Takes action Notifies

NIP, National Immunization Programme; NRA, National Regulatory Authority; **1.** Initial report; **2.** Report to action level; **3.** Investigation; **4.** Send on reports meeting criteria; **5.** Report for consultation/action; **6.** Decision communication (regulatory, public health); **7.** Public statement; **8.** Contract information.

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AEFIs that are causing community concern should receive immediate attention and be reported to the national immunization centre without delay. This plan concentrates on AEFIs that may pose serious or widespread risk to the public, to the NIP, or both.

Patient and health care worker

Once an AEFI occurs, the patient is likely to present to the clinic or hospital where the vaccine was administered, or to a referral hospital or other medical facility in the region (**1** in Fig. 1). Whatever the situation, the examining health care worker is responsible for identifying the AEFI and reporting it as soon as possible to the appropriate authority (**2** in Fig. 1).

In clinics or other primary health care facilities, the health care worker should submit a report to his or her supervisor at the district level (**2** in Fig. 1). When the AEFI is seen at a referral medical facility, the report needs to be submitted without delay to the NIP office (**2** in Fig. 1), particularly if the event resulted in hospitalization. This, however, does not suggest that these reports should not be sent to a supervisor at the district level as well. Such reports may be sent to the NIP by an appropriately qualified health care worker, or his/her supervisor.

Recommendations concerning the initial detection, reporting and management of AEFIs by health care workers have been published (*2*).

Supervisor

Reports of AEFIs are referred to the supervisor or manager, usually at district level. The supervisor is responsible for promoting and encouraging reporting among health care workers providing immunization services. The supervisor and health care worker concerned may further investigate the AEFI or clusters of AEFIs as well as treat and comfort the patients and their parents (**3** in Fig. 1). The supervisor should also compile details of the AEFI data for reporting to the central NIP office (NIP coordinator) (**4** in Fig. 1). The report should be prepared according to clear criteria of seriousness and importance. Guidelines for this are described elsewhere (*2*).

National immunization programme

The NIP coordinator receives reports from supervisors or directly from referral facilities. Ideally, data should be submitted to the NIP quickly, with as much relevant information as possible. The central NIP office coordinates further investigations and actions. Special investigation of serious AEFIs or AEFI clusters by expert personnel may be necessary. The data and outcome should be entered into a permanent record, which may be computerized and reported as necessary to other authorities for further consultation, advice and information (**5** in Fig. 1).

Other authorities

These include the drug safety monitoring unit of the NRA, the ministry of health, the procurement agency, and manufacturers or suppliers of the vaccine concerned (UN agencies such as UNICEF). Contact persons within each of these organizations should be designated when the system is established; they need to be appropriately trained and supported. These other authorities should be contacted by the NIP for further information including the results of any independent investigations which they may have conducted (**5** in Fig.1).

Effective collaboration between the NIP and the NRA requires delineation of the functions and responsibilities for each. While the role of the NRA monitoring system is pivotal in the process, it is recommended that the management and coordination of immunization safety initiatives be based within the NIP. The NRA and NIP need to coordinate and agree to any action plans and communications with the ministry of health and the public (**5** in Fig.1).

After consultation, any regulatory decisions or other appropriate public health decisions taken by the NRA should be communicated to all the parties within loop 2 who may be affected by such decisions. This may include the vaccine manufacturer, UNICEF, or the procurement agency; the NIP and the appropriate officials within the ministry of health (e.g. Minister of Health, media liaison officer etc.) (**5**, **6** and **8** in Fig.1). Their responsibilities in dealing with such problems require definition. Manufacturers should have in place operating procedures and systems for dealing with vaccine quality problems as a condition for being awarded the tender for their product in a national programme. Any contractual agreement between a manufacturer and the procurement agency which supplies vaccines for the national programme may need to be reconsidered after an AEFI (**8** in Fig.1).

Communicating with the public

The NIP should submit a report as soon as possible, together with a plan for action and communication, to the ministry of health (**5** in Fig.1). The liaison or public relations office within the ministry of health may need to issue statements on behalf of the NRA and the NIP to the general public and to health care workers and supervisors involved in the AEFI communication chain (**7** in Fig.1). Personal communication with patients, parents and health workers is necessary in certain cases (**7** in Fig.1).

Monitoring outcome

The outcome of any actions taken to address a vaccine safety concern should be monitored and evaluated critically to ensure continuous improvement.

Critical factors for success

Factors critical to the success of this information and action programme include those described below.

- ***Professionalism and expertise***. Individuals are required who have the necessary expertise and responsibility to identify, prioritize and manage

the AEFIs that occur within their individual frame of reference, with a sense of purpose that is in harmony with others with whom they must interact. All those involved need training and access to the resources necessary to conduct their duties effectively. An advisory committee or other informal or formal access to consultants for case investigations and review and causality assessment is critical in enhancing the credibility of actions taken by the ministry of health. Occasionally, advice from international organizations such as WHO or other NRAs may be useful.

- ***Data collection and analysis information systems***. A custom-designed national database for AEFIs, vaccine utilization data and descriptions of vaccine safety scenarios occurring in various countries, linked to an international system, would assist NIPs in detecting signals, sharing experiences and harmonizing presentation of their AEFI data. Moreover, the information needs to be shared between NIPs and NRAs. The role of the WHO International Drug Monitoring Programme and the WHO Vaccines and Biologicals Department in providing technical and informational support and expertise needs to be developed in this regard. Finally, patient and reporter confidentiality must be maintained, especially when individual case information is submitted to nongovernmental bodies such as the manufacturer or public media.
- ***Adequate resources***. The costs of sufficient personnel, access to medical information, computer equipment and communication tools such as telephones, fax machines, e-mail, and the Internet should be included when determining a budget for the national AEFI programme. Provision for unanticipated on-site case investigations, expert advice, and public announcements should also be made.
- ***Efficiency***. The efficiency of the conduct of work and speed of response affect the impact of AEFIs on the public and its response to them. Time constraints and reporting procedures must be adhered to and should be monitored over the long term to ensure a reliable system. Performance indicators, such as reporting rates, report quality, media exposure and immunization coverage, should be developed.
- ***Communication***. Understanding and acceptance of the communication arrangements by all the people involved is of overriding importance. They should realize that their primary concern is public health. All the lines of communication and information-sharing described in this article should be used and there must be a proper understanding of the importance of the media in promoting the paramount importance of vaccine safety. The press should be advised of their responsibilities in this regard. There should be active inquiry and pursuit of local and international information necessary for the effective operation of the NIP. Communication between NRAs and NIPs should be such that there is rapid and complete exchange of information, so that regulatory decisions will have international relevance.
- ***Creating an ethos of risk–benefit awareness***. Good AEFI surveillance encourages health care workers to take responsibility for the products they administer. Their approach should inspire confidence and public trust, promoting the importance and safety of immunization practice. The needs of patients are paramount. AEFI management should be generally regarded as a public programme that is supported and encouraged by policy-makers and politicians. Most importantly, reporting of AEFIs and adverse drug reactions in general should be actively encouraged among health care workers. It is imperative that pressures from consumers, media, and legal, political and commercial sectors do not interfere with the objectivity and quality of the decisions made by the NIP, the NRA and the ministry of health. This can be partly assured by educating consumers, lay press and political and commercial sectors about the risk–benefit assessment of vaccines and their impressive performance record.

Proposed training programme

The proposed 5-day training programme on AEFIs combines teaching, problem-based workshops and intensive trainee participation. The training focuses primarily on the activities carried out in loop 2 of the operational model (see Fig. 1). Lectures provide an understanding of the immunological basis of vaccines, the nature of AEFIs occurring with commonly used vaccines, concepts in risk–benefit assessment and decision-making, causality assessment, and communication of risk–benefit information to the media.

The problem-based component of the course involves the study of actual cases of vaccine "scares" reported in a number of countries, selected to provide a broad range of experiences. Trainees are required to develop and present action plans and communication reports such as press statements. Mock television interviews with journalists are included. The training affords the participants the opportunity to work in a collaborative and constructive manner to deal with specific immunization safety issues using the skills, resources and training provided.

To ensure that the participants consider the relevance of the training programme to the systems already in place in their individual countries, they are required to present an appropriate plan of action for their own countries on the final day for implementation when they return home.

Research

Research is not the primary objective of the training programme described in this article. However, it

would be logical and stimulating to make the most of the research potential of such a programme. By regarding the training course as an intervention both for the individual attending and for his/her country, it should be possible to assess the pre- and post-intervention situation in simple terms of knowledge and practice. Attitudinal studies could be included. However, countries are generally improving their vaccine practices, despite disruptions and other problems from time to time, and this and other potential confounding issues would need to be incorporated into such research design and interpretation. Perhaps the elements of a "good system" in immunization practices might change as a result of the intervention provided by the programme. Effects on immunization coverage, structures put into place to deal with and to anticipate vaccine accidents, and attitudinal changes should be measurable. It is an objective of the training programme to identify individuals with a special interest in analysing what happens in relation to the GTN in their countries, encouraging them to put such analysis onto a systematic basis. In addition, there is a case for encouraging basic research on vaccine reactions to provide a stronger scientific basis for causality assessment. In countries with established and sophisticated AEFI monitoring systems, more robust epidemiological methods for establishing causal associations, such as cohort and case–control studies could be employed.

Conclusion

The limitations of the system and training programme described in this paper are such that long-term effects are not detected. The passive surveillance methods need to be supplemented with a variety of other epidemiological methods, including long-term follow-up using registries of patients and dedicated studies of individual problems and concerns (*4*). Underreporting and wrong diagnosis limit the value of this activity. The cultural, social and political contexts within which an AEFI monitoring system operates have not been considered, but it should be possible to draw on the experiences of the trainees in that regard. ■

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Résumé

Mise en place d'un système national de prise en charge des effets indésirables des vaccins

Le réseau mondial de formation de l'OMS (GTN) est une initiative qui vise à améliorer la qualité des vaccins et à faire en sorte qu'ils soient mieux utilisés. Un nouveau programme en vue de fournir une formation intensive à la gestion des effets indésirables de la vaccination a récemment été ajouté au GTN. Ce programme est destiné au personnel des services nationaux de réglementation et des programmes de vaccination et de surveillance qui travaillent dans le domaine de la sécurité des vaccins.

Si les vaccins figurent parmi les produits pharmaceutiques les plus sûrs, la présence d'un effet indésirable grave ou d'un groupe d'effets indésirables peut rapidement faire planer une grave menace sur la santé publique. Pour pouvoir réagir efficacement face à des effets indésirables de la vaccination, les responsables de la sécurité vaccinale doivent pouvoir travailler ensemble de façon systématique et efficace. Un modèle de communication et d'action concertée est exposé ici. Il s'emploie à résoudre les difficultés rencontrées pour réagir rapidement en cas d'effets indésirables.

La mise au point d'un système national de prise en charge des effets indésirables de la vaccination doit tenir compte des éléments propres aux vaccins qui les distinguent des autres médicaments, dont certains sont décrits dans cet article.

Dans les populations vaccinées, il n'est pas rare de rencontrer des maladies imputables aux vaccins. Les malades et les agents de soins de santé incriminent souvent le vaccin si l'effet indésirable est associé dans le temps à l'administration de celui-ci, sans envisager d'autres causes éventuelles. Il faut distinguer les événements programmatiques et fortuits des effets indésirables liés au vaccin lui-même ou à d'autres constituants du vaccin. De nombreux programmes nationaux ont cherché à résoudre le problème posé par l'évaluation de l'étiologie des pathologies induites par les vaccins en créant un groupe spécial ou un comité consultatif de cliniciens et d'experts chargés de mener les études et analyses de cas.

La nécessité de disposer de systèmes pour faire face aux craintes du public en matière de vaccins est plus visible au cours des campagnes de vaccination, car les gens sont davantage sensibilisés aux effets indésirables des vaccins du fait d'une augmentation apparente de ces derniers dans les rapports. Les erreurs programmatiques, telles que les injections à risque, peuvent être plus nombreuses pendant ces périodes d'activité intense,

entraînant un risque accru d'effets indésirables. Il est absolument nécessaire de surveiller et de gérer les situations de crise au cours de ces périodes.

Un système possédant les caractéristiques qui suivent devrait être mis en place : notification rapide des informations essentielles concernant tout cas de réaction indésirable à la vaccination ; évaluation rapide et efficace de cette information ; réponse rapide et efficace apportée au problème ; moyen permettant de mesurer le résultat ou l'efficacité de l'intervention ; et un personnel suffisamment bien entraîné.

Le modèle décrit sera analysé, examiné de façon critique et adapté par les participants au programme de formation GTN pour être ultérieurement mis en place dans leur propre pays. Pour parvenir à cette situation idéale, il faut recenser les embûches et problèmes potentiels.

Les facteurs décisifs pour le succès de ce programme d'information et d'action sont les suivants : le professionnalisme et la compétence du personnel de santé ; l'existence de systèmes de collecte de données et d'analyse de l'information ; des ressources suffisantes ; l'efficacité du système ; une communication ouverte entre tous les acteurs en jeu ; et la création d'un système de valeurs basé sur la sensibilisation au rapport avantages/risques et sur la compréhension.

Dans les pays qui disposent de systèmes de surveillance des effets indésirables de la vaccination rodés et sophistiqués, des méthodes épidémiologiques plus solides permettant d'établir des relations de cause à effet, telles que les études de cohorte et de cas témoins, pourront être employées.

En conclusion, il serait logique et encourageant de tirer le meilleur parti possible du potentiel de recherche du programme de formation décrit. Un cours de formation de cinq jours, destiné à renforcer les systèmes nationaux s'occupant des effets indésirables de la vaccination, a été élaboré mais il n'en est encore qu'à ses balbutiements.

Resumen

Desarrollo de un sistema nacional para manejar los episodios adversos postinmunización

La red mundial de capacitación (GTN) de la OMS es una iniciativa encaminada a mejorar la calidad de las vacunas y el uso de las mismas. Recientemente, se ha incorporado a la GTN un nuevo programa de materias concebido para impartir formación intensiva en el manejo de los episodios adversos postinmunización (EAPI). El programa está destinado al personal de los organismos nacionales de reglamentación (ONR) y de los programas de inmunización y vigilancia que operan en el ámbito de la seguridad vacunal.

Aunque las vacunas se encuentran entre los productos farmacéuticos más seguros, un episodio adverso grave ocasional o una serie de episodios adversos pueden convertirse rápidamente en una peligrosa amenaza para la salud pública. Para garantizar un correcto manejo de los EAPI, los responsables de la seguridad de la inmunización deben poder colaborar de un modo sistemático y eficaz. Se describe un modelo para la comunicación y acción entre esos responsables, con el que se responde a los desafíos que hay que superar para manejar prontamente los EAPI.

Para desarrollar un sistema nacional de manejo de los EAPI deben considerarse las diferencias existentes entre las vacunas y otros medicamentos, algunas de las cuales se describen en este artículo.

En las poblaciones vacunadas, no es infrecuente la atribución de enfermedades a la vacuna administrada. Los pacientes y los agentes de salud a menudo atribuyen la enfermedad a una vacuna cuando se da una asociación temporal entre el episodio adverso y la administración de la misma, sin considerar otras posibles causas. Es preciso distinguir los episodios programáticos y casuales de los episodios adversos relacionados con la vacuna misma o con alguno de sus componentes. Muchos programas nacionales han hecho frente a las dificultades que plantea la evaluación de la etiología de las enfermedades provocadas por las vacunas, creando a ese efecto un grupo especial o comité consultivo compuesto por médicos y expertos que deberán investigar y analizar los casos.

La necesidad de sistemas de respuesta a las alarmas públicas causadas por las vacunas se hace más evidente durante las campañas de inmunización, en las que la sensibilización respecto a los EAPI es mayor, a consecuencia de un aumento aparente de los casos. Los errores programáticos, como la administración peligrosa de inyecciones, pueden multiplicarse en esos periodos de intensa actividad, resultando de ello un mayor riesgo de EAPI. La necesidad de sistemas de vigilancia y manejo de las crisis es fundamental durante esos periodos.

Debería establecerse un sistema de las siguientes características: notificación rápida de la información básica sobre cada EAPI; evaluación rápida y eficaz de la información sobre los EAPI; respuesta rápida y eficaz ante los EAPI; un sistema de evaluación de los resultados o la eficacia de la acción; y una educación y capacitación adecuadas del personal oportuno.

Los participantes en el programa de capacitación de la GTN harán un análisis, un examen crítico y una adaptación del modelo descrito para aplicarlo posteriormente en sus países. A fin de lograr esa situación ideal, será preciso identificar los posibles errores y problemas.

Entre los factores decisivos para el éxito de este programa de información y acción cabe citar los siguientes: la profesionalidad y los conocimientos técnicos del personal implicado; la recopilación de datos y los sistemas de análisis de la información; unos recursos suficientes; la eficacia del sistema; una comunicación abierta entre los participantes; y el fomento de la toma de conciencia y la comprensión de los riesgos y los beneficios.

En los países que cuentan con sistemas afianzados y avanzados de vigilancia de los EAPI, podrían emplearse métodos epidemiológicos más sólidos para establecer asociaciones causales, como estudios de cohortes y de casos y testigos.

En conclusión, parece lógico, amén de interesante, aprovechar al máximo el potencial de investigación del programa de formación descrito. Se ha programado un curso de capacitación de cinco días para fortalecer los sistemas nacionales que se ocupan de los EAPI, si bien el curso está sólo en sus comienzos.

References

1. **Duclos P, Bentsi-Enchill A.** Current thoughts on the risks and benefits of immunisation. *Drug Safety,* 1993; **8**: 404–413.
2. Global Programme for Vaccines and Immunization: Expanded Programme on Immunization. *Surveillance of adverse events following immunization. Field guide for managers of immunization programmes*. World Health Organization, Geneva, 1997 (unpublished document WHO/EPI/TRAM93.02 Rev.1).
3. **Pless R, Duclos P.** Reinforcing surveillance for vaccine-associated adverse events: the Advisory Committee on Causality Assessment. *Canadian Journal of Infectious Diseases,* 1996, **7**: 98–99.
4. **Jefferson T.** Vaccination and its adverse effects: real or perceived. *British Medical Journal*, 1998; **317**: 159.