Developing an immunization safety surveillance system in the Philippines

Mehta et al. have outlined the principles for developing a national system for monitoring adverse events following immunization (AEFIs) (*1*). The Philippines is developing a system building on the adverse drug reaction monitoring system. The feasibility and value of AEFI surveillance was established during the 1998 measles mass vaccination campaign.

Damage had been done to the immunization programme by false reports in 1995 that millions of women had received antifertility vaccinations under the guise of being inoculated against tetanus (*2*). Although tests conducted by six independent laboratories and a case(control study (*3*) failed to find any evidence for such a claim, tetanus immunization among women dropped. Even now, five years after the event, health workers still receive questions from women about the false allegations, and in one city tetanus toxoid vaccine is not offered because of them.

With a target population of 27 million children for the 1998 campaign against measles, many adverse events could be expected, with the potential to disrupt the campaign. A reporting system was developed for the campaign which, as well as pinpointing events for investigation, produced reporting rates for AEFIs (Table 1). Although only a fraction of adverse reactions were reported, the reporting efficiency increased with the severity of the reaction. There were also many reports of collapse and anaphylaxis which turned out to be vasovagal reactions to the anxiety and/or pain of injection rather than vaccine reactions. The results of these investigations (as well as investigations of a few deaths) showed the value of investigation in addition to monitoring.

Developing a national system required a collaborative approach that involved commitment and coordination of several key agencies. The Maternal and Child Health Service is responsible for maintaining the Expanded Programme on Immunization in the Philippines and for the procurement of vaccines and vaccine equipment, national training, and the organization of mass immunization campaigns. The Field Epidemiology Training Programme (FETP) is the epidemiological group that investigates and analyses adverse events, and the Bureau of Food and Drugs is the national regulatory authority responsible for licensing vaccines.

Building on the experience of the measles campaign and in order to improve the regulatory capacity of the Bureau, a working group chaired by the Bureau and FETP was subsequently formed to develop an Immunization Safety Surveillance System (ISSS). Each of the key agencies was represented, as were private physicians and academia. As each agency had a slightly different understanding of and ideas for the mechanism and development of an ISSS, the group provided a necessary forum to build consensus and to agree on objectives and processes. Focal points from each agency were also identified to serve as a communication channel.

The working group has identified three key elements for the ISSS: system (procedures, forms, database, etc), training (for reporting and investigation), and advocacy (to promote the system to health workers and the public), and has created a sub-committee to accelerate work in each of these areas. The aim is to have a system ready so that it can be piloted in Bohol, where a pneumococcal vaccine trial will start in mid-2000. This trial provides an ideal opportunity to test the system, with the intention of building a nationwide system.

Developing a system is a collaborative approach involving all the key agencies, so as to utilize all relevant experience. There has also been recognition of the need to train health workers and field epidemiologists; to build networks and develop media skills to respond to anti-immunization allegations in a coherent, credible and proactive way; and to involve the private sector (physicians and hospitals) and academia. ■

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1. **Mehta U et al.** Developing a national system for dealing with adverse events following immunization. *Bulletin of the World Health Organization*, 2000, **78**: 170–177.
2. Concerns for the safety of tetanus toxoid in the Philippines 1995. Geneva, World Health Organization (Vaccines safety information bank, available at: http://www.who.int/vaccines-diseases/safety/infobank/ttox.htm).
3. **Catindig N et al.** Tetanus toxoid and spontaneous abortion: is there an epidemiological association? *Lancet*, 1996, **348**: 1098–1099.
4. *Immunization safety surveillance: guidelines for managers of immunization programmes on reporting and investigating adverse events following immunization.* Manila, World Health Organization Regional Office for the Western Pacific, 1999 (document WPRO/EP1/99.01).

Table 1. **Adverse events reported in the measles immunization campaign in the Philippines, 16 September–30 November 1998**[a]

Adverse event	Number of cases	Incidence	Expected incidence[b]	% of expected cases reported
Fever	69	0.0003%	5–15%	0.0018–54
Rash	65	0.0003%	5%	0.0051
Febrile convulsions	23	1 in 1 113 525	~1 in 10 000	0.9
Serious allergic reaction	27	1 in 948 558	1–2 in 100 000	5–10
Anaphylaxis	3	1 in 8.5 million	1 in 1–3 million	12–35

[a] Total number of children immunized = 25 611 081; data from Field Epidemiology Training Programme (FETP) nationwide data.

[b] Expected incidence from ref. 4, with adjustment of febrile convulsion rate as only about 1/3 of vaccinees were of age to suffer febrile convulsions.

