Under special scrutiny

Honesty and transparency in vaccination safety – monitoring adverse reactions to vaccines

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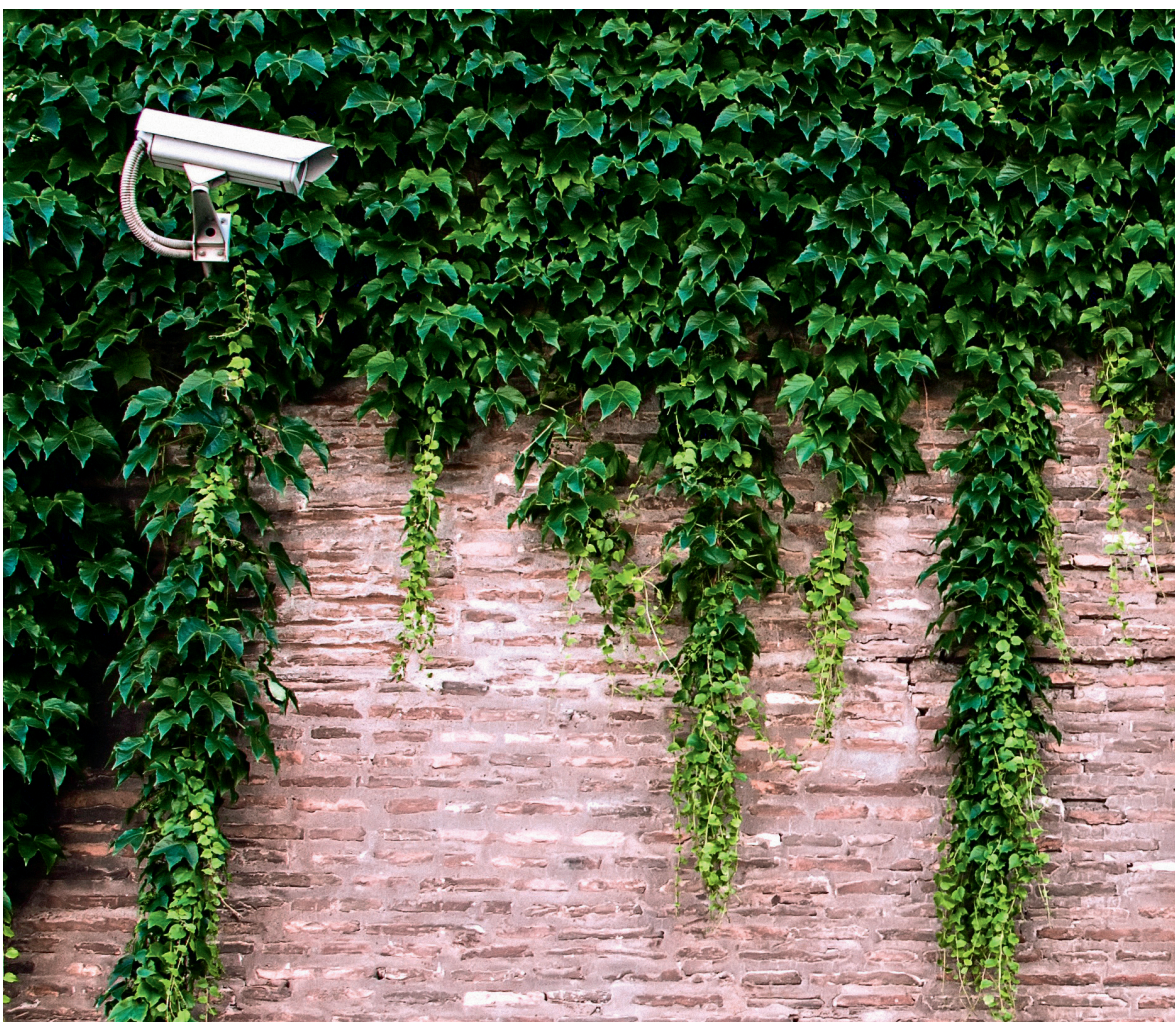
Efforts to ensure that vaccinations are safe is a key element underlying the acceptance and success of vaccination programs in all countries. This is largely because the majority of vaccines are administered to babies and children as part of compulsory immunization programs or are recommended to specific populations. In the vast majority of cases, they are given to healthy individuals. It has been estimated that the threshold of social acceptance for side effects is approx. 1:100,000 for vaccines, compared to between 1:1 and 1:100 for other drugs. Since vaccines are expected to have significantly higher safety profiles, they are subject to far higher standards than other medicinal products; for example, each batch of vaccines is tested before it is released into the market. Complex systems for monitoring the safety of vaccines on national and international levels have been developed over many



years by independent experts, resulting in the drafting of transparent procedures.

All medicinal products undergo in-depth testing and analysis prior to release, as relevant bodies aim to determine whether the therapeutic benefits of the given drug definitely outweigh the risks. Clinical studies determine the effectiveness and safety of each medicine prior to its release; once the drug is on the market, it undergoes further tests for factors such as immunological durability. As concerns vaccines, before a new batch is released it is tested by an independent laboratory following protocols established for the given vaccine. However, just like all other medicines, vaccines can still sometimes cause adverse reactions which may present in certain but not all individuals.

Monitoring adverse reactions to vaccines is a key element in the process of assessing their safety. In Poland, the system was introduced in the latter half of the 1990s. It was devised by the Institute of Epidemiology of the National Institute for Public Health – National Hygiene Institute based on the recommendations of the WHO Drug Monitoring Programme, Expanded Programme on Immunization. The system of monitoring adverse effects is an element of routine epidemiology studies conducted in Poland, providing important information on the safety of vaccines in the context of new, unusual and rare reactions, monitoring known reactions, determining risk factors for specific reactions, identifying vaccine batches producing higher incidences of reactions, and controlling the safety of new vaccines. Additionally, monitoring adverse effects is an important source of input into developing sensible vaccination policies, taking into account risks and side effects as well as effectiveness. It also forms a basis of a rational assessment of adverse effects and provides evidence against aggressive anti-vaccination propaganda. This information is used to formulate new, effective vaccines and support comprehensive vaccination policies.

National level

The AEFI (adverse events after immunization) risk assessment process examines the cause and effect relationship between vaccines and side effects, and its results are used in decision making and implementing specific activities. The assessment is conducted on the basis of data collected from reports of adverse effects. It should be noted that in many countries, adverse events are reported directly by patients, doctors or institutions where the vaccination was administered, therefore the quality of data varies and it is not always possible to draw a direct link between reaction and vaccination, apart from the time correlation.

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In Poland, the AEFI managing system is covered by legislation from 5 December 2008 on the prevention and treatment of infections and infectious diseases in the Polish population and the Health Minister's regulation from 21 December 2010 on AEFIs and their diagnosis, monitoring and reporting. The AEFI report form includes several sections to be completed by the doctor, a member of the Sanitary Inspectorate and member of the National Institute of Public Health – National Institute of Hygiene. The ministerial regulation is appended with a list of adverse events which must be reported, stipulating that any such adverse event is to be diagnosed by a doctor or another medical professional and reported to the Sanitary Inspectorate. In turn, the Sanitary Inspectorate passes the report on to the National Institute of Hygiene where it is filed, verified and analyzed.

According to the current definition of an AEFI, any health problem which might be linked to vaccination must be reported. This means that if parents or care-givers note any symptoms in the child following immunization, they must immediately report them to a doctor. The same applies to adults undergoing vaccination. The doctor examines the patient and decides whether to report the case further using the official list of AEFI symptoms and the likely or confirmed etiology of health problems being reported by the patient. We have many years of experience with numerous vaccines and monitoring adverse events in Poland as part of routine epidemiological assessment, resulting in a reliable database of side effects linked to individual vaccines.

Around 15–20% of adverse events reported each year occur in the wake of the tuberculosis vaccination, whereas the highest share of adverse events (65%) is linked with the combination diphtheria, tetanus and pertussis (DTP) shot. It should be noted, however, that such vaccines including the pertussis component are the ones administered most frequently, since the compulsory immunization program includes them in a cycle of five doses. When we look at adverse events in terms of the most commonly listed symptoms, the majority of reports concern localized reactions such as redness or swelling at the inoculation site. The most common general symptom is a temperature >38°C. Serious adverse events are rare or very rare, but in the majority of cases they require hospitalization for observation and possible further diagnostics and treatment. The frequency of AEFI registered as part of routine epidemiological monitoring depends on the type of vaccine, and it is estimated to be approx. one event per 10,000 vaccinations.

It should be stressed that the broad definition of adverse events allows for the detection of rare side effects, those which have not previously been observed or others which are temporary. Each reported health problem is analyzed and qualified on the basis of criteria defined by experts in the field.

Family level

Poland's passive epidemiological monitoring of AEFI has its limitations, one of which is low sensitivity. Although passive epidemiological surveillance is commonly used in Europe due to its low cost, it is highly dependent on the professionalism and reliability of the medical personnel reporting the adverse events. The system also requires parents to be vigilant and aware of potential side effects, since many adverse events may not present until several hours or even days following inoculation. As such, systematic education of parents/caregivers and medical professionals on AEFI is key for improving the sensitivity of the system.

In summary:

1. Vaccines are the most thoroughly tested pharmaceuticals.
2. Quality controls and safety monitoring in Europe and ongoing research are a guarantee that only vaccines of a verified quality, safety and effectiveness are used.
3. Monitoring of AEFI is key in the ongoing assessment of vaccines following registration.
4. The system managing AEFI is covered by legislation from 5 December 2008 on the prevention and treatment of infections and infectious diseases in the Polish population and the Health Minister's statement from 21 December 2010 on AEFI and their diagnosis, monitoring and reporting.
5. Although the monitoring system currently in place functions relatively well, improving its sensitivity remains a challenge.

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Kari S. Lankinen et al. Vaccinovigilance in Europe – requirements. *Bulletin of the World Health Organization*, Nov., 2004, 82 (11)