

# The assessment of vaccine safety in low and middle income countries

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Ensuring the safety of vaccines utilized outside industrialized countries is an increasing challenge for a number of reasons: due to their large population size, low- and middle-income countries (LMIC) utilize almost twice as many vaccine doses as do industrialized countries; most vaccines products used in LMIC differ from those available in the industrialized world hence assumptions about vaccine safety are not necessarily transferable; the possibility of programme error as a confounding factor may be higher in countries with weak immunization systems; and with progress in the control of vaccine-preventable diseases, attention to vaccine reactions has been increasing in LMIC, just like it did in high-income countries over the past decades. To date, the surveillance of adverse events following immunization (AEFI) remains limited in a majority of LMIC. As a result the safety of vaccinations against adequate standards is more difficult to ensure in many of those countries and safety signals that could not be adequately addressed have also resulted in unnecessary disruptions of vaccination activities.

In response to an increasing demand for technical support on vaccine safety, WHO is working with national authorities and vaccine safety experts to develop a global plan for enhancing vaccine safety activities in LMIC. This plan is considering two main strategic axes: at country level, a set of managerial criteria are proposed in order to define a minimal capacity that should be available in all countries in order to effectively respond to vaccine safety signals; at the international level, a support structure that provides harmonized methods and tools, facilitate information exchange across countries, maintains a pool of experts and institutions that can support countries for capacity building and in investigating vaccine safety signals, independent expert advice on vaccine safety issues, and a resource for monitoring rumours and providing communication tools adapted to the needs of communities, health care workers and decision-makers.

Newly available vaccines present one additional opportunity that is particularly emphasized in this global plan. In order to ensure that the safety profile of those vaccines is adequately monitored beyond the clinical development stages, it is proposed that all manufacturing countries and all early introducer countries institute active AEFI surveillance for those products. WHO is currently assembling a global network of technical experts who would be available to provide the necessary support to national authorities upon request. The information generated through those additional activities should provide the basis for updated safety profiles of vaccine products within time intervals that are comparable to what can be accomplished in industrialized countries. Methods that take advantage of modern information technologies, such as the establishment of a facility for analyzing computerized medical databases, will be proposed so that vaccine safety signals of particular interest can be thoroughly investigated