

Post-marketing Surveillance Network for Vaccines

Jerry Labadie

The UMC is a partner in an exciting WHO project which will help to boost the number and quality of reports of adverse events following immunization (AEFI): The Global Network for Post-marketing Surveillance of Newly Pre-qualified Vaccines (PMS Network). UMC tools VigiFlow and Vigibase are key elements in the reporting, management and analysis of the reports of the AEFI. Through the Global PMS Network, enhanced reporting of vaccine safety data to the UMC is expected in coming years. In turn this will assist ongoing efforts (supported by WHO's Global Advisory Committee on Vaccine Safety) to use the resources and experience of UMC for data mining and signal detection to improve global vaccine safety monitoring.

Objectives

The PMS Network is an initiative of the WHO Department of Immunization, Vaccines and Biologicals (IVB) and is funded through a grant from the Bill and Melinda Gates Foundation to support WHO's activities to pre-qualify vaccines for supply through UN agencies (http://www.who.int/immunization_standards/vaccine_quality/vq_index/en/index.html). There is no funding support for this network from industry.

The primary objective of the Global PMS Network is to ensure a standardized approach to monitoring and assessing serious, rare, or unexpected AEFI with newly pre-qualified vaccines.

Secondary objectives are to:

- contribute to improved knowledge about safety of the vaccines of interest and to ensure data are collected to help address unanswered safety questions, particularly regarding new, unusual or rare AEFI
- identify and address potential signals of real vaccine reactions in a timely manner (including where applicable issuing recommendations for more controlled studies)
- determine host risk factors for particular types of reported events
- monitor trends in known vaccine reactions
- ensure adequate safety information to support vaccination policy and recommendations.

Global spread of participants

Eleven countries (distributed across all six WHO Regions) have been selected by WHO based on criteria which include evidence of adequately functioning post-marketing surveillance systems. The selected countries are Senegal, Uganda, Brazil, Mexico, Iran, Tunisia, Albania, Kazakhstan, Vietnam, Sri Lanka and India (one selected state). Since all but one of the countries participate in the WHO Programme for International Drug Monitoring the existing passive surveillance systems in the countries will be used and strengthened. However, countries will be required to incorporate certain standardized elements agreed by the network (for instance,

standardized case definitions, methods of analysis, reports to the network) to ensure comparability of safety data among network countries.

VigiFlow in use

AEFI reports from the PMS Network countries will be sent to the global database of the WHO-UMC programme by VigiFlow. VigiFlow has been modified to capture vaccine specific data. The reported AEFI will be subjected to UMC's routine data mining procedures. This will improve the vaccine safety monitoring capacity and data-mining tools at UMC.

Spin-offs of the project

Added value of the PMS Network for participating countries:

- ♦ strengthening of vaccine safety data management and data analysis capacities
- ♦ funding and technical support of country-specific training needs
- ♦ use of internationally recognized standardized case definitions
- ♦ strengthening of collaboration between different national bodies involved in post-marketing surveillance (e.g. national immunization programme, national regulatory authority, national pharmacovigilance centre, and other bodies such as clinical professional groups)
- ♦ contribution to improving global monitoring of vaccine safety including the use of resources and tools of the WHO-UMC programme
- ♦ building synergies between drug safety monitoring and vaccine safety monitoring activities in countries.

Through this network, WHO and UMC expect to further strengthen the infrastructure and capacity for post-marketing surveillance in PMS Network countries. Furthermore, the expected outcomes of the PMS Network activities, including the resources developed to support the PMS Network, will benefit other non-Network countries.