



Book Review

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A Report of the Safety and Surveillance Working Group

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With increasing incomes and support from various international agencies, drugs and vaccines are reaching more people in low- and middle-income countries (LMICs). This may improve lives and reduce morbidity and mortality. However, there may also be adverse effects as LMICs have only limited systems for post-marketing surveillance (PMS). PMS is important because not all adverse reactions to a drug/vaccine can be predicted from pre-clinical studies and clinical trials. The Safety and Surveillance Working Group (SSWG) was a collaborative effort initiated by the Bill and Melinda Gates Foundation and other organisations to develop practical and scalable strategies to support PMS of drugs and vaccines in LMICs. LMICs have traditionally relied on data from more developed countries for therapeutic decision making. For many years I was involved with two regional pharmacovigilance centres in Nepal, an LMIC in South Asia, and am aware of the challenges regarding medicine and vaccine safety in resource-limited settings. East Africa, West Africa, and South Asia are benefiting from various initiatives like the GAVI Alliance, Global Fund, and the Neglected Diseases Initiative.

The SSWG report first addresses the question of where stakeholders should invest to strengthen PMS in LMICs. The report proposes risk-based criteria based on a determination of which drugs and vaccines are likely to be introduced in LMICs over the next 10 years and the countries in which they would be introduced. An assessment of the potential adverse effects of the drugs and vaccines and of the existing post-marketing/pharmacovigilance systems in LMICs is also recommended. World maps showing the geographic distribution of product launches, the relative risk of new

product launches, and the pharmacovigilance capacity of countries, are especially useful.

Pharmacovigilance systems in LMICs have traditionally concentrated on passive methods (with the focus being on reporting by health professionals), coupled with the hope that as a country's capacity and competence improves active surveillance can be implemented. The report states that passive surveillance may be ill-suited to detect adverse effects of newly introduced drugs and vaccines because the number and range of reports from passive surveillance are low. Underreporting was a major problem in Nepal and other LMICs. The authors state that pharmacovigilance systems in LMICs should be developed according to local needs and priorities, and must actively involve local governments and industry. The system must stretch the limited resources and address as many post-marketing safety needs as possible. The SSWG report mentions using the resources of public health programmes that introduce new drugs and vaccines to strengthen and improve PMS in LMICs. The introduction of the Japanese encephalitis vaccine in India is mentioned as an example. The International Pharmacovigilance Program has 110 countries as full members and 32 associate member countries.

The report also mentions strategies to improve political commitment to pharmacovigilance, but more discussion on this would have been helpful. Pharmacovigilance can be successful only if the general public and the politicians are aware of its benefits. While conducting pharmacovigilance, differences between drugs and vaccines should be considered. Vaccines are administered to large numbers of young, healthy persons. Also, the public is less willing to accept risks associated with vaccines. In addition, maintaining the cold chain associated with vaccines may be difficult in LMICs. Many LMICs have public health programs and expertise from these programs can be used to support pharmacovigilance.



The report recommends setting up a multi-donor trust fund to initiate pilot programs and also developing regional technical facilities and centres of excellence to support drug and vaccine safety initiatives. The table showing the relative pharmacovigilance capacities of LMICs was interesting. Surprisingly, some LMICs were either not a member of the International Drug Monitoring Program or had only joined recently. Bangladesh and Myanmar in South Asia are not yet members. India, Nigeria, Uganda, and Vietnam are countries with the greatest capacity in pharmacovigilance. The report concludes with a glossary of key terms related to safety surveillance and pharmacovigilance.

This report would be of special interest to persons involved in pharmacovigilance in LMICs as it outlines possible future developments and trends in this area. Many drugs and vaccines are likely to be introduced in these countries in the coming decade placing enormous challenges on PMS systems. The SSWG report provides an overview of challenges in medicine and vaccine safety in LMICs and a road map on how to respond to them.

About the book:

Bollyky TJ, Stergachis A. A Report of the Safety and Surveillance Working Group. 2014.

The report can be downloaded for free from:
https://docs.gatesfoundation.org/documents/SSWG%20Final%20Report%2011%2019%2013_designed.pdf
