

33rd Annual Meeting of Representatives of National Pharmacovigilance Centres participating in the WHO Programme for International Drug Monitoring Accra, Ghana 1 - 3 November 2010



The annual meeting was held in Accra, Ghana. Eight working groups were set up to discuss issues related to the development of pharmacovigilance. Several recommendations were made following these discussions.

WG1. The role of pharmacovigilance centres in preventing medication errors

The working group discussed the scope and limits of pharmacovigilance (PV) centres in preventing medication errors and how PV centres can have proactive role in preventing medication errors. The working group recommended the following:

- National PV policies should include medication error issues as part of functions of PV centres.
- Standardized definitions/terminologies for medication errors are needed.
- Existing tools should be modified to capture specific information on medication errors.
- National centres should advocate for reporting of medication errors even when they do not lead to adverse events.
- Medication errors should be incorporated into PV training curricula for students and in-service training modules for health-care professionals.

WG2. How to improve the quality of individual case safety reports (ICSRs)

This working group looked at problems of the quality of ICSR and possible solutions. First a 'good quality' ICSR has to be defined. Many reporters are not very used to reporting ICSR and may not include relevant information such as laboratory test results in their reports, which would allow better causality assessments.

The working group suggested that possible solutions could be: improved design of reporting forms, and analysis and review of national reporting requirements and practice. The Uppsala Monitoring Centre (UMC) has set up a tool for the analysis of completeness and quality of ICSR submitted to the international PV database which may be helpful in this respect. It may be possible to identify different quality problems in reports from different groups of reporters (i.e. company reports, direct health-care professionals' reports and consumer reports) and address these separately.

WG3. Establishing pharmacovigilance centres: difficulties and solutions

This working group discussed common problems and challenges when setting up or strengthening a PV centre and how to address these. Some of the problems identified were: underreporting, low quality of adverse drug reaction (ADR) reports, shortage of qualified staff at national centres, lack of funding of PV centres, lack of interaction with the regulatory authority, the government and other policy makers, and limitation of the legislation base.

In order to enhance reporting and a 'notification culture', the working group proposed the following actions:

- To include PV training in undergraduate and postgraduate curricula of all health-care professionals, including physicians, pharmacists and nurses;
- To establish active surveillance components, specifically to use public health programmes and the Global Fund PV initiative for the incorporation of PV into the national health-care system;
- To enhance PV promotional activities, especially by engaging professional organizations of health-care providers, internet facilities, mass-media, professional conferences etc.;
- To motivate and stimulate reporting by providing feedback;
- To make reporting mandatory for health-care professionals and the industry.

The working group also considered several funding resources to tackle lack of funding of PV centres; government funding (minimal financing), regulatory resources such as fees, the Global Fund, PEPFAR and similar initiatives, and support by non-profit organizations.

WG4. AEFIs: Causality Assessment and signal detection

It is important to ensure the continued safety of vaccines by monitoring Adverse Events following Immunization (AEFIs). Vaccine-related adverse events that are not rapidly and effectively dealt with can undermine confidence in a vaccination programme and ultimately have dramatic consequences for immunization coverage and disease incidence. It is therefore imperative that methods for reporting ADRs to vaccines, causality assessment and signal detection of AEFIs are in place within PV systems.

Even though most countries have systems in place for AEFI reporting, in many countries there is no proper synergy as regards AEFI reports between the National Regulatory Authorities (NRA), National Immunization Programs (NIP) and PV centres.

The working group recommended:

- Effective communication and collaboration between regulatory authorities, national PV centres and national immunization programs are key to monitoring vaccine safety.
- Standard operating procedures and guidelines need to be developed to make channels of communication clearer.
- The public and the media should be included in any collaborative efforts to monitor AEFIs.

WG5. Optimizing pharmacovigilance activities to fight substandard and poor quality medicines

The problem of poor quality, contaminated and substandard medicines is a challenge and systems need to be put in place for the prompt identification and withdrawal of such medicines from the market.

This working group discussed how PV activities can be extended to tackle these issues.

Recommendations:

- PV centres could be the first point of call for reporting sub-standard and poor quality medications.
- Tools need to be redesigned for data collection to make provisions for the reporter to indicate substandard medicines, medication errors (see related working group report), drug abuse etc.
- Advocacy, education and training and timely information dissemination are key in merging efforts to detect ADRs along with fighting poor quality and substandard medicines.
- Effective collaborations with various parties will be important in achieving and sustaining these initiatives.

WG6. Building human resource capacity for pharmacovigilance

In many national centres PV activities are undertaken by staff that are involved in other areas and therefore cannot focus their efforts on PV and are not adequately trained for this role.

Many PV centres also face the problem of high staff turnover.

The working group discussion centred on who should be trained, competencies needed and who should be responsible for building and financing human resource capacities in PV centres.

Recommendations:

- National centres should have a minimum qualification/skill profile for PV personnel
- PV modules should be included in the training curricula of various health professionals to give basic awareness of medicine safety issues
- Training packages should be developed for specific and continuous development of staff working in PV. Developing these training curricula will require cooperation with WHO collaborating centres for PV, academia and the use of both internal and external PV consultants
- PV centres should include resources for training within their budgetary requirements for pharmacovigilance.

WG7. How to improve awareness of drug safety issues: social marketing of PV

PV in most countries is not well publicized and there is a general lack of understanding of the basics of this concept. Social marketing involves selling “the need for” and “the benefits of” PV to various parties with the aim that they adopt desired behaviours to enhance drug safety.

Recommendations:

- Marketing of PV should be geared towards behavioural changes that will promote ADR reporting. PV marketing should be geared not only to health professionals but also to the general public.
- Marketing can be done via various means, such as through the media and other public initiatives.
- The impact of any PV marketing efforts should be measured by analyzing prescription data before and after, analyzing media coverage and assessing behavioural changes.

WG8. Good practice of pharmacovigilance inspections/assessments

Conducting PV inspections is key to ensuring best practices in pharmacovigilance.

PV inspections are currently only conducted by a limited number of countries. The power to carry out PV inspections is generally a legal power, so it is enforced by the National Regulatory Authority (NRA), which may be separate from the PV centre. Also, the targets for inspection are therefore those that are regulated by the NRA, generally pharmaceutical companies rather than individual health professionals. It is important however to note that definitions of PV inspections will vary from country to country.

PV inspections can be conducted on a ‘routine’ (for example, all new companies should be inspected) or when needed (for example, when an anomaly is detected) basis. Based on the experience of countries that have recently commenced PV inspections, it was suggested that a pragmatic approach is that countries start by setting a level of PV inspections which they have the capacity to perform, for example to inspect a certain number of facilities per year.

The working group discussed recommendations for the coordination, conduct and procedures for carrying out PV inspections.

Recommendations:

- National Regulatory authorities (NRA) should take the responsibility of carrying out PV inspections. Collaborations between the NRA and national PV centres will be important in instances where the national PV centre is not part of the regulatory authority.
- Guidelines and procedures need to be developed for carrying out PV inspections and the WHO could take the lead on this together with countries that already have established procedures for PV inspections.