

WHO News

Vigilance of HIV/AIDS drugs. Monitoring anti-retrovirals in sub-Saharan Africa ¹

Bruce Hugman reports on a major training initiative to enhance the safety of HIV/AIDS patients under treatment

Twenty-six representatives of eight African countries met in Pretoria, South Africa, from 1–10 September on a WHO-sponsored training course² to study how antiretroviral (ARV) therapy on the continent could be monitored for quality, safety and effectiveness.

Countries represented were: Kenya, Malawi, Mozambique, Nigeria, South Africa, Uganda, United Republic of Tanzania, and Zambia. Teaching was provided by staff from WHO HQ, the UMC, a number of experts from around the world and by participants themselves.

As HIV/AIDS treatment programmes roll out across Africa, and more and more patients gain access to ARVs, the need for post-marketing surveillance becomes ever more urgent. While much is already known about ARVs from the experience of developed countries, there is little data on patients from a wider ethnic spectrum, where the introduction of multi-source generics, as well as genetics, diet and other variables may influence the effectiveness and risks of ARVs.

Host country

South Africa was chosen for the training course because of the high percentage of the nation's infected population and because considerable progress has been made in developing safety monitoring activities in the country.

During the course, participants attended the opening of the MEDUNSA³ Pharmacovigilance Centre by the Minister of Health, The Hon. Dr. M.E. Tshabalala-Msimang. This brand-new facility will complement the existing ADR monitoring centre at Cape Town University and will give priority to monitoring of ARVs.

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²Financial contributions from the governments of Japan and Ireland and the European Commission made it possible to organise this workshop.

³Medical University of South Africa.

A tough curriculum

The participants faced a packed, ten-day programme which covered the following major topics, amongst much else:

- Theory and practice of pharmacovigilance;
- Establishing and running a pharmacovigilance centre;
- The WHO 3 by 5 strategy⁴;
- Risk evaluation and causality assessment;
- Current knowledge about ARV therapy, toxicity, side-effects and prognosis;
- Reporting, data collection and research methods;
- Communications issues, including training skills, media relations and crisis management;
- Development of an action plan for each country;
- Plans for future networking and collaboration.

Mary Couper, from the WHO Quality and Safety of Medicines team, who organised the course on behalf of the Essential Drugs and Medicines Policy division, commented on the quality of the participants and their work:

“As ever with limited time, the programme was very ambitious in terms of its scope and depth. However, any anxieties we may have had were swept away by the energy of the group and its evident hunger for knowledge. Particularly impressive was the way that the participants who were already experienced in drug safety issues took the opportunity to push the boundaries of their knowledge forward, and contributed generously to the group’s learning.”

The challenge of effective therapy

A major issue which became dramatically clear was the degree of attention that patients on ARVs need if they are to enjoy optimal benefits and quality of life. Adherence and tolerance of side-effects were two of the big issues in patient management.

No-one was left in any doubt that only meticulous management of patients and recording of every aspect of therapy and response, including side effects, would provide the best hope for the welfare of individuals and for the accumulation of knowledge that would lead to improved therapy in the future: access to ARVs was only a part of the story.

The future

Among participating countries, South Africa and Tanzania already have pharmacovigilance systems in place, while Mozambique and Zambia are in the early stages of development; Nigeria’s was launched on 9 September, just as the course finished. Plans were made for following up countries’ progress after

⁴The global objective of having three million patients in developing and middle income countries under ARV treatment by the year 2005.

the course, and for future collaboration. It was the hope of all that the importance of post-marketing surveillance of ARVs would become unconditionally accepted by the authorities, and that adequate, harmonised systems would soon be in place across the continent.

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