

Lareb Intensive Monitoring

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This year the Netherlands Pharmacovigilance Centre Lareb will start a web-based intensive monitoring program in order to receive earlier information about the safety of new drugs.

Intensive monitoring programs are observational cohort studies, investigating specific (new) drugs. These programs are used in some countries as part of the national pharmacovigilance system. The New Zealand Intensive Medicines Monitoring Programme (IMMP) was established in 1977¹. Since 1980, the United Kingdom uses a form of intensive monitoring called *Prescription Event Monitoring* (PEM)². In both systems questionnaires about the investigated drugs are sent directly to the prescribing physician, two to six months after the first prescription. Cohorts vary between 10,000 and 50,000 patients.

Intensive Monitoring at Lareb

Lareb Intensive Monitoring (LIM) is based on two pilot studies, carried out in the Netherlands in 1995 and 2001^{3,4}. In the first study, the questionnaires were given directly to the patients. In the second study they were sent by the pharmacist to the prescribing physician. Those studies showed that the first prescription signal in the pharmacy computer system provides a valuable tool for an early detection of patients who start with a new drug.

For Lareb Intensive Monitoring we have developed a website-based system, which automatically generates questionnaires. The electronic forms are sent directly to the users of a new drug.

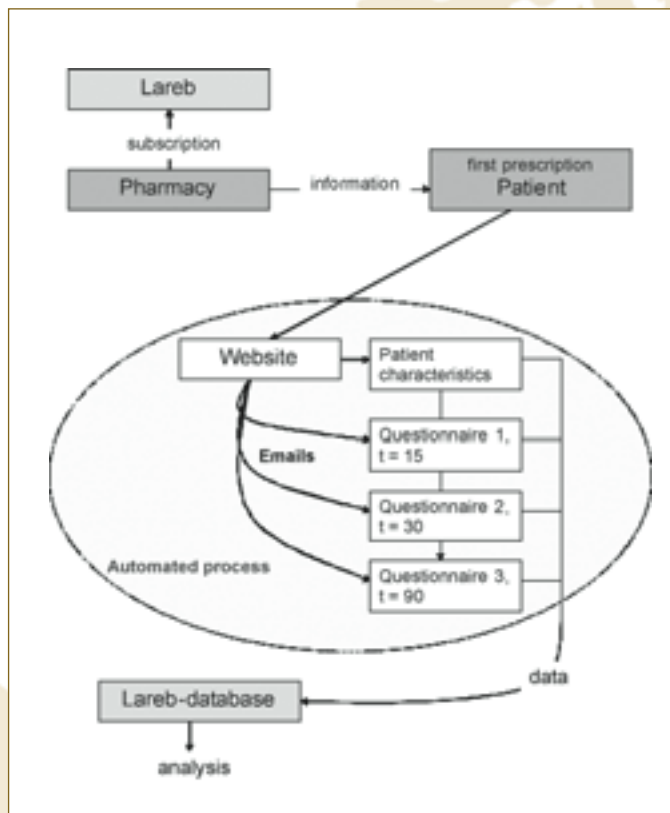
The choice for such a system is an obvious consequence of earlier changes in our organization. Since 2003 patients can report adverse events directly to Lareb. A first analysis shows that these consumer reports are reasonably well documented and can contribute to the generating of new signals⁵. For this reason we chose a direct patient approach in our intensive monitoring system. The second project which led to the design of the system was our 'transparency website', started in 2005. On this website we made all ADR reports and publications accessible for everybody. The good experiences with the development of such internet technology resulted in the website based approach of Lareb Intensive Monitoring.

How does it work?

Patients who start for the first time with a new drug are selected in their own pharmacy using the first prescription signal. The pharmacist asks if the patient has internet access and would like to participate in a nationwide study concerning new drugs. The patient receives, together with his drugs, information about the intensive monitoring system and a pharmacy-unique login code. With this code, the patient can register himself on our website as a participant in Lareb Intensive Monitoring. Two weeks after starting the new drug, the patient receives his first electronic questionnaire by e-mail. As long as he continues the use of his drug, follow-up questionnaires will be sent automatically at several specific points in time. These moments can vary between the monitored drugs. In addition to questions about adverse drug reactions and drug use, it

is possible to add extra questions to every questionnaire for each specific drug. All answers are stored in a central database, separate from our regular reports.

We do not send direct feedback to the participating patients, but we inform their pharmacists about general (preliminary) results. Each pharmacist receives a private account on our website where they can see which patients from their pharmacy participate in the intensive monitoring program.



Co-operation

The Dutch Medicines Evaluation Board (MEB) will fund the Lareb Intensive Monitoring system for the next three years. The choice for the monitored drugs will be made in close co-operation with the MEB. When there are safety issues, for example in a European context, the MEB can ask for specific analysis. Because the role of the pharmacist is crucial in this form of intensive monitoring we co-operate with several pharmacy organizations. The Royal Dutch Pharmaceutical Society (KNMP) is an official partner. In addition we get the support of several large collectives of pharmacies.

Potential benefits

With Lareb Intensive Monitoring we monitor the first users of a new drug, directly from the first intake. This facilitates an early finding of unexpected adverse drug reactions. Because we receive our information directly from the drug users, also associations which

are at first sight not pharmacologically plausible will be reported; there is no 'professional filter'.

All kind of adverse events will be reported, known and unknown, serious and non-serious. This generates a broad overview of the ADR profile of the monitored drug. In addition we have the possibility to investigate other topics, because we can add additional questions to each questionnaire.

At this moment we are performing a short study in 20 pharmacies, to collect experiences with the system from patients and pharmacists. We will start to monitor the first drugs in summer 2006. From that moment all Dutch pharmacies can participate in the Lareb Intensive Monitoring program.

References:

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Uzbekistan – first course on pharmacovigilance and patient safety

A partnership between two health consumer organizations DrugInfo Moldova and the Consumer Institute 'Kilen' in Sweden, financially supported by the Swedish aid organization Sida, has resulted in a series of conferences in Eastern Europe and Central Asia about patient safety in general and people living with HIV/AIDS and TB in particular. The UMC was involved in a pharmacovigilance training course in Chisinau, Moldova in April 2004 (see UR 30); as it was considered successful and useful it was followed by a similar training workshop in Tashkent, Uzbekistan, on 28 to 31 March this year.



Dr H K Jalilov, head of the drug control agency, addressing the workshop.

The first day plenary lectures were held in the offices of Ministry of Health. The following days were devoted to working group sessions and discussions held at the Department of Drug and Medical Equipment Quality Control which is the drug regulatory authority of Uzbekistan. Participants represented all significant partners involved in the health care and pharmaceutical supply system in Uzbekistan, most of them from the Tashkent area. Teaching institutions were also involved. Presentations were made by Uzbek experts, by representatives of the Moldovan and Swedish organizers, and by Sten Olsson from UMC, representing the WHO Pharmacovigilance Programme.



Dr B Sh Shaislamov, chairman of the pharmacological committee, head of the pharmacovigilance centre

The presentations stimulated lively discussions among the course participants who, towards the end of the week, changed the planned course programme. It was felt essential that the meeting should result in tangible recommendations for managers of various sectors of the Uzbek health care system to particularly address patient safety issues during drug therapy. A series of recommendations were agreed upon by the course participants. They were submitted to the Department of Drug and Medical Equipment Quality Control for consideration and action. Kilen and DrugInfo Moldova organized a meeting also in Samarqand, on 3 to 5 April, at which the recommendations were discussed. The drug control agency later circulated the recommendations to relevant parties in other parts of Uzbekistan to solicit a broad acceptance of measures needed to improve pharmacovigilance and patient safety in the country. Since the recommendations are still not available in English they unfortunately cannot yet be quoted here.