

# Uppsala Reports 46

UPPSALA REPORTS July 2009

For everyone concerned with the issues of pharmacovigilance

**WHO Programme members introduced**

**Global network for vaccines safety**

**Latest research at the UMC**

**Traditional medicines initiative**

**Alice in Vigiland**



# ALICE IN VIGILAND



Alice took blue tablets from one of two bottles. She woke up under a giant toadstool looking at the Mad Hatter. "Curiouser and curiouser", she said.

"Alert or signal?" he replied.

"I'm certainly not alert, nor do I want to make anyone else alert; but I do want to send a signal that I am here because of those blue tablets."

"Can't!" he shouted, " 'cos you don't know how you got here."

"I only got here, stupid, after I took the tablets. I didn't do anything else: it must be those. I want to report that – and you!"

"Keep your hair on!" he said, observing her hair floating slightly, "Is it a spontaneous report you want to make, or the 'new passive stimulated report'?"

"Well the report isn't going to happen unless I make it. And I HAVE thought about what I want to write, so it's not spontaneous. I am very stimulated to write and certainly NOT passive. Aren't there any different reports I can write, that aren't silly?" she asked crossly. "I TOLD you I want to send a signal."

The Mad Hatter's eyes glazed. He cackled hysterically, doubling up until his head hit the ground. He started back upright, caught his breath, and managed to stutter, "A signal! By which d-d-d-definition. Ha haah! Caught you! caught you!"

Alice was shocked at his manic outburst; what could it mean? she asked.

"There's one, another, another and another," the words came staccato from the Hatter, "I'll tell you. Listen! A signal is," and he began to recite –

"Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented."

"A report (or reports) of an event that may or may not have a causal relationship to one or more drugs; it alerts health professionals and should be explored further."

Alice caught sight of her hair in a conveniently-positioned mirror. It was transformed into a

large red cat. She screamed, because it had five heads and many claws simultaneously pulling in different directions. "I'm the Committee Cat," said the cat, arranging itself singularly for an instant before metamorphosing into ten, joined by a multi-coloured tail.

The Mad Hatter continued: "A signal in pharmacovigilance is more than just a statistical association. It consists of a hypothesis together with data and arguments, arguments in favour and against the hypothesis. These relate to numbers of cases, statistics, clinical medicine, pharmacology (kinetics, actions, previous knowledge) and epidemiology, and may also refer to findings with an experimental character."

He was disturbed by loud snoring from underneath a table. A dormouse was sleeping soundly, but then opened one eye, and sleepily offered, 'Twinkle, twinkle little star....' and dropped off again.

The Hatter, undeterred, went on, each word relished, "Information that arises from one or multiple sources (including observations and experiments), which suggests a new potentially causal association, or a new aspect of a known association, between an intervention and an event or set of related events, either adverse or beneficial, which would command regulatory, societal or clinical attention, and is judged to be of sufficient likelihood to justify verifiable and, when necessary, remedial actions."

The Mad Hatter paused for breath, "And there's more....."

"Off with their heads. One definition for me, and one for all," shouted the Queen of Hearts who had appeared with her entourage. She looked threateningly around her, as her pack of pharmacovigilantes rapidly dispensed themselves into hiding amongst the undergrowth.

The Committee Cat had grown considerably and enveloped Alice's head and shoulders, threatening to suffocate her. "No stop, stop! Please, please, all I want to do is to tell somebody about this awful thing that's happened to me and have them help me to get back." Alice cried. "I do also want to warn other people about it," she added.

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The Uppsala Monitoring Centre (*the* UMC) is the field-name of the WHO Collaborating Centre for International Drug Monitoring, responsible for the management of the WHO Programme for International Drug Monitoring.

An independent centre of scientific excellence, *the* UMC offers products and services, derived from the WHO database of Adverse Drug Reactions (ADRs) reported from member countries of the WHO Programme.

With an independent and global perspective on drug safety, *the* UMC provides resources for regulatory agencies, health professionals, researchers and the pharmaceutical industry.

The UMC's important worldwide work is financed solely by the organisation itself, without support from WHO, the Swedish Government, member countries of the WHO Programme or any grant-making body.



## 4 UMC international course

From around the world, students descended on Uppsala at the end of May for the biennial pharmacovigilance training course.



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## 13 Spanish achievements

Among several conference reports, a quarter of a century in Spain celebrated in Oviedo...



## 15 Traditional medicines

...and an important gathering of stakeholders in traditional Chinese medicine meet in Hong Kong to discuss classification.

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## Uppsala trains the world

Anna Celén

For two weeks from May into June, and with varying weather, the UMC organized its 12<sup>th</sup> international pharmacovigilance course in Uppsala. The total number of participants since the course started in 1993 has reached 300, and the demand for training is ever-increasing with tough competition to get on the course. Only a third of the 100 applicants from 50 countries got places, but the final group consisted of a great mix of dedicated pharmacovigilantes, from regulatory authorities, pharmaceutical companies and other institutions.

### Theory and practice

The course is intended primarily to support the development of programmes for spontaneous adverse reaction reporting and to give an introduction to other methodologies, and as before, the course consisted of different modules. The first module, common for all participants, dealt with many aspects of pharmacovigilance in general, both theoretical and practical. The theoretical parts included lectures, group discussions and presentations of national pharmacovigilance systems by some of the participants. Practical sessions included recording of case information in, and retrieval of information from VigiBase.



Course participants assembled on the steps in front of Uppsala cathedral.

This year's course included some parallel sessions to meet the specific needs of industry representatives. While the participants from regulatory agencies were learning how to establish a pharmacovigilance centre and how to design effective ADR reporting forms, the participants from industry settings were getting into regulations, Periodic Safety Update Reports and Risk Management Plans.

After the first module, most of the group stayed on and a few additional participants arrived to take part in one of the two second modules that focused on pharmacoepidemiology and effective communications, respectively.

The principal faculty during the two weeks consisted of a number of UMC staff as well as experts from other organisations: WHO Headquarters, the Medical Products Agency (Sweden), Swissmedic (Switzerland), the Regional office for Patient Safety in Copenhagen, Utrecht University and Elliot Brown Consulting.

### Countries represented

|            |            |                   |
|------------|------------|-------------------|
| Andorra    | Ghana      | Republic of Korea |
| Barbados   | Hungary    | Rwanda            |
| Belgium    | India      | Saudi Arabia      |
| Cambodia   | Iraq       | Senegal           |
| Chile      | Jamaica    | Sierra Leone      |
| Estonia    | Japan      | St. Lucia         |
| Ethiopia   | Kenya      | Sweden            |
| Finland    | Mozambique | Switzerland       |
| The Gambia | Nigeria    | Tanzania          |
| Germany    | Peru       | Turkey            |

### Being social

Building valuable new relations with other course participants and having a great time is as important as the scientific part of the training course. A number of social gatherings were arranged, including a welcome reception, an official course dinner and an opportunity to visit the UMC office and meet up for dinner in the evenings. The official course dinner took place on a boat along the Fyris river running through Uppsala, and gave participants a glimpse of the surrounding countryside. The main venue of the course, Gustavianum, also offered a unique environment as the oldest



The ancient Gustavianum building, main course venue.

preserved building of Uppsala University, founded in 1477. Some sections of this extraordinary building date back to the Middle Ages and the highlights are the anatomical theatre constructed in the 1660s and the Augsburg art cabinet given as a gift to a former Swedish king.

## ...and the result?

The general opinion about the course was very positive in spite of the heavy programme. After the closing ceremony, where the UMC Director Ralph Edwards proudly handed out the course certificates, the participants left Uppsala exhausted but with new friendships, ideas and enthusiasm. It will be very exciting to follow-up on the progress in their respective countries as a result of their acquired knowledge, experience and strengthened commitment to patient safety.



*Bruce Hugman leads the module II group on communication.*

## Feedback from Course participants

"It was a great pleasure to learn so many things from a cross-cultural group."

"Exposure to concepts and innovative solutions was intellectually stimulating."

"It was fully packed and covered the breadth of pharmacovigilance."

"I would have wanted more detail on a lot of things, for which there was not enough time."

"The course equipped me with the necessary tools as a pharmacist to perform my day-to-day activities."

"Speakers should always give a list of references for further readings."

"The concept of partly dividing the group, into 'National Centre module' and 'Industry module' was very good."

## 32<sup>nd</sup> WHO Programme meeting

A preliminary agenda for the annual meeting of countries participating in the WHO Programme for International Drug Monitoring has now been decided.

The meeting, to take place in Rabat, Morocco from 2-5 November 2009 will, as ever, allow representatives from the increasing number of countries in the WHO Programme to meet and discuss important issues affecting pharmacovigilance centres.

Among the plenary lectures will be presentations on cohort event monitoring (updates on the major projects in Tanzania and Nigeria and on data management issues), the WHO Biosimilars guideline, safety monitoring in a possible flu pandemic, and the possibility and desirability of harmonization in the approach to risk management plans.

There will also be reports from matters arising at the Uppsala meeting last year and which have been worked on during the year, and regular updates, from the UMC, as well as from guest speakers on training needs to promote patient reporting, Affordable Medicines for Malaria (AMfM), the role of the WHO advisory committee ACSoMP, and the WHO-ART/MedDRA bridge.

Two sets of working groups will cover such diverse topics as medication error, harmonization with norms and standards groups, obtaining resources for pharmacovigilance programmes, generic manufacturers in pharmacovigilance, pregnancy and medicines, and interaction between academia and regulation.

The meeting will also include the traditional pre-meeting seminar for new delegates to learn about the work of the UMC, as well as a MedDRA workshop and a VigiFlow User Group meeting. A meeting of the Global Network for Post-marketing Surveillance of Newly Pre-qualified Vaccines (*see page 11 of this Uppsala Reports*) will follow the Annual Meeting.

Country representatives will present and discuss early case hypotheses in the 'Problems of Current Interest' sessions, and interactivity and discussion will be emphasized throughout.

National Centres will have access to more information and travel instructions over the coming weeks via the UMC website, and will also be sent more details by post. 25 countries have already indicated that their representatives will be present in Rabat. Enquiries about the meeting can be made at any time to Geoffrey Bowring or Sten Olsson at the UMC.

## Sudan

*Bushra Elnagar*

*Head of the Pharmacovigilance Department, Sudan Federal Pharmacy and Poisons Board*

In Sudan, with hundreds of ethnic and tribal groups and an estimated population of about 40 million, many drugs have been extensively used for a long time among these populations; unfortunately they have not been accompanied by monitoring of their safety profile.

### History

The importance of monitoring drug safety was set out in the Sudan National Drug Policy, and the requirements for a proactive method for monitoring adverse drug reactions and interactions was comprehensively addressed in the Pharmacy Strategic Plan (2000–2025). The pharmacovigilance programme was established in the Pharmaceutical Inspection Department of the Directorate General of Pharmacy in February 2006, as a post-marketing surveillance unit. It was concerned with assuring the safety of medicines circulating in the Sudanese market as part of the global trend in containment of counterfeit medicines, focussing on drug quality and reporting of any suspected non-compliance cases. The unit expanded its remit to include monitoring of adverse drug reactions in February 2007, when the first ADR case report form was developed.

Restructuring in the Directorate General of Pharmacy has resulted in the separation of policy functions from the regulatory functions (as recommended by the WHO). This resulted in the organisation of pharmaceutical services within the Ministry of Health. The Federal Pharmacy and Poisons Board are now responsible for regulation and administration of drug-related legislation; the pharmacovigilance programme moved to the Board in 2008.



*Bushra Elnagar*

ADRs as well as guidance for healthcare professionals on filling out the ADR case report form. The quality and quantity of ADR reports received was not good, but this was expected as our pharmacovigilance programme was still in its infancy and yet to gain the momentum needed to cope with the demands of a country that is already under the pressure of war, instability and high disease burden.

In May 2008, in collaboration with the Euro Health Group, the pharmacovigilance department conducted a pilot project to monitor ADRs in the three public health programmes: HIV/AIDS, TB and

malaria. At the conclusion of this project a workshop was held to present information to health care professionals who had participated and also to physicians, specialists and pharmacists from other hospitals. The workshop had a direct impact on both the quality and quantity of ADR reports received subsequently. Driven by this workshop Sudan generated a sufficient number of reports to become a full member of the WHO Programme.

In our department we believe that the reporting of adverse drug reactions by health professionals needs continuous stimulation and it is very important to create a positive attitude towards pharmacovigilance among health care professionals so that reporting becomes an accepted and understood routine. So alongside workshops or seminars in hospitals, we encourage health care professionals to report ADRs by calling them or visiting them in the hospitals. We also provide easy access to reporting forms in hospitals, acknowledge receipt of ADR reports, and provide feedback to reporters by e-mail or telephone.

The department plans to introduce pharmacovigilance in the curriculum of medical colleges for undergraduate students, after the successful introduction of pharmacovigilance into the internship training programme for graduate pharmacists.

The Sudan pharmacovigilance programme's medium-term objectives are to engage more healthcare professionals and non-governmental organizations (NGOs) in the drug monitoring process and the dissemination of information in order to generate a broad-based adverse drug reactions database on the Sudanese population and share this information with the global healthcare community through the Uppsala Monitoring Centre.

The department works very closely with the major public health programmes and is now preparing for a long-term project to monitor the adverse drug reactions caused by the drugs used in these programmes.

### Current and future challenges

Within the WHO Programme, the optimal national pharmacovigilance centre sends over 200 reports per million inhabitants per year. The main challenge for us is therefore to generate sufficient ADR reports relative to our population and to enter and analyze these data regularly, to avoid a backlog. The other challenges are to train and maintain a pharmacovigilance team that can implement and manage a pharmacovigilance programme over several years including timely adverse drug reactions data processing and sharing of information with appropriate health authorities.

The Sudan programme is now well-known and gradually improving. We hope to overcome challenges over the coming years, putting more effort into achieving such operational efficiencies as would make the Sudan National Pharmacovigilance Programme a benchmark for global drug monitoring endeavours.

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# Barbados

*Rosamund Lovell*

As was reported in UR43, Barbados became a full member of the WHO Programme for International Drug Monitoring in July 2008. Barbados is an island of some 430 sq km (166 sq miles) in the Caribbean with a population of 264,000.

So far, the Barbados Drug Service, the agency responsible for pharmacovigilance on the island, has designed a reporting form and disseminated it to the main hospital, polyclinics and private health facilities. Medical practitioners have been informed about the reporting and attempts are on-going to engage with pharmacists.



*The main building for pharmacovigilance activity in Barbados.*

As with all new centres, there are challenges to be faced, among them, legislative changes, stimulating reporting, and lack of staff time. However, progress has been made on the legislative front, and a member of staff recently attended the 2-week pharmacovigilance course in Uppsala to broaden their knowledge and skills in the area. VigiFlow is being used as the reporting and analysis tool, and there is close co-operation with other centres in the Caribbean and central America.

The current contact is Mrs Maryam Hinds, Director, Barbados Drug Service, and the address is:

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# Madagascar

*Dr Jean-René Randriasamimanana, Dr Donat Rakotomanana*

On 13 February 2009, Madagascar became the 94th full member of the WHO International Drug Monitoring Programme.

The Madagascar Centre National de Pharmacovigilance (CNPV) was created in February 2006 after the Agence du Médicament de Madagascar (AMM) director's visit to the Centre de Pharmacovigilance et de Matérovigilance, in Algeria, and a national workshop held in Antananarivo where WHO Roll Back Malaria introduced the new combination therapy with Artesimin-Amodiaquine. This workshop was the chance for Madagascar to set up the Malagasy national pharmacovigilance system, with a realistic national action plan.

Following intensive training of the CNPV staff at the Moroccan Centre Antipoison et de Pharmacovigilance, in Rabat, several activities were carried out in 2007 including the development and testing of an adverse drug event (ADE) reporting form, and a training curriculum designed for health professionals working at primary health care level.

66 trainers from the 22 regions of the country have now been trained in basic technical competence in organizing and running a pharmacovigilance training session. Moreover, 426 health professionals, including medical doctors and nurses, attended training sessions to get general and practical knowledge on pharmacovigilance, and learnt how to use the ADE reporting form.

The training at the district level will continue during 2009. As a result of these efforts, there has been an increase of the number of ADEs reported from different parts of the country including many areas with ongoing mass treatments initiated by WHO.

In 2007-2008, active monitoring was carried out with UNICEF during the operational research about 'Intermittent Preventive Treatment of malaria in Infants', using the sulfadoxine-pyrimethamine combination, and 2,656 ADEs were collected.



*From left to right: Dr Sabrina Lock Njarsoa (Assistant), Dr Jean-René Randriasamimanana (Director, AMM), Dr Donat Rakotomanana (Head of CNPV), Dr Hantamalala Ravelomanantena (Assistant).*

From passive reporting, 478 ADEs have been so far reported to CNPV, with antimalarials, antihelminthics such as praziquantel and anti-anemia drugs as the main therapeutical classes involved.

In 2007, for the first time, the Centre attended the Annual Meeting of the national pharmacovigilance centres, in Buenos Aires, Argentina. During the meeting, the CNPV staff learnt more about sharing experiences with colleagues from other countries and ways to improve the use of VigiFlow. The meeting was also an opportunity to realize the importance of visual materials in communication and raising public awareness on drug safety issues.

All these achievements have been made possible thanks to the strong support of the Malagasy Ministry of Health and with international technical and financial help. The Agence du Médicament de Madagascar and the CNPV team are very grateful and would like to address their special thanks to the following:

- ◆ WHO Roll Back Malaria
- ◆ CDC Atlanta
- ◆ the UMC
- ◆ USAID
- ◆ US Pharmacopeia Drug Quality and Information Program
- ◆ MSH/RPM-Plus
- ◆ UNICEF
- ◆ the Centre Anti-Poison et de Pharmacovigilance of Morocco
- ◆ the Centre de Pharmacovigilance et de Matéiovigilance of Algeria.

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## Stop Press

As we go to press, Senegal has fulfilled the requirements to become a Full member of the WHO Programme for International Drug Monitoring, and thus becomes the 95th member of the Programme. Further information and contact details will follow in the next Uppsala Reports.

In April Burkina Faso submitted an application to be part of the Programme, and has therefore joined the group of Associate members.

## Sierra Leone

*Sahr Emmanuel Gbomor*

*Drug Information and Pharmacovigilance Department Pharmacy Board of Sierra Leone*

Sierra Leone is on the western coast of Africa. Emerging from a decade-long civil conflict, it is addressing the negative impact that had on social services, particularly health care. The GDP per capita one of the lowest globally, infant and maternal mortality are amongst the highest, there is a lack of appropriate public health finance systems and expenditure on health is predominantly out-of-pocket with medicines representing the largest proportion of such expenditure.

Including public, private and NGO sectors, Sierra Leone has 83 hospitals and 862 primary health care units, but a very poor ratio of health personnel to population, especially in surgeons and paediatricians; the population is 5 million (41% aged under 15).

### Background

Our programme is hosted by the Drug Information and Pharmacovigilance Department (DIPD) of the Pharmacy Board of Sierra Leone which serves as the National Pharmacovigilance Centre. The programme was launched in 2006; in August 2008 a technical mission from WHO completed an assessment of the implementation of the drug safety monitoring programme (see UR43 p7). Sierra Leone attained full membership of the WHO Programme for International Drug Monitoring as its 87th member, in October 2008.



*Staff at the Sierra Leone national centre.*

### Implementing agency

The DIPD consists of three units: Pharmacovigilance, Import and Narcotics Control, and Information Services, with a staff of eight. There is a nine-member Expert Committee on Drug Safety, (two physicians, a pathologist, surgeon, public health specialist, one from disease prevention and control, a hospital pharmacist, industrial pharmacist, and community pharmacist).

### Stakeholders

The stakeholders in the implementation of the drug safety monitoring programme in Sierra Leone include all public health programmes:



malaria, HIV/AIDS, school health, TB and leprosy, EPI and reproductive health. The national programme maintains contact with all government-owned hospitals and primary health units, forces medical services, private clinics, the WHO and the Uppsala Monitoring Centre.

Reporting is mainly through healthcare providers although patients can also report directly. Report flow from the provinces is through our regional offices/public health programmes.

### Current position

Although a little over two years old the programme has made a number of strides. Training for over 350 health care providers of different cadres has been undertaken countrywide. 6,000 ADR report forms have been distributed, and material on the reporting of adverse drug reactions have been developed and distributed. The DIPD now publishes a quarterly newsletter. Jingles educating the general public on the need to report adverse drug reactions to the Board have been developed and are currently being aired on the radio.

A one-year action plan to further strengthen the programme was agreed following the 2008 technical mission. Discussions are almost complete for the setting up of pharmacovigilance structures within public health programmes and discussions on the harmonization of the current ADR form used by the DIPD with that used by EPI are complete.

### Challenges

Despite initial successes, the department is faced with the challenges of inadequate financial support, lack of logistics to reach every corner of the country, low reporting on the part of health care providers and inadequate staff strength at headquarters. In future the DIPD envisages:

- a pharmacovigilance element within all public health programmes, along with strengthening regional offices to carry out pharmacovigilance visits
- having pharmacovigilance made part of the curriculum of tertiary institutions involved in the training of healthcare providers
- recruitment of more staff for the DIPD.

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## A new level of UMC presence in Africa

An agreement was recently signed between the UMC and Alex Doodoo, Acting Director, Department of Tropical Clinical Pharmacology, Korlebu Teaching Hospital, Accra, Ghana, with the objective of increasing the capacity of UMC support to pharmacovigilance development in African countries. It is envisaged that Dr Doodoo will act as a liaison person between national pharmacovigilance centres and public health programmes in Africa and WHO/UMC. He will help in defining and channeling the specific needs of African pharmacovigilance programmes while stimulating the optimal use of UMC tools, services and training facilities in Africa.

Activities will support the strategic goals of the WHO Programme and will include strengthening of networks, and support to drug safety research, particularly cohort event monitoring in public health programmes. Alex Doodoo will also be active in promoting pharmacovigilance and assist in resource mobilization for patient safety activities.

Alex Doodoo's activities on account of the WHO Programme are financed by a fellowship from the UMC. The agreement is valid for a five year period with annual reviews of performance and progress.

## Developments in VigiFlow

### VigiFlow™ 4.1 released

The Individual Case Safety Report (ICSR) management system developed by the UMC has been updated. The new version is VigiFlow 4.1 and it was released on June 25, 2009. The biggest change is a complete new functionality for searching for and selecting drugs from the WHO Drug Dictionary and reaction terms from WHO-ART. Those users that have MedDRA have a new functionality for searching for and selecting MedDRA terms.

Another major change is that the functionality to update committed reports has been adjusted. The words used are now the same as for E2B: 'follow-up' and 'amendment'. Also in VigiFlow 4.1 the decision if the update is a follow-up or an amendment is made when the updated report is committed again.

Yet another change is that the filters for searching in the list of committed reports and list of reports under assessment has been extended with many new filter options. The new filters will significantly simplify the search for duplicates in VigiFlow.

All changes are described in the release notes for VigiFlow 4.1; these can be received by e-mail from the UMC on request. The User Guide (available after log in to VigiFlow) has also been updated with the changed functionalities.

Next year, a major change in the Search and Statistics module in VigiFlow is planned. This is where all VigiFlow users can perform advanced searches and statistical analyses of their own reports in VigiFlow. If you want to influence how the new Search and Statistics module is developed, please contact the UMC by e-mail. A presentation of the planned changes will be given at the National Centres meeting in Rabat and it will also be possible to give input there at the User Group meeting.

Please send VigiFlow related e-mail to [vigibase@who-umc.org](mailto:vigibase@who-umc.org)

### VigiFlow training

The UMC is currently developing a web-based course for VigiFlow users. The course content includes an introduction to VigiFlow, an overview of the fields and functions of the interface, and exercises to consolidate and deepen the knowledge of how to enter ICSRs into VigiFlow.

A pilot version of the course has been evaluated during the last few months by VigiFlow users with different levels of previous experience. The course is now being adjusted according to the feedback from pilot users and also updated with the changes in VigiFlow 4.1. As soon as this has been completed, the course will be available to all current and new VigiFlow users.

## PaniFlow

### Prepared to monitor adverse events during the influenza A (H1N1) pandemic

The WHO officially declared the outbreak of the new A (H1N1) influenza to be a pandemic on June 11, 2009. Part of the pandemic preparations concerns the development and production of vaccines against the influenza A (H1N1) virus. Given the time constraints these new pandemic influenza vaccines will have an incompletely described safety profile. In the setting of a pandemic, with mass vaccinations on a global scale, one of the challenges is the early detection of (new) adverse events.

In order to meet this challenge the UMC has developed PaniFlow by order of and in collaboration with the Swiss medicines agency, Swissmedic. PaniFlow is a web-based system to specifically monitor adverse events following administration of drugs and vaccines during a pandemic. PaniFlow has data-entry and management tools similar to VigiFlow. Analysis is currently undertaken with an internal tool developed by Swissmedic.

At the moment PaniFlow is only available for Switzerland, but the system can be adapted to accommodate the specific monitoring needs of other countries. A more extensive description of the PaniFlow system will be published in the next Uppsala Report.

The focal point at UMC for information on PaniFlow is Jerry Labadie ([jerry.labadie@who-umc.org](mailto:jerry.labadie@who-umc.org)).

# 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](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.

## ISPE in Stockholm

Anna Kindlundh Högberg and Richard Hill

On April 27 several UMC staff attended ISPE's mid-year symposium 'From thalidomide to pharmacovigilance and pharmacoepidemiology: has drug safety and effectiveness really improved since thalidomide?' at the Karolinska Hospital in Stockholm, just an hour away from Uppsala.

### Morning: Pharmacovigilance

There were two talks about the thalidomide tragedy: The first, 'From Thalidomide to Pharmacovigilance to Pharmacoepidemiology in Sweden' was from Barbro Westerholm (Professor Emeritus, Karolinska Institutet, Member of the Swedish Parliament), the second 'The Irony of the Thalidomide Experience – When Will We Apply Its Lessons to Safety Surveillance for Antenatal Exposures?' by Allen A Mitchell (Slone Epidemiology Center at Boston University, USA). Allen Mitchell addressed the lessons learned from thalidomide, specifically, that drugs can cross the placenta; that drugs may be safe for the mother but dangerous to the child; that drugs cause specific birth defects; and that timing in pregnancy of drug administration is crucial.

Ralph Edwards of the UMC gave a long and interesting talk on 'The WHO International Programme: From Tabulated Case Reports to Knowledge Finding in Multiple Global Data Sets', which covered the most important work and tools behind signal detection at the UMC.

In 'New European Activities in Drug Safety Research: EMEA and ENCePP' Miriam Sturkenboom (Erasmus University Medical Centre, The Netherlands) discussed a range of EU activities, including the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCEPP – [www.encepp.eu](http://www.encepp.eu)), specific programmes, including one examining the safety of NSAIDs ([www.sos-nsaids-project.org](http://www.sos-nsaids-project.org)), and a project data mining electronic health records ([www.euadr-project.org](http://www.euadr-project.org)). Liselotte Diaz Högberg (Deputy Director of ReAct on Antibiotic Resistance, Sweden) gave a talk on 'Antibiotic Resistance – The Hidden Threat to Global Public Health and The Missing Link in Pharmacovigilance': antibiotics are widely misused clinically in terms of over treatment, with an increased risk of antibiotic resistance and thus treatment failure.

### Afternoon: Pharmacoepidemiology

Sebastian Schneeweiss (Harvard Medical School/Brigham & Women's Hospital, USA) had a presentation about 'Comparative Effectiveness Research from the Perspective of a Pharmacoepidemiologist', where he stressed the benefits of comparative effectiveness research in order to evaluate effectiveness from treatment outcomes in routine care, and claimed that adjusting for large numbers of covariates may improve control of confounding, as these variables may collectively be proxies for unobserved factors. Data sources could be combined (electronic medical records and prospective registry studies) in comparative effectiveness research.

Thomas MacDonald (Medicines Monitoring Unit, University of Dundee, United Kingdom) spoke about comparative effectiveness under the title 'Methodological Challenges in Comparative Effectiveness Research'. Michael Kelly (National Institute for Health and Clinical Excellence (NICE), United Kingdom), in 'Non-Randomized

Effectiveness Data and Decision Making in Sweden' raised a number of principles to consider when designing non-randomized studies to assess comparative effectiveness in health care, such as cost effectiveness, openness and transparency, contestability, impendency of government and pharmaceutical industry.

Göran Isacson (Department of Psychiatry, Karolinska Institute) in 'Individual-Based Studies Indicate a Strong Suicide Prevention Effect of Antidepressants' talked about a large study including 16,937 suicides and 33,426 controls between the years 1995-2005, which found a causal relationship between treatment of antidepressants and decrease in suicide (published in *Acta Psychiatr Scand.* 2009 Jul;120(1):37-44.)

Johan Askling (Department of Medicine, Karolinska Institute), in 'The Swedish System for Quality Assurance of RA Care: From Capture of Routine Data on Treatment, Through Register Linkages, to Post-Marketing Effectiveness and Safety Studies', presented a national biologics registry called ARTIS and mentioned that several European countries are establishing registries on treatment of rheumatoid arthritis.

Madlaina Costa-Scharplatz (Health Economics and Outcomes Research Scientist, AstraZeneca, Sweden) spoke about 'The Challenges of Non-Randomized Comparative Effectiveness Research When Making Payment Decisions' and to complete a valuable and stimulating day, Jerry Avorn (FISPE, Harvard Medical School/Brigham & Women's Hospital, USA) had a presentation about 'Implications for Health Policy and Clinical Practice'. He stressed the relevance to take policy issues (the rise of CER and its backlash), pharmaco-epidemiological issues (when is observational data good enough to document a difference?; when is a real RCT required?), clinical issues, and the role of ISPE and its members into consideration (for further reading see [www.powerfulmedicines.org](http://www.powerfulmedicines.org)).

# 25 years of Spanish pharmacovigilance

Mariano Madurga

The Spanish Human Pharmacovigilance System held its Ninth 'Annual Pharmacovigilance Journey' on 4–5 June 2009, in Oviedo, Spain, at the Regional Centre of Asturias. About 250 participants, health professionals from different settings, those responsible for pharmacovigilance from pharmaceutical companies, and technical staff from the 17 regional centres attended the meeting.

The inaugural lecture was presented by Dr Mohamed Farah, from the UMC: "Herbal Pharmacovigilance, Patient Safety and Traditional Medicines" which prompted much interest and many audience questions.

The two-day programme included two round tables:

- ◆ How to manage signals in different areas
- ◆ Future of the Pharmacovigilance

More than ten oral presentations and 73 posters about a wide range of pharmacovigilance issues included: hospital programmes, issues with oral anticoagulants, bisphosphonates and hip fractures, a pharmacovigilance teaching project for general practitioners, electronic submission of ICSRs between the Spanish Medicines Agency, AEMPS, and pharmaceutical companies, observational post-authorisation studies and results of different strategies to promote spontaneous reporting.



Pharmacovigilance staff of the Spanish Human Pharmacovigilance System at the 25th anniversary meeting.

## Anniversary

The meeting also celebrated the 25th Anniversary of the Spanish Human Pharmacovigilance System (SEFV-H). During this special session Prof Joan-Ramon Laporte explained the importance of pharmacovigilance for patients, while Prof Albert Figueras set out initiatives from Spanish Medicines Agency to promote the training in pharmacovigilance of Latin-American teams from several countries over the last ten years. Mariano Madurga, Secretary of the Technical Committee, illustrated important stages during the last 25 years: when Spain was incorporated in the WHO Drug Monitoring Programme in 1984, the report of Dr Inga Lunde, from WHO-Europe

in March 1984; of the different regulations, and photos from the eight previous Annual Meetings in different Spanish cities.

The celebration session was chaired by the Vice-Minister of Health and Social Policy, Consuelo Sánchez, accompanied by the General Director of Quality and Innovation in Health Services of the Government of Asturias, Jose R Riera; Vice-Dean of Ordination New Academic Degrees of the University of Oviedo, Maria Paz Suarez, AEMPS Director, Cristina Avendaño, and the Deputy General Director for Medicinal Products for Human Use of the AEMPS, Emilio Vargas.

## Awards for achievement

The Spanish Ministry of Health and Social Policy (with AEMPS) made the celebration of the 25 Anniversary of SEFV-H the opportunity to inaugurate annual awards to acknowledge those healthcare professionals who had made important contributions to different activities, signal detection, training, etc.

Dr Angel Hernández (Andalusia) was acknowledged for his contribution to the generation of important signals related to hepatotoxicity of certain medicines and medicinal plants. Dr Francisca González (Aragon) was selected for her continued co-operation in the reporting of suspected adverse reactions, enthusiastic educational work with new general practitioners and her participation in major projects. Dr Pilar G<sup>a</sup> Ortega (Castilla y Leon) was noted for her outstanding co-operation in the reporting of suspected reactions, her outreach and training in rational use of medicines, and her contribution to projects such as EUDRAGENE.

Honourable Mention Awards went to Prof Felix Lobo, for his decisive contribution to Spanish drug safety from 1982 to 1988 as General Director of Pharmacy and Health Products, the creation of the Spanish Pharmacovigilance System as a decentralized structure, establishment of the National Commission of Pharmacovigilance, and for ensuring the momentum necessary to facilitate the training of qualified staff. Prof Alfonso Moreno was acknowledged for his dedication to the safety assessment of drugs and his outstanding work to create a culture of drug safety in the world of health.

The closing session, given by Dr Luis A García-Rodríguez (CEIFE, Spanish Centre for Pharmacoepidemiological Research), entitled 'NSAIDs and risk of acute myocardial infarction', ended the meeting with a flourish.

Next year, the 10<sup>th</sup> Spanish Pharmacovigilance Journeys will be at Valladolid. The conference proceedings and more information are available at the website: [http://www.agemed.es/actividad/actCongresos/2009/FV\\_IXjornada-25ani\\_jun09.htm](http://www.agemed.es/actividad/actCongresos/2009/FV_IXjornada-25ani_jun09.htm)

## More Philippines Outreach



*Organisers and speakers on the Philippines outreach training.*

Cynthia Diza, ADR co-ordinator of the Philippines NRA, Bureau of Food and Drugs, reports that the ADR unit has embarked on a nationwide project of pharmacovigilance training which targets all government hospitals under the Ministry of Health. The first batch was conducted between the 4th and 8th of May 2009 with doctors, nurses and pharmacists: the second and third batches are set for 20th to 24th July and 17th to 21st August 2009. After this they intend to go out to the local government level and to private institutions as well. Topics included counterfeit drugs, legal issues in reporting (with a physician-lawyer as speaker) and pharmacoepidemiological methods in pharmacovigilance. See also UR45 p14.

## African francophone training

*Souad Skalli*

The Moroccan national centre ran a further pharmacovigilance course for Francophone countries in Africa from 8th to 12th June. Countries which participated were Senegal, Burkina Faso, Cameroon, Djibouti, the Congo, Côte d'Ivoire, Mali, Chad, Democratic Republic of the Congo and Morocco.

The course comprised eight modules:

1. Adverse drug reactions
2. Pharmacovigilance organization
3. Notification in pharmacovigilance
4. Imputation or causality assessment
5. Crisis management
6. Pharmacovigilance data management
7. Pharmacovigilance and health programs
8. Pharmacovigilance of herbal medicines



*The course in Rabat.*

The course, conducted in French, included exercises in causality assessment, VigiFlow, bibliographical research; many working groups about aspects of ADR reporting forms, and how to develop a pharmacovigilance centre according to WHO guidelines; and planning action to implement a pharmacovigilance system.

The facilitators of the course were Rachida Soulaymani and Souad Skalli from the Centre AntiPoison et de Pharmacovigilance du Maroc, Morocco; Shanthi Pal Narayan from WHO, along with other Moroccan experts.

## Chinese Traditional Medicines: classification, use and safety

WHO working group on development of traditional medicine modules for inclusion in the International Classification of Disease: ICD-TM, Hong Kong, 11-13 May, 2009

Ralph Edwards

This was an extraordinary meeting of Asian and Western country participants to explore the way forward in classifying Traditional Chinese Medicine (TCM) in the WHO Family of Classifications (WHO-FIC).

### The scope of traditional medicines

Such an aim may not sound much, but it involves diagnostic and use criteria, the therapies themselves, and outcomes. Not only is the original TCM approach based on 4,000 year-old written traditions, but also there are different modifications between Asian countries, from the original TCM, such as Japanese Kampo medicine. This is not to neglect other traditional practices throughout the world! We also had Ayurvedic and other medical practices to consider, each providing a unique challenge with similar richness of tradition and widespread use. Homeopathy, for example, was under consideration at the meeting, and many others were mentioned. So what did we do?

It is not easy to adjust one's thinking to a new medical paradigm; a diagnosis may be more a formulation of the patient's holistic state, and seems to include what I might designate as pre-illness signs. Expected outcomes in TM are often intended to achieve balance between factors in the body which do not easily fit into my Western medical anatomical and physiological thinking. The actions of the often complex herbal (plus mineral, animal and other) components are obscure to me. But all is not strange since there have been considerable efforts made by Asian researchers to investigate the pharmacology and physiology behind TCM and its treatments. We were given other explanatory presentations about some of the other medical archetypes which were fascinating and useful.

Safety and proper practice were accepted by all as of paramount importance.

### Direction of the working group

We were also lucky to have the wise leadership of Dr Bedihran Üstün, who reminded us both of our immediate task and the power of relational databases, as well as the ultimate benefits in understanding to be gained by having structured data which can be carefully and transparently linked as wiser people than I begin to unravel the relationships between different medical paradigms.

Some other major points from the discussions were:

- to consider only established, written, and not oral, traditional medicine in the first instance for practical reasons
- to work with TCM and derivatives used by different countries as some priority
- that safe use and understanding of TCM was an important matter as TCM and other TMs spread to other countries where

modifications of medications were made. Use other than the traditional may be more hazardous.

After the plenary discussions, working groups tackled some of the matters raised. In the time we had, there was no opportunity to explore anything other than some of the challenges ahead. In the pharmacovigilance area, there was discussion about the relevance of the ATC structure to the more holistic TCM. It was seen by many of the TM practitioners that adverse reactions were more professional failures in correct use, or substandard product, rather than there being any intrinsic risk with treatment in the accepted Western sense. There was a need for the WHO Drug Dictionary to include ingredients other than plants. There was also discussion about other medical interventions such as acupuncture and how one should record adverse events related to those.

Support for the use of international botanical nomenclature, and the website project by the Royal Botanic Gardens, Kew, England seemed to fit the requirements of the group. This is good since the UMC has signed an agreement with the London poisons control centre to employ Dr Debbie Shaw part-time to work in liaison with Kew and the UMC to ensure that TCM and other TMs are properly represented with their ingredients in the WHO-DD. It was also good that Dr Peter de Smet was present to chair several sessions and to make the link with the WHO ATC work done by the Collaborating Centre in Oslo.

### A major step forward

The major outcome from the meeting was to go ahead and to seek funding to continue the project. At first sight this may seem a trivial achievement after three days work. On the other hand, it is a major step forward to agree on a common classification exercise and to obtain active involvement from such diverse medical practices.

The meeting was jointly held under the auspices of WHO-FIC, the WHO Traditional Medicines Unit, and the safety section of the WHO-Quality & Safety of Medicines cluster (QSM).

## UMC participate in European project

Niklas Norén

In May, the EU's Innovative Medicines Initiative (IMI) allocated €46 million euros of funds to support research co-operation for faster development of better medicines. Fifteen research projects, aimed at bringing innovative medicines to the market more quickly, have been selected to receive funding from the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The UMC is one of 29 public and private participants in one of the fifteen topics, on 'Strengthening the monitoring of benefit/risk', entitled PROTECT (which stands for 'Pharmacoepidemiological Research on Outcomes of Therapeutics by a European Consortium'), co-ordinated by the European Medicines Agency (EMA), and managed by the Danish Medicines Agency.

### Integrating benefit-risk data

The goal of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in the EU. This is to be achieved by developing innovative tools and methods to enhance the early detection and assessment of adverse drug reactions from different data sources, and enable the integration and presentation of data on benefits and risks. These methods will be tested in real-life situations, to provide patients, prescribers, public health authorities, regulators and pharmaceutical companies with accurate, useful information to support risk management and continuous benefit-risk assessment.

A methodological framework for pharmacoepidemiological studies will be developed to enable data mining, signal detection and evaluation in various types of datasets, including spontaneous reports, registries and other databases. Means of combining results from clinical trials, spontaneous reporting and observational data will be developed, comparing Bayesian modelling, multi-criteria decision analysis and other analytical methods. Expressing benefit-risk using graphical methods will be tested with different stakeholders.

### Direct patient data collection

The PROTECT project will trial direct patient data collection using web-based, telephone and text messaging systems. It will test the transferability of the data into a common language and explore linkages to data from electronic health records and registries.

Using methods developed in the project, validation studies performed with additional data resources available in the EU will help create the foundation for multi-site investigations. This will continue beyond initial IMI funding, with training given and results disseminated using the European Network of Centres for Pharmacovigilance and Pharmacoepidemiology and relevant publications.

The UMC will be co-leading work package 3 of this topic, which covers new methods for signal detection in both individual case safety reports and longitudinal electronic patient records.

### Improving pharmaceuticals in Europe

The overall IMI objective is to encourage the more rapid discovery and development of better medicines for patients while improving the competitiveness of the European pharmaceutical industry. The projects will help to increase predicted safety and efficacy of medicines, enhance data exchange between researchers and improve education and training in the sector. Other IMI-funded projects include a medicines safety training programme, and a pharmacovigilance training programme.

## Utrecht



Jeroen Derijks

Jeroen Derijks, a PhD student at Utrecht university, together with Professor Toine Egberts and Dr Ronald Meyboom, has previously studied the reporting of hypoglycaemia and, paradoxically, also hyperglycaemia in connection with the use of antidepressants in VigiBase. In the unravelling of the occurrence of such opposite side effects in connection with one and the same group of drugs, they have developed a novel classification of antidepressants, based on their receptor and transporter affinity profiles.

Because this classification is rooted in the pharmacological properties of the drugs, it is expected to have more value in predicting side effects and cross-intolerance. For a further study, putting the new classification to the test in a more general way, Toine and Jeroen came for a one-day visit to the UMC for a meeting with Niklas Norén and Kristina Star of the research team, focusing on the best quantitative way of evaluating the data stored in VigiBase.

Dr Patrick Souverein is coordinating the work at Utrecht by keeping the UMC updated about study plans and final manuscripts. Currently, there are around ten studies at different phases undertaken by junior and senior scientists of the Division of Pharmacoepidemiology in Utrecht. The April morning Kristina, Niklas and Ron spent with Toine Egberts and Jeroen Derijks was an intensive session. There is much to say about e-mailing and teleconferences, but it comes a point when meeting face to face can be more productive.



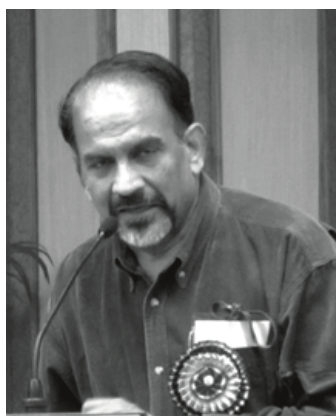
## Indian pharmacovigilance revisited

Sten Olsson

India has seen many pharmacovigilance initiatives since the early 1990s. In November 2004 the Central Drug Standard Control Organization launched a nation-wide pharmacovigilance network with support from the World Bank (see UR25). The success of this initiative has been limited however. It has not led to the establishment of a national ICSR database and safety information from the national pharmaceutical market has not become a part of benefit/harm assessments carried out by the drug regulator, the Drugs Controller General of India (DCGI).

A meeting was organized by the DCGI in collaboration with the New Delhi zonal pharmacovigilance centre at the All India Institute of Medical Sciences (AIIMS) on 24 – 25 April, 2009, to review the situation and to identify ways of invigorating the Indian pharmacovigilance system. Responsible officers from healthcare and academic institutions and drug regulatory authorities, both on federal and state levels, were present at the meeting.

After having listened to presentations from major stakeholders, selected representatives of the audience assembled for a brainstorming session to elaborate a roadmap for further development of pharmacovigilance in India. It was agreed that reasons for the limited success of earlier initiatives should be analyzed and lessons be learned from them. It was also suggested that pharmacovigilance could become a more efficiently run activity if outsourced from the DCGI to an independent public institution. The WHO Programme and UMC were requested to assist in providing management tools, IT-solutions and pharmacovigilance training to support the further development of pharmacovigilance in India. Sten Olsson reassured the participants that India is a priority country for the global programme and that UMC is committed to assist India as far as its resources allow.



Y.K Gupta

Introductory addresses were made by among others, Professor Y K Gupta, head of the zonal centre at AIIMS, Dr K Weerasuriya, pharmaceutical adviser at the WHO regional office for South East Asia and by Dr Surinder Singh, the Drugs Controller General of India. It was noted that the introduction of the comprehensive regional system in 2004 had been associated with high ambitions and expectations. Reasons why they had not been fulfilled were

identified. The DCGI reaffirmed his commitment into making the Indian pharmacovigilance system one of the best in Asia and mentioned that the federal government now, for the first time, had identified a designated budget for pharmacovigilance.

Professor Nilima Kshirsagar, Mumbai, gave a presentation on the current status of pharmacovigilance in India and Mr Sten Olsson, the UMC, presented a vision for future development of pharmacovigilance in India from a WHO/UMC perspective. The need for pharmacovigilance in public health programmes was addressed by Mr Paul Lalvani, RaPID pharmacovigilance, and by Dr Neena Valecha of the Indian Malaria Programme.



Surinder Singh



Left to right, Neena Valecha, M.C Gupta, Y.K. Gupta and Nilima Kshirsagar.

# Gender differences in pharmacovigilance – a master's thesis at the Uppsala Monitoring Centre

Sarah Fridén



Sarah Fridén

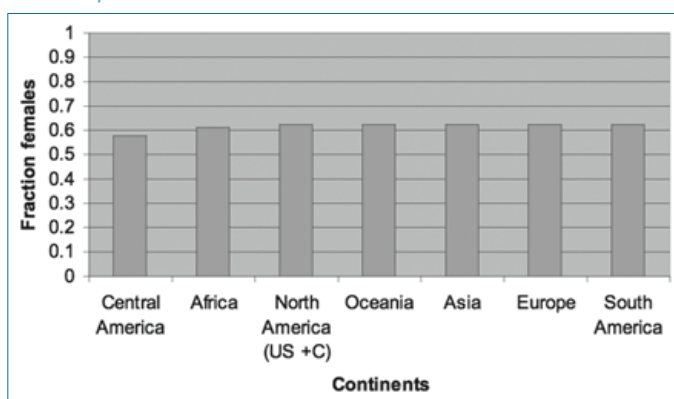
My first contact with the UMC was through a university course in 'Global pharmacy' that was held mainly in Taiwan but with some introductory lectures at the UMC. I immediately got a feeling of a warm and genuine atmosphere and an interesting working place with people from all over the world. I decided there and then to try and see if I could spend my next spring semester at the UMC, writing my master's thesis.

I got the opportunity to do this, investigating the subject of gender differences in international adverse drug reaction surveillance. This study was requested by the UMC research team as part of a general project of investigating reporting patterns in sub-populations. I was welcomed to the UMC in January 2009.

## Investigating previously published literature

I started by doing an extensive investigation of articles written on the subject of gender differences in adverse drug reactions (ADRs). I looked into differences in reporting patterns, differences in actual ADRs and how the body constitution, pharmacokinetics and pharmacodynamics differ between males and females. Humans are complex, both in bodies and minds, and the reasons why ADRs might differ between the sexes is not a simple one. How we consult doctors, how doctors prescribe medicines, our habits of using over-the-counter medicines and herbals are important factors, as well as our body's ability to adsorb, metabolize and excrete drugs. My literature searches showed that females seem to report more ADRs, and many articles also concluded that females suffer from more ADRs.

Figure 1. Gender distribution in VigiBase by continents. Fraction female reports.



## Retrospective review of gender differences in Signal

All signals issued in the Signal document during the years of 1998–2008 were reviewed to see if there was a difference between the relative reporting rates for males and females in the signals and whether these differences had been identified and/or commented on. Several signals had a considerable gender difference when comparing the relative reporting rates.

## Characterization of VigiBase reports according to gender

It was very interesting to be able to categorize VigiBase reports according to gender distribution by ADR, drug, reporting country, type of reporter etc. A female predominance was seen in most categories. Overall, the findings in VigiBase were consistent with the findings I had discovered in my review of literature.

## In the future

I'm very grateful to my advisors Niklas Norén and Kristina Star for all their guidance and support and to the rest of the staff at UMC for making me feel so welcome and sharing their knowledge with me. This has been a great experience and led me to a deeper interest in pharmacovigilance for the future.

# Let's hear about your troubles and triumphs!



*Please contribute to the next edition of Expecting the Worst*

Expecting the Worst, UMC's popular crisis management manual, is being revised for publication of a new edition in 2010.

We'd like to include real-life examples of crisis and recovery from member countries of the WHO Programme and our other readers.

If you've been through a medicinal product crisis (vaccines, ADRs, withdrawals, herbals, counterfeiting or other problems), please would you write and tell us the story, or point us in the direction of internet, media or other sources which will bring us up to date?

If you have an up-to-date crisis plan (like the one from Malaysia we published in the first edition), would you be willing to share it with us and future readers? Such examples can be very helpful to those in the process of making their own plans, or who are thinking of starting.

The book must reflect the real needs of real people struggling with complex issues in the real world: you can help us and our readers by contributing your thoughts, your experience, and your tips for survival and success.

If you'd like to contribute, or discuss the possibility of doing so, please contact the editor, Bruce Hugman ([mail@brucehugman.net](mailto:mail@brucehugman.net)) or Geoffrey Bowring at UMC ([geoffrey.bowring@who-umc.org](mailto:geoffrey.bowring@who-umc.org)).

*And if you wish, we'll be very happy to acknowledge your help in print!*

## Continued from page 2

"Warn other people! Warn other people!", expostulated the Queen, "You must send the report TO ME in less than 15 days – or was it 13 days – and not a single day longer, or YOUR head will roll. I will decide what to do then."

Alice, now tearful, said, "I only want someone to help me and to help others. Why are you so horrid to me? I think I am going mad."

Alice: But I don't want to go among mad people.

The Cat: Oh, you can't help that. We're all mad here. I'm mad. You're mad.

Alice: How do you know I'm mad?

The Cat: You must be. Or you wouldn't have come here.

Alice: And how do you know that you're mad?

The Cat: To begin with, a dog's not mad. You grant that?

Alice: I suppose so.

The Cat: Well, then, you see, a dog growls when it's angry, and wags its tail when it's pleased. Now I growl when I'm pleased, and wag my tail when I'm angry. Therefore I'm mad.<sup>2</sup>

The now singular Committee Cat took pity on Alice and purred soothingly as it wove its way around Alice's legs, "You could take the two red ones," he said and pointed a long claw to another bottle Alice had not noticed.

She did.

She awoke crying, "What an awful nightmare," she wailed as her mother came in to her room.

"Don't worry. Just take your SSRI," she said. Her mother took a bottle of tablets, and Alice caught sight of the label, which said, 'Read the directions and directly you will be directed in the right direction.'<sup>3</sup>

"Please, not again!"



1. Hauben M. and Aronson JK. Defining 'signal' and its subtypes in pharmacovigilance based on a systematic review of previous definitions. *Drug Safety*, 2009, 32(2): p99-110.
2. <http://quotations.about.com/od/moretypes/a/alice3.htm>
3. <http://quotations.about.com/od/moretypes/a/alice1.htm>

*With apologies to Lewis Carroll (Rev. Charles Dodgson) who wrote 'Alice in Wonderland'*

## WHO Drug Dictionary Browser

In June 2009, an updated WHO Drug Dictionary Browser was released, which has both useful new features as well as updates of existing features. Existing browser users have been contacted to upgrade their WHO DD Browser licence in order to get the latest additional functionality. Key features include:

- **Export** – Users can save browser queries and export the dictionary data to an XML file that can be opened and analysed in MSExcel and SAS. When evaluating protocol inclusion or exclusion criteria, users can make the list of medications in the browser.
- **Compare** – Which drug code should you choose? Users can compare all drug code related data for each product side by side in one interface (ATC code(s), countries, pharmaceutical forms, strength, preferred base etc.); a real time saver!
- **Request** – Users can communicate new drug requests and change requests directly to the WHO Drug Dictionary Support Team and keep track of the request status.

Previous versions of the dictionaries may also be accessed using the additional Dictionary Version selection function. CROs may work with several sponsors that use different dictionary types; the additional Dictionary selection function makes it possible to change the browser settings and adapt the browser to the sponsor's dictionary subscription.

If you have any questions regarding the WHO Drug Dictionary Browser, if you would like to apply for a one week test account or a live demo, please contact [drugdictionary@umc-products.com](mailto:drugdictionary@umc-products.com)

If you wish to upgrade your WHO DD Browser licence to get the new additional functionality, please contact [sales@umc-products.com](mailto:sales@umc-products.com).

### Compare

| Product Name            | Dolmen   | Dolmes  | Dolmen  |
|-------------------------|--|---|---|
| Drug Code               | 00649901001  | 00685301016   | 01363802008                                     |
| Name specifier(s)       |  |   |   |
| Active Ingredient(s)    | Acetylsalicylic acid<br>Ascorbic acid<br>Codeine phosphate                 | Tenoxicam   | Dexketoprofen trometamol                        |
| Preferred base name     | Dolmen   | Tenoxicam   | Dexketorofen                                    |
| Preferred salt name     |  |   | Dexketorofen trometamol                         |
| Generic                 |  |   |   |
| Preferred               | Yes  |   |   |
| ATC code(s)             | N02AA Natural opium alkaloids<br>N02BA Salicylic acid and<br>derivatives   | M01AC Oxicams official  | M01AE Proponic acid derivatives<br>official     |
| MAH(s)                  | Uriach   | Sigmatau<br>Sigma-lau<br>Sigmatau labs., rome   | Berlin-ch<br>Menarini<br>Berlin-Chemie Menarini |
| Countries               | Spain  | Czech Republic<br>Italy   | Estonia<br>Latvia<br>Lithuania                  |
| Pharmaceutical form(s)  | SUPPOSITORIES, ADULT<br>SUPPOSITORIES, PAEDIATRIC<br>TABLETS, EFFERVESCENT | AMPOLLES,<br>INTRAMUSCULAR<br>COATED TABLETS, FILM<br>POWDERS, UNIT DOSE<br>SUPPOSITORIES, ADULT<br>TABLETS | COATED TABLETS, FILM<br>TABLETS                 |
| Strength(s)             |  |   | 25.0 mg   |
| Medicinal Product ID(s) |  |   |   |

### Export

| ID | Product Name | Drug Code   | ATC         |
|----|--------------|-------------|-------------|
| 1  | Dolmen       | 00649901001 | N02AA/N02BA |
| 1  | Dolmen       | 00685301016 | M01AC       |
| 1  | Dolmen       | 01363802008 | M01AE       |

## UMC video

The UMC Marketing department have produced a five minute video 'Uppsala Monitoring Centre- Safeguarding Patients' about the background to the UMC and its work. The video may also be found on the YouTube website.

## Visitors from Rocky Mountain

The UMC had the pleasure of receiving visitors from the Rocky Mountain Poison and Drug Center (RMPDC), in Denver, Colorado, USA on 14th of May. They were Richard Dart, Executive Director and Jody Green, Associate Research Director. In addition to a general overview of the activities of the UMC and the WHO Programme, provided by Sten Olsson, they also had a more detailed discussion with Cecilia Biriell and Helena Sköld about management of individual case safety reports, data retrieval and signal analysis. At the UMC we learned that the RMPDC is a certified regional poison centre for Colorado, Nevada, Idaho, Montana and Hawaii and also runs adverse reaction reporting programmes on behalf of commercial clients. Discussions emerged which included the appropriateness of using dictionaries and other tools provided by the UMC in the RMPDC operations.



*Cecilia Biriell with Jody Green and Richard Dart of the Rocky Mountain Poison and Drug Center.*

## Staff News



### Welcome to Tomas

**Tomas Bergvall** has just joined the UMC, to work in the Research Department.

He was born and grew up in Uppsala and also studied at Uppsala University, reading Bioinformatics and completing a Master of Science degree in January 2008. He spent a year sabbatical from university traveling along the east coast of Australia.

Following graduation, Tomas took a job as a programmer at Travelocity Nordic AB in Stockholm. After a year he felt that he liked programming but wanted to apply it to something a bit closer to biology. Then in December 2008 he saw an ad in the local Uppsala newspaper where the UMC were looking for programmers in the Research department.

"I now work as a Research Engineer at the UMC mainly with data extraction/presentation. I hope that I will be able to take advantage of some of the Bioinformatic methods I learned during my education to develop the signal detection processes. I really like the atmosphere here at the UMC and it's been great to see people with different backgrounds coming together to reach our common goals."

"Outside of work I play golf (for fun) and innebandy (also for fun, but a bit more seriously). My biggest merit is to have won the Swedish student championships in innebandy in 2006. I like to watch almost any kind of sports; I will probably record Eurosports broadcasts of the Tour de France in July so I can watch them. You could definitely describe me as a bit of a sports nerd."

### Farewell

**Andrew Bate**, manager of the UMC research department, has decided to pursue his future career outside of the UMC, which he joined in January 1997. He will leave our organization in August, moving to New York. His wife, **Jenny Bate**, currently serving at the UMC signal analysis unit is joining him and will quit her position at the same time after eight years at the Centre. We wish them both well for their careers in the future.

Acting manager of the UMC research department is Niklas Norén; he can be reached at [niklas.noren@who-umc.org](mailto:niklas.noren@who-umc.org)

### New expert in the team

UMC is acquiring additional resources and competence in the area of herbal medicines, specifically Chinese traditional medicines, by attaching **Dr Debbie Shaw**, of the Medical Toxicology Unit at Guy's and St Thomas's Hospital, London, to the organization for a period of six months. Debbie, also a member of the UMC's signal review panel, will be working part-time for the UMC, operating from London.

## Recent articles

The following articles involving the UMC have recently been published.

### Drug-induced photosensitivity

Verdel BM, Souverein PC, Meyboom RHB, Kardaun SH, Leufkens HGM and Egberts ACG.

Risk of drug-induced photosensitivity: focus on spectroscopic and molecular characteristics. *Pharmacoepidemiology and Drug Safety* (2009).

*Wiley InterScience* ([www.interscience.wiley.com](http://www.interscience.wiley.com)) DOI: 10.1002/pds.1760

Drug-induced photosensitivity is difficult to predict and remains a challenge in dermatological clinical practice and pharmacovigilance.

This study assessed the association between spectroscopic and molecular characteristics and the occurrence of photosensitivity reactions. For 143 well-known photosensitisers (e.g. tetracyclines, diuretics), information was retrieved on spectroscopic and molecular parameters. All reports in the WHO global individual case safety report (ICSR) database with suspected adverse drug reactions of the study drugs were selected and all reports on photosensitivity reactions identified, and defined as cases. All other reports were selected as non-cases. A case-non-case approach was performed to assess the spectroscopic and molecular exposure variables as a factor for photosensitivity reactions. Logistic regression was used to calculate odds ratios (OR) with 95% confidence intervals (CI).

The study concluded that reporting of photosensitivity reactions to established phototoxic drug classes is strongly influenced by spectroscopic and physicochemical characteristics of individual drugs.

### Intranasal corticosteroids and migraine

Pokladnikova J, Meyboom RH, Vlcek J, Edwards IR.

Can intranasal corticosteroids cause migraine-like headache?

*Cephalalgia*. 2009; 29:360-364.

(Epub 2008 Oct 22).

Intranasal corticosteroids (INCs) act predominantly locally and are considered to exert minimal systemic effects. On reviewing the international data in the WHO global ICSR database an unexpected cluster was found of 38 case reports of migraine in suspected connection with INCs. These reports came from five countries (May 2007) and concerned six different drugs. Further study is needed to determine if the reported association is true or not and, if so, what the possible mechanism is.

### Anti-depressants and glucose homeostasis

Derijks HJ, Meyboom RHB, Heerdink ER, de Koning GHP, Janknegt R, Lindquist M & Egberts ACG.

Associatie tussen antidepressivagebruik en glucosedisregulatie: bewijs op basis van bijwerkingenmelding / The association between antidepressant use and disturbances in glucose homeostasis: evidence from spontaneous reports.

*PW Wetenschappelijk Platform* 2009; 3(2):22-27.

Depression is common in patients with diabetes, and the use of antidepressants may impair glycaemic control. This study assessed the association between antidepressant use and hyperglycaemia and hypoglycaemia. Based on spontaneous reports listed in the WHO global individual case safety report (ICSR) database, a case-control study was conducted. The study base consisted of all adverse drug reactions ascribed to antidepressants, antipsychotics and benzodiazepines between 1969 and 2005. Cases were defined as reported adverse drug reactions classified as hyper- or hypoglycaemia and separated in different study populations. All other reports were considered as controls. Exposure to antidepressants was the primary determinant investigated. Overall, the use of antidepressants was associated with hyperglycaemia [ROR 1.52 (CI95: 1.20-1.93)] and of hypoglycaemia [ROR 1.84 (CI95: 1.40-2.42)]. The association with hyperglycaemia was most pronounced for antidepressants with affinity for the serotonin 5HT<sub>2C</sub> receptor, histamine H<sub>1</sub> receptor and norepinephrine reuptake transporter. The association with hypoglycaemia was most pronounced for antidepressants with affinity for the serotonin reuptake transporter.

The results of this study strengthen the findings in individual case reports that the use of antidepressants is associated with disturbances in glucose homeostasis.

This study follows the paper in the *European Journal of Clinical Pharmacology*, by Derijks HJ, Meyboom RHB, et al, noted on p22 of UR41.

# COURSES & CONFERENCES

| DATES                | TITLE   | PLACE                          | ORGANISER/CONTACT   |
|----------------------|---|--------------------------------|---|
| 4-8 August 2009      | 10th Commonwealth Pharmacists Association Conference  | Accra, Ghana                   | CPA Accra 2009<br>E-mail: <a href="mailto:info@psgh.org">info@psgh.org</a><br><a href="http://www.psggh.org/cpa">www.psggh.org/cpa</a>  |
| 16-19 August 2009    | 25th Anniversary International Conference on Pharmacoepidemiology & Therapeutic Risk Management | Providence, Rhode Island, USA  | ISPE<br><a href="http://www.pharmacoepi.org/meetings/25thconf/index.cfm">www.pharmacoepi.org/meetings/25thconf/index.cfm</a><br>E-mail: <a href="mailto:ISPE@paimgmt.com">ISPE@paimgmt.com</a>  |
| 3-8 September 2009   | 69th International Congress of FIP: Responsibility for Patient Outcomes - are you ready?        | Istanbul, Turkey               | FIP Congress Department<br>PO Box 84200, 2508 AE The Hague, The Netherlands<br>E-mail: <a href="mailto:congress@fip.org">congress@fip.org</a> <a href="http://www.fip.org/istanbul2009/">www.fip.org/istanbul2009/</a>                  |
| 9-10 September 2009  | Back to basics in pharmacovigilance   | Southampton, UK                | Drug Safety Research Unit (DSRU)<br>Tel: +44 (0)23 8040 8621<br>E-mail: <a href="mailto:jan.phillips@dsru.org">jan.phillips@dsru.org</a> ; <a href="http://www.dsru.org/">www.dsru.org/</a>   |
| 23-24 September 2009 | Critical appraisal of medical and scientific papers   | Southampton, UK                | DSRU<br>Tel: +44 (0)23 8040 8621<br>E-mail: <a href="mailto:jan.phillips@dsru.org">jan.phillips@dsru.org</a> ; <a href="http://www.dsru.org/">www.dsru.org/</a>   |
| 28-30 September 2009 | Advanced Pharmacovigilance  | London, UK                     | Management Forum Ltd<br>Tel: +44 (0)1483 730008<br><a href="http://www.management-forum.co.uk">www.management-forum.co.uk</a><br>E-mail: <a href="mailto:registrations@management-forum.co.uk">registrations@management-forum.co.uk</a> |
| 6-9 October 2009     | Annual Meeting of the International Society of Pharmacovigilance (ISoP)                         | Reims, France                  | ISoP<br><a href="http://www.isoponline.org/upcoming-meeting.html">www.isoponline.org/upcoming-meeting.html</a>  |
| 12-16 October 2009   | Excellence in Pharmacovigilance: Clinical Trials and Post Marketing                             | Berlin, Germany                | DIA Europe<br>Tel: +41.61.225.51.51<br><a href="mailto:diaeurope@diaeurope.org">diaeurope@diaeurope.org</a>   |
| 14-15 October 2009   | Risk benefit assessment in pharmacovigilance  | Southampton, UK                | DSRU<br>Tel: +44 (0)23 8040 8621<br>E-mail: <a href="mailto:jan.phillips@dsru.org">jan.phillips@dsru.org</a> ; <a href="http://www.dsru.org/">www.dsru.org/</a>   |
| 23-25 October 2009   | 4th Asian Conference on Pharmacoepidemiology (ACPE)   | Tainan, Taiwan                 | ACPE<br>Tel: +886-2-8226-1010 ext.97<br>Fax: +886-2-8226-2785<br>E-mail: <a href="mailto:acpetaiwan@gmail.com">acpetaiwan@gmail.com</a>   |
| 11-12 November 2009  | Case narrative writing for reporting adverse events   | Southampton, UK                | DSRU<br>Tel: +44 (0)23 8040 8621<br>E-mail: <a href="mailto:jan.phillips@dsru.org">jan.phillips@dsru.org</a> ; <a href="http://www.dsru.org/">www.dsru.org/</a>   |
| 18-19 November 2009  | Pharmacovigilance in products subject to licensing agreements                                   | Southampton, UK                | DSRU<br>Tel: +44 (0)23 8040 8621<br>E-mail: <a href="mailto:jan.phillips@dsru.org">jan.phillips@dsru.org</a> ; <a href="http://www.dsru.org/">www.dsru.org/</a>   |
| 20-22 November 2009  | Annual conference of society of Pharmacovigilance of India (SOPI)                               | Sirsa (Haryana), India         | SOPI<br>Professor K C Singhal<br>E-mail: <a href="mailto:vc@nimsr.com">vc@nimsr.com</a>   |
| 3-4 December 2009    | Pharmacovigilance planning and risk management  | Southampton, UK                | DSRU<br>Tel: +44 (0)23 8040 8621<br>E-mail: <a href="mailto:jan.phillips@dsru.org">jan.phillips@dsru.org</a> ; <a href="http://www.dsru.org/">www.dsru.org/</a>   |
| 10-14 January 2010   | DIA Annual Conference for Contemporary Pharmacovigilance and Risk Management Strategies         | Washington DC, USA             | Drug Information Association<br>Tel: +1 (215) 442 6100 Fax: +1 (215) 442 6199<br>E-mail: <a href="mailto:dia@diahome.org">dia@diahome.org</a><br><a href="http://www.diahome.org">www.diahome.org</a>                                   |
|                      | Certificate in Pharmacoepidemiology & Pharmacovigilance   | London, UK / distance learning | London School of Hygiene Et Tropical Medicine<br><a href="http://www.lshtm.ac.uk/courses">www.lshtm.ac.uk/courses</a><br><a href="mailto:Ann.Arcscott@lshtm.ac.uk">Ann.Arcscott@lshtm.ac.uk</a>   |

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