

UFR47

UPPSALA REPORTS October 2009

For everyone concerned with the issues of pharmacovigilance

Introducing our new Director

PaniFlow

UMC Signal work

Commonwealth pharmacists

Ralph Edwards tribute



GREETING FROM THE UMC'S NEW DIRECTOR



Marie Lindquist
Director
the Uppsala Monitoring
Centre

This prime spot in *Uppsala Reports* has, for the whole life of its publication, been the place where the Director has had the privilege of speaking directly to you, our readers. It's a practice I intend to continue – until, at least, you tell me you've had enough!

First, I want to thank those many people round the world who've offered me their good wishes on my appointment. I am grateful for the immense amount of goodwill and support you've shown – but it reminds me (as so many things do) of the great responsibility I carry and of the important duties we have here at the UMC to so many individuals, organisations and countries – and, of course, ultimately to patients.

We cannot do our work successfully and be of use to our worldwide community without the active involvement of all our partners and colleagues. What we do must be driven by the real, practical needs and wishes of those we serve. We can learn about those only through active engagement and debate. So, this is a repeat of a basic and very sincere call: tell us what you feel we should be doing; criticise (and maybe praise us sometimes) for what we are doing; help us to be more useful and effective.

A controversial notion

All of us are stakeholders in the enterprise of patient safety. I have heard some strong disapproval of this term 'stakeholders', but although I rather dislike the word myself, I have not been able to find another that appropriately describes the concept that I am after: any organisation or individual that has a direct and legitimate interest in our actions or decisions; their interest may be because they will have a role in implementing the decisions, or because they will be affected by the decisions. So, when I use 'stakeholder' I refer to a community of people whose success (and maybe health and happiness) is inextricably linked to the achievement of a vision and to the collaborative means of achieving it. UMC is one of a multitude of stakeholders in pharmacovigilance and in the larger vision of patient safety. We can play our part only in step and in harmony with others. We can maybe lead from time to time, but we have no monopoly of wisdom.

Reaching for the best

In any field where there are political, commercial, economic, scientific and sociological considerations (to name but a few), it is easy to be distracted from the main goals. Our vision is to contribute to the welfare and safety of patients. In pursuing that ideal we have to strive for quality in everything we do. Ockham's principle that "entities should not be multiplied unnecessarily" (in other words, pursue the simplest satisfactory theory or solution) seems to me to be at the heart of quality thinking and action. Quality is often about simplicity, and clarity. Effectiveness – yes, of course – but by the direct route, with transparency and the absence of hidden agendas.

Keep in touch

I am grateful for the opportunity to tackle the big challenge of leading the UMC, and I want to make a success of it for the sake of all those we are in a position to help and influence. To achieve that, I need the support and involvement of you, our readers, colleagues, friends, partners and customers around the world, and, of course, the UMC's splendid staff. Please take me at my word: let me know what you think and how we can be more useful to you and others.

A handwritten signature in black ink that reads "Marie Lindquist".

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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.

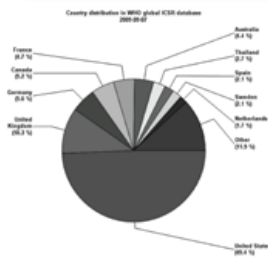
With an independent and global perspective on drug safety, *the* UMC provides resources for regulatory agencies, health professionals, researchers and the pharmaceutical industry.

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.



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Senegal joins the Programme

Dr Birame Dramé, National Pharmacovigilance Co-ordinator

Dr Diarra Aminata Lo, Pharmacovigilance

The Republic of Senegal is at the extreme west of Africa with an area of 196,000 km²; the population is around 12 million, of whom 42% live in urban areas. The system of care in the public sector consists mainly of 22 hospitals and 76 health centres, with 971 health professionals. The private sector consists of a denominational hospital, 32 clinics, 70 maternity hospitals, 131 medical offices, 77 dispensaries, 900 pharmacies; with five wholesale distributors, pharmaceutical companies (Pfizer, Sanofi Aventis, Valdafrique) and the Pasteur Institute of Dakar which produces the yellow fever vaccine. The pharmacovigilance centre is sited in the Department of Pharmacy and Laboratories, which is the National Regulatory Authority, led by Professor Papa Amadou Diop.

History

It has been recognised for a long time the need to monitor the adverse effects of medicines on the market. It takes courage to implement pharmacovigilance in a country where there are two major obstacles: lack of knowledge about pharmacovigilance in health professionals, and the level of resources available to the National Regulatory Authority (NRA). In Senegal, medicines surveillance started officially, by ministerial decree, on February 6, 1998.

The Expanded Programme on Immunization (EPI) began early on to work with the system of pharmacovigilance during its campaigns of mass vaccination. It was necessary for EPI to manage Adverse Events Following Immunization (AEFI), as well as counter suspicions about what might happen as a result of having the vaccine. So training of health workers started throughout the country. For several years, pharmacovigilance in Senegal was limited to just EPI activities, with weakness in the reporting and in the causality of cases.

This tentative system remained until 2005, when the National Programme of Fight against Malaria introduced the Artemisinin Combination Therapy (ACT). This public health programme with funding from the Global Fund has allowed the necessary resources to support the implementation of pharmacovigilance. Monitoring of adverse reactions to ACT has thus helped revive pharmacovigilance. Currently, other public health programmes (against tuberculosis, AIDS) are being actively integrated into the system of pharmacovigilance.

Organization of national pharmacovigilance system

A new decree was issued in April 2009 to improve the system and adapt to the evolving pharmacovigilance programme in Senegal, taking into account all those involved in pharmacovigilance, including health professionals, the poison centre, health programmes and hospitals. This system is actively coordinated by the NRA, which is the nodal point of the system.

Senegal and the WHO Programme

For the first time, in October 2008, at the invitation of WHO, Senegal was an 'observer country' at the annual meeting of pharmacovigilance centres in Uppsala, which enabled us to realize the importance of participating in this Programme.

At the request of health authorities in our country, our candidacy for membership was submitted and we were admitted as associate member of the Programme in December 2008. In July 2009, Senegal became the 95th full member country. Senegal is also member of the WHO network for the post marketing surveillance of newly pre-qualified vaccines, due to the local vaccine production and the good relationship between NRA and EPI.



Staff at the Department of Pharmacy and Laboratories in Senegal

Training

Senegal has benefited from the support of pharmacovigilance centres of Tunisia and Morocco. At national level, training is undertaken first with training of trainers, who in turn train health professionals in their area. Between 2007 and 2008, 1,376 people were trained at least once in pharmacovigilance and there is a focal point for pharmacovigilance in medical districts and regions.

Reporting

The notifications received by the national pharmacovigilance centre, while low, are growing steadily. From 2001 to 2006, only 148 cases were received; between 2007 and 2008, 912 cases were reported to the pharmacovigilance centre. However, much remains to be done; only a small fraction of adverse drug reactions is reported.

Strategies

For more efficiency, our strategy for developing pharmacovigilance is based around public health programmes fighting against malaria, AIDS, tuberculosis and the immunization programme. These collaborate with the national pharmacovigilance centre in the interest of public health. However, we advocate that the pharmacovigilance centre itself have sufficient resources to carry out its activities.

Challenges

Beyond drugs from public health programmes, our goal is to effectively monitor all medicines on the market. For this, efforts

should be made in training and in advocacy to really anchor the culture of reporting ADR. The private sector should be taken account of in all activities. To achieve this goal the pharmacovigilance system will need more human and material resources.

Pharmacovigilance is a discipline 'new' to us and most developing countries; much time, sacrifices and patience will be required for pharmacovigilance finally takes a special place in our care systems.

We wish especially to thank the following partners who have supported the development of pharmacovigilance in Senegal:

- ◆ WHO
- ◆ United States Pharmacopeia/Drug Quality Information
- ◆ Uppsala Monitoring Centre

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Two new associates

During the last quarter, Angola and Guinea-Bissau have applied to join the WHO Programme.

Reporting in Denmark

There have been some interesting recent changes to the ADR reporting processes in Denmark.

The Danish Medicines Agency is now requiring doctors and dentists to report all suspected ADRs to the Agency within 15 days. The civil registration number of the patient suffering the ADR must also be included for correct identification and to prevent duplicate entries.

From now, only serious or unexpected side-effects have to be reported to generic medicines, as common reactions associated with them will be previously-known. The Agency has also instituted measures for an 'increased obligation to report' for ADRs for specific medicines, meaning that doctors will need to notify all ADRs associated with a particular drug – even if it had been previously subject to detailed scrutiny or was usually exempt, as with older generic products.

Last December, Danish law set out that correspondence about ADR reports between doctors and companies should be undertaken via the national agency. Previously, doctors had sent their ADRs direct to the relevant company, which in turn were also able to contact doctors direct with queries over their reports.

Consultants meet in Mozambique

Sten Olsson

In 2007 WHO-QSM took the first initiative to assemble a pool of experts to act as 'pharmacovigilance consultants on call' for African countries. A first advanced training workshop was held that year in Accra, Ghana, to build capacity for pharmacovigilance and specific expertise in identified technical areas, with a second workshop, again in Ghana, in 2008.

This year the pharmacovigilance consultants met in Maputo, Mozambique, from 25 July – 1 August, for a follow-up workshop with extended participation. Countries represented were Botswana, Cameroon, Ghana, Morocco, Mozambique, Nigeria, Sierra Leone, Tanzania, Togo, Uganda, Zambia and Zimbabwe. Mary Couper, Shanthi Pal and Jitka Sabartova attended from WHO Headquarters, with Magnus Wallberg and Sten Olsson from the UMC. David Coulter from New Zealand was the special expert on Cohort Event Monitoring (CEM). Topics covered included: techniques in CEM, data management tools, issues around quality of medicines and testing laboratories, counterfeits, the relevance of the WHO pre-qualification programme for medicines, medication errors, risk management plans, issues in crisis management, networking and advocacy for pharmacovigilance. Country participants presented on-going work in their country settings and progress made since 2008. Recommendations and action points from each of the sessions were developed.



Ambrose Isah (Nigeria) with staff from Mozambique

The WHO approach of providing in-depth pharmacovigilance training to a limited number of African experts has been fruitful. Several trained consultants have been on missions to other African countries, providing support and guidance for development of national pharmacovigilance systems. The number of African countries joining the WHO Programme for International Drug Monitoring in the last few years, either as full or associated members, has increased. The expansion of the WHO network is only a first step to achieving the ultimate goal of building self-sustaining, competent pharmacovigilance systems in all African countries, capable of protecting the African population from unnecessary drug-related problems.

It's Rafe, actually

Ralph Edwards retired as UMC director on 31 August 2009

Sten Olsson

Ralph (Rafe) Edwards joined the WHO Collaborating Centre for International Drug Monitoring (later the Uppsala Monitoring Centre, UMC) in September 1990. He came to Uppsala after having served as head of the New Zealand national pharmacovigilance centre for eight years. It was the late 'Beje' Wiholm who managed to find Rafe a position as medical officer at the Swedish Medical Products Agency (MPA) which he held while at the same time becoming the director of the UMC without payment. The timing was perfect. The same year the Swedish government, then having full control of the board of the foundation WHO Collaborating Centre for International Drug Monitoring, decided that the centre could use income from its sales and consultancy services to commercial customers to supplement its annual grant from the government. Since at that stage the UMC already had a steady stock of subscribers to the WHO Drug Dictionary, it could soon afford to pay its director and Rafe could quit his position at the Medical Products Agency.



Rafe's farewell to the WHO Programme, at Uppsala Castle, October 2008

And Rafe made five

Rafe joined a dedicated team of four, three of them still working at the UMC; Sten Olsson, Cecilia Biriell and Marie Lindquist. He succeeded Professor Kjell Strandberg, General Director of the MPA, who had served as both acting director and chairman of the board of the WHO Centre since 1983. Rafe soon realized that the management structure of the WHO Programme was far from clear. At the time the budget was provided by the Swedish government while WHO-HQ, according to the agreement between Sweden and WHO, decided on all policy matters. There were sometimes conflicting interests between the two masters. For instance, it was WHO policy to stimulate accession of new countries to continuously expand the monitoring programme while the Swedish government put a ceiling to the budget allowance. Rafe's response was to fill the gap with commercial revenues, primarily through a more professional marketing of the WHO Drug Dictionary. This could not be done under the name of the WHO Centre and instead the UMC name was created.

Driving a vision

Rafe joined the WHO Collaborating Centre with a vision. He was determined to develop the science of pharmacovigilance, the methods and tools to be used, sources of data for safety analysis etc. In driving these developments with his growing team he gave the UMC a leadership role in the WHO Programme. I will here mention only a few of the initiatives taken under his leadership:

- The UMC became involved in **data analysis of poisoning information** collected by the WHO - IPCS (International Programme on Chemical Safety) network.
- A **biannual two-week training course** was started in Uppsala, offering basic training in the theory and practice of pharmacovigilance. The course has contributed to capacity building in over a hundred countries in all continents.
- **In collaboration with IMS Health**, the UMC received a research grant from the European Commission, combining adverse reaction information (numerator data) from the WHO database (VigiBase®) with pharmaceutical sales statistics (denominator data) from IMS. This research produced many interesting new insights.
- Inadequacies were identified in the way drug safety information is communicated to prescribers and patients and other stakeholders in healthcare. **A series of international meetings on communications in pharmacovigilance** were organized in partnership with the University of Ancona, Italy, EQUUS (Bruce Hugman) and CIOMS. Outcomes of the activities included the Eric Declaration, two books on communications in pharmacovigilance and new UMC services – Uppsala Reports, Signal, and Vigimed.
- A research project was initiated with the Royal Institute of Technology, Stockholm, (later with the University of Stockholm) exploring the use of **Bayesian statistics** and neural network computing in the identification of early safety signals from VigiBase. This led to a first ground-breaking publication in

1997, three PhD theses and the subsequent use of the BCPNN methodology as a UMC routine analysis tool.

- In partnership with the Swiss regulatory authority, Swissmedic, the UMC developed the **web-based individual case safety report management tool VigiFlow** compatible with the international E2b standard.
- Development of new data mining methods for **duplicate detection**, unaided pattern recognition and documentation grading of individual case safety reports (ICSRs).
- To secure the financial viability of the UMC, the **WHO-Drug Dictionary** was expanded into WHO-Drug Dictionary Enhanced which has become the standard source of basic medicinal product information for the vast majority of the research based pharmaceutical industry. A major effort was also made to improve the **classification and naming of herbal medicines** in collaboration with the Royal Botanical Gardens, Kew, UK.
- In collaboration with WHO-HQ, and with support from the World Alliance for Patient Safety and close partnership with the Moroccan national pharmacovigilance centre, the UMC analysed VigiBase for indicators of **medication errors**. Patient Safety has since become an overriding concept for the WHO Programme, not only the more limited monitoring for adverse drug reactions.
- In a new collaborative project with IMS Health the BCPNN data mining technology was developed to **analyse longitudinal patient records**. The project was later brought into a new partnership financially supported by the European Commission (PROTECT).

Throughout his UMC career Rafe has demonstrated his extraordinary wide competence, his networking ability and entrepreneurial mindset. Not all the projects he initiated have been successful, but that is common when many ideas are competing for limited resources.

Patients at the centre

Rafe has passionately defended the right of the patient. He has criticized, with great integrity, actions by stakeholders in the international healthcare arena that, in his view, have acted contrary to the direct interests of patients, be it the pharmaceutical industry, regulatory agencies, the media or even WHO. He was, for example, committed to demonstrating the unacceptable safety risks to Africans, having a high prevalence of G6PD deficiency, of being exposed to the new anti-malarial combination of chlorproguanil-dapsone (Lapdap). Rafe has published a great deal on medicine safety in the scientific literature but also written many articles on philosophical issues, for instance in his quarterly editorial in *Uppsala Reports*. The majority of these editorials are collected in a document on the UMC web site and provide an interesting account of important contentious issues in patient safety over the past 10 years. By not shying away from controversy and debate he sometimes created animosity from opponents, a price he has been prepared to pay for following his professional conscience.

Expansion and diversification

As UMC Director Rafe managed the expansion of the centre from a small team of 5 to a diverse organization of 60 employees. He could attract staff members with various professional skills and cultural backgrounds, convinced that diversification provides better capacity for problem-solving.



A good catch

In ensuring the UMC was in direct contact with partners around the globe Rafe has often had the most daunting travel itineraries. In spite of his busy work schedule he has managed to keep his vitality and engagement until his retirement and beyond. He will remain available as a resource for the Centre for a few more years.

It may be said that replacing Rafe as Director of the UMC will be difficult, considering his capacity and the importance he has had for the organization in a variety of areas. It could equally be claimed that he will be easy to succeed, since he has led the Centre to a position of strength in many areas, opening up many opportunities for new development in the service of patient safety. For me personally it has been a great privilege to work closely with him for 19 years. It has been challenging, inspiring and very joyful. By using his wisdom I hope Rafe will now slow down a bit and focus his mind on some of those loose ends he left behind while he lived his hectic directorial life, still there waiting for his attention.

VigiBase – ICSR reporting from member countries

Sara-Lisa Fors and Lovisa Sällstedt, The Reporting Team

The WHO Programme for International Drug Monitoring continues to expand. During 2009 so far, the national centres in Botswana, Madagascar, Saudi Arabia and Senegal have fulfilled the criteria for becoming full members of the programme. The current number of member countries is 95.

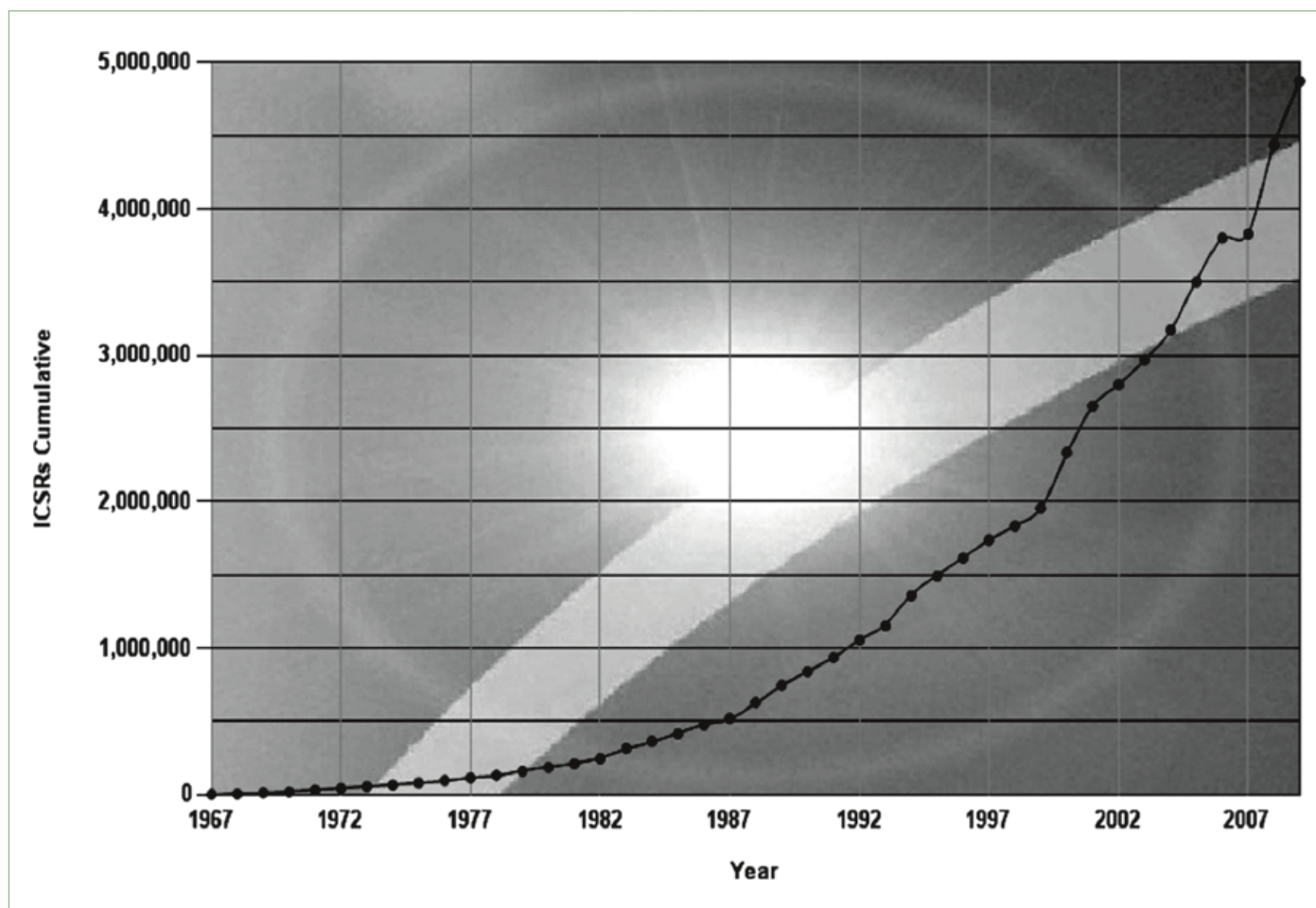
To be able to regularly present relevant statistics on the reporting of Individual Case Safety Reports (ICSRs) from WHO Programme member countries, a new statistics tool has been implemented in connection to the WHO global ICSR database (VigiBase). Twice a year statistics including the cumulative number of reports, the reporting rates, the country distribution and the submission frequency will be published in Uppsala Reports and on the UMC website.

Cumulative reporting

Figure 1 shows the cumulative number of active ICSRs in VigiBase. As of 7th of September 2009, the total number of active ICSRs was 4,873,587.

Since 1st of January 2009, the number of active cases in VigiBase has increased by 434,556 ICSRs. This means that the number of entered reports during 2009 is already higher than for previous whole years (the increase during 2008 was a result of a delay in the processing of reports from 2007 to 2008, see UR44). One of many explanations is of course the ever-growing number of new countries contributing with reports. Another explanation is that a few countries with reporting problems in the past managed to submit large backlogs of cases in 2009.

Figure 1. Cumulative number of active ICSRs in VigiBase



Reporting rates and country distribution

Figure 2 shows the twenty countries submitting most ICSRs per million inhabitants per year.

Figure 2. Reporting rates (per million inhabitants and year) to the UMC (September 2004 to September 2009)

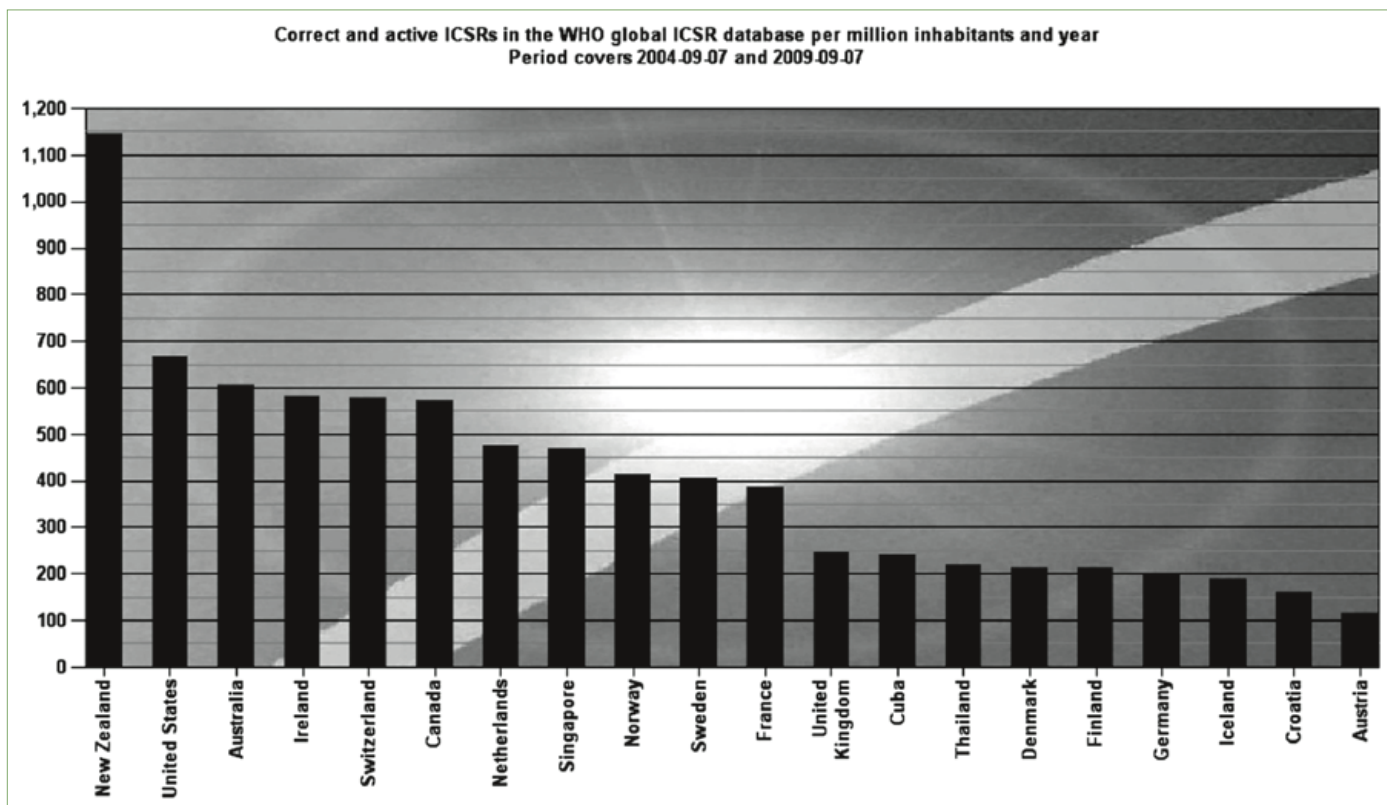
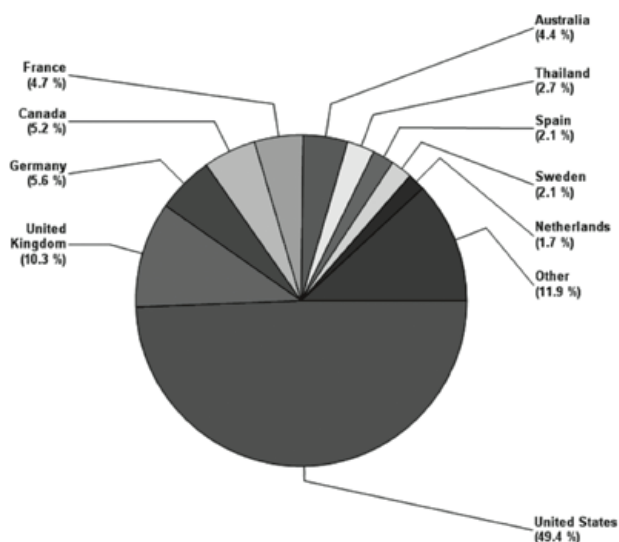


Figure 3 shows the percentage of ICSRs from different countries in VigiBase.

Figure 3. Country distribution of ICSRs in VigiBase as of September 2009 (total number of ICSRs = 4.87 million)

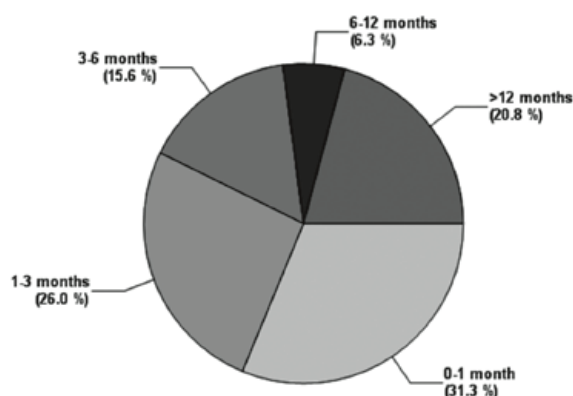


Submission frequency

WHO Programme member countries should submit ICSRs to the UMC on a regular basis; preferably once a month, but at least every quarter. This is important to keep VigiBase updated with the most recent safety information. During the last 12 months however only 44% of the member countries fulfilled the minimum requirement of submitting

ICSRs at least every quarter. As shown in Figure 4, one third (31.3%) of the countries have submitted ICSRs during the last month, and a quarter (26%) during the last 1-3 months. Although one fifth of the Programme member countries has not submitted any cases at all during the preceding twelve months, the rates have improved compared with the last reporting statistics published in UR45.

Figure 4. Time elapsed since last submission (proportion of countries as percentage) as of September 2009



Preparing for Influenza pandemic

Jerry Labadie

Background

Unprecedented numbers of individuals are expected to be vaccinated with the A/H1N1 2009 pandemic influenza vaccines. This is anticipated to lead to an increase in reporting of temporally-associated events regardless of causal association to vaccination (compared with seasonal vaccine). But potential safety issues will also emerge when pandemic influenza vaccination campaigns commence in October/November 2009.

Even before the vaccines are available serious concerns of the public about safety of the A/H1N1 2009 pandemic influenza vaccines have been expressed in the media. These concerns prompted WHO to issue a special briefing note 'Safety of pandemic vaccines, WHO Pandemic (H1N1) 2009 briefing note 6' to address these concerns (*see: http://www.who.int/csr/disease/swineflu/notes/h1n1_safety_vaccines_20090805/en/index.html*).

Additional pharmacovigilance activities to monitor the safety of the A/H1N1 2009 H1N1 pandemic influenza vaccines used during a pandemic are therefore needed. In ICH member countries pharmacovigilance of Adverse Events Following Immunization (AEFI) associated with use of pandemic influenza vaccines is well covered (e.g. Eudravigilance in the European Union and VAERS in the USA).

On 18 September 2009 WHO announced donations of pandemic vaccine for the developing world made by the United States of America, Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, and the United Kingdom. Together with the doses pledged by vaccine manufacturers these donations will give access to A/H1N1 2009 H1N1 pandemic influenza vaccines for populations that would otherwise not have access. The UMC is well prepared for the monitoring and analysis of AEFI associated with the vaccines that WHO will make available in Africa, Asia and South-America.

UMC is prepared

Drug Dictionary

Identification of the monovalent A/H1N1 2009 pandemic influenza vaccines in the WHO Drug Dictionary/ WHO Drug Dictionary Enhanced should be unambiguous and avoid confusion with the annual trivalent seasonal influenza vaccines. It is to be expected that reporting will be by non-proprietary /common names to a large extent, and not by trade/brand-name, even though different brands differ relevantly in production methods and ingredients (i.e. adjuvants). The UMC is prepared for updating the Dictionaries as soon as A/H1N1 2009 pandemic influenza vaccines are approved by competent authorities.

We greatly appreciate your help in the identification of the A/H1N1 2009 pandemic influenza vaccines that are approved by your National Competent Authority! Please notify our focal point Jerry Labadie

PaniFlow

In UR46 we announced the availability of PaniFlow – a specially-created extension of the UMC's ICSR management tool VigiFlow. In PaniFlow, the UMC has a powerful tool specifically designed to capture AEFI of A/H1N1 2009 H1N1 PANdemic Influenza vaccines and of the adverse events associated with treatment with the neuraminidase inhibitors oseltamivir (Tamiflu®) and zanamivir (Relenza®). In addition, electronic notification can facilitate reporting, help control quality of AEFI reports, and support notifications when infrastructures (paper reporting forms by regular mail) break down due to the pandemic.

The EMEA's Committee for Medicinal Products for Human Use (CHMP) recently adopted a document which specifies pharmacovigilance activities, additional to previously-submitted pharmacovigilance plans of pandemic influenza vaccines to be used during an influenza pandemic: 'CHMP Recommendations for the Pharmacovigilance Plan as part of the Risk Management Plan to be submitted with the Marketing Authorisation Application for a Pandemic Influenza Vaccine' (Adopted by CHMP in November 2006, Revision 1.0 adopted by CHMP on 25 June 2009: <http://www.emea.europa.eu/pdfs/human/pandemicinfluenza/35938109en.pdf>)

Adverse event		
Please select (with the "+"-symbol) all reactions that apply in section a) to c) and/or add other severe adverse events as freetext in section d) below. By pointing on a ? details about the listed adverse event are shown. Any details, further explanations, and results (like lab values) should be added in the box in section d).		
Date of first reaction [][] [][][][] (dd mm yyyy)	Interval between last administration of vaccine and onset	duration
a) Application site and general disorders		
<input type="checkbox"/> Severe local reaction ?		
<input type="checkbox"/> Adenopathy ?		
<input type="checkbox"/> High Fever (>39 degrees C)		
b) Hypersensitivity reactions (allergy)		
<input type="checkbox"/> Severe skin reaction: Stevens Johnson ?		
<input type="checkbox"/> Severe skin reaction: Lyell syndrome ?		
<input type="checkbox"/> Urticaria		
<input type="checkbox"/> Erythema		
<input type="checkbox"/> Angio oedema / face swelling		
<input type="checkbox"/> Dyspnea ?		
<input type="checkbox"/> Larynx oedema		
<input type="checkbox"/> Bronchospasm		
<input type="checkbox"/> Anaphylaxis with hypotension / shock		
<input type="checkbox"/> Arthritis, joint swelling: new onset ?		
<input type="checkbox"/> Arthritis, joint swelling: exacerbation ?		
<input type="checkbox"/> Vasculitis ?		
<input type="checkbox"/> Serositis ?		
<input type="checkbox"/> Serum sickness syndrome ?		
<input type="checkbox"/> Oculo-respiratory syndrome ?		
<input type="checkbox"/> Other allergic reaction		
c) Nervous system disorders		
<input type="checkbox"/> Convulsion, with fever		
<input type="checkbox"/> Convulsion, without fever		
<input type="checkbox"/> Guillain-Barre Syndrome or related syndromes ?		
<input type="checkbox"/> Paresis, including Bell's palsy		
<input type="checkbox"/> Neuropathy		
<input type="checkbox"/> Encephalitis / Encephalopathy		
<input type="checkbox"/> Meningitis		
<input type="checkbox"/> Multiple sclerosis: new diagnosis		
<input type="checkbox"/> Optic neuritis: new onset		
<input type="checkbox"/> Optic neuritis: exacerbation		

For spontaneous reporting from health care professionals this CHMP document lists Adverse Events of Special Interest (AESI): neuritis, convulsions, anaphylaxis, encephalitis, vasculitis, Guillain-Barré syndrome, Bell's palsy, demyelinating disorders, vaccination failure. PaniFlow covers most of these 'AESI' as pre-listed AEFI with tick boxes, and free text fields allow for entry of additional AEFI (see screen shot, p10).

UMC makes PaniFlow available

PaniFlow is very similar to UMC's adverse drug reaction management tool VigiFlow. For this reason UMC has decided to make PaniFlow available to the member countries of WHO's International Drug Monitoring Programme that have experience with using VigiFlow. As of early September 2009, only 14 of the 29 National Centres using VigiFlow had ever reported AEFI to the UMC. After analysis of past

performance in reporting AEFI, we have decided to offer PaniFlow free of charge to the National Centres using VigiFlow in:

- Croatia, Lithuania, Morocco, Serbia and Turkey - who have the best track record of reporting AEFI over the past four years
- Togo and Sierra Leone - who are in the top 5 of AEFI reporting NCs in 2009.

National Centres that are not eligible on past performance but would like to use PaniFlow to monitor the safety of drugs and vaccines against the new influenza A/H1N1 2009 virus are encouraged to contact the UMC's PaniFlow focal point for information: Jerry Labadie (jerry.labadie@who-umc.org).

Official Launch in Kenya

Dr Jayesh M Pandit, Head, Department of Pharmacovigilance

The Department of Pharmacovigilance at the Pharmacy and Poisons Board (PPB), the National Medicines Regulatory Authority in Kenya, has been working actively over the last four years to develop a national system for pharmacovigilance in Kenya. The hard work finally came out to the Kenyan public on the 9th of June 2009 when a formal launch took place at the Panafric Hotel in Nairobi.

Line-up for launch

Top representatives from the Ministry of Medical Services and Ministry of Public Health and Sanitation, including the Directors of both these Ministries graced the occasion. Present were also the Chief Pharmacist, Dr K C Koskei, Deputy Registrar of the PPB, Dr F M Siyoi, and members of the Board and its Secretariat.

Various stakeholders also attended the meeting: over 70 people drawn from the Division of Pharmacy, Ministry Headquarters, provincial directors of health, provincial nursing officers, provincial pharmacists, public health programme representatives, mission facilities, professional societies, research institutions, World Health Organization - Country Office and academia from across Kenya.

The launch signalled the commitment of the Pharmacy and Poisons Board in availing safe, efficacious and quality medicines to all in the country. Ralph Edwards, sent a congratulatory note to the PPB and looked forward to welcoming Kenya as a full member of the WHO Programme for International Drug Monitoring.

Roll-out of training

The Department of Pharmacovigilance has developed a detailed 5-day training programme for all health workers in Kenya as a minimum standard training in pharmacovigilance. It is accompanied by specific manuals for trainers and participants that will be used to roll out pharmacovigilance in Kenya. The course equips all healthcare workers across the healthcare delivery system with the necessary skills, knowledge and attitudes that will enable them effectively to identify, assess, report and take appropriate action for ADRs. Ultimately the health care workers will be inspired to become

observant professionals and active reporters in pharmacovigilance to enhance safety of the Kenyan population.



Jayesh Pandit speaking during the launch in Nairobi.

It is hoped that other countries, especially in Africa, may use these vast resources in training their teams on pharmacovigilance, to complement those available from UMC/WHO HQ. The following documents were officially launched at the event:

- Guidelines for the National Pharmacovigilance System in Kenya
- Suspected ADR Reporting Form
- Alert Card
- Poor Quality Medicinal Product Complaint Form
- Training and Implementation Guide
- Trainer's manual
- Participant's manual.

Signal Detection at the UMC

Richard Hill

An important activity of the UMC is to detect new pharmacovigilance signals (defined as "... possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously") among the case reports we receive from National Centres. Here I present an overview of the signal detection process as it currently operates at UMC.

The UMC receives reports of suspected adverse reactions to medicines from WHO Programme member countries, and enters these reports into the WHO Individual Case Safety Report (ICSR) database, VigiBase. Each report lists at least one medicine and one suspected adverse drug reaction (ADR), giving rise to a number of potential drug-ADR pairs, which we refer to as 'combinations', any of which may represent new, clinically significant signals. For signal detection, the Information Component (IC), a measure of disproportionality, is used to highlight drug-ADR pairs appearing in VigiBase more frequently than expected. A combination of automated and manual techniques is used to examine VigiBase for new signals.

Screening for disproportionality

Every quarter, all combinations entered in VigiBase during the previous quarter are initially screened automatically for statistical disproportionality, defined as $IC_{025} > 0$, where IC_{025} is the lower 95% credibility interval of the IC.¹

Subsequently additional triage criteria are applied, specifically selecting for global relevance (number of reporting countries > 1) and the presence of either an emerging signal (increase in $IC > 1$ since previous quarter) or a serious suspected reaction to a new drug (WHO-ART 'critical' term and drug first entered in the database within the last 5 years).^{2,3}

Key points:

1. UMC utilises a combination of automated and manual methods in the signal detection process
2. Each potential signal undergoes detailed clinical review
3. The UMC Signal Review Panel consists of a group of pharmacovigilance experts from a wide range of clinical specialties
4. Signals from the UMC are currently circulated only among WHO program member countries and the Review Panel
5. Further developments of the signal detection process are planned, including incorporation of new methods developed by UMC's Research Department.

Reviewing

Combinations selected by the automated method (around 600 to 800 combinations per quarter) are further screened by staff of the UMC signal team for expectedness (based on labelling, standard drug references, and further literature searching as required) and confounding (particularly by disease under treatment, concomitant medical condition, or concomitant drugs).

Those combinations judged potentially to represent new safety issues are sent for detailed review, either by members of the UMC's Signal Review Panel, or by UMC staff ourselves. The Signal Review Panel is a group of experienced pharmacovigilance experts who have been invited by the UMC to review potential signals. Current membership of the Panel can be found on the UMC website (see also p13).

The detailed review process involves consideration of the clinical significance of the reports, along with a review of relevant literature. Original reports may be requested directly from the relevant national centres if desired (this is not done routinely). Those combinations assessed as being new, clinically interesting signals, may be included in the 'restricted' WHO document SIGNAL, which is produced quarterly and circulated to all members of the WHO Programme, and to Review Panel members. Ideally, we aim to have a finalised review in SIGNAL within 1-2 quarters of the potential signal first being detected in VigiBase.

Where a unique marketing authorisation holder can be identified for a patented medicine, the company is provided with a draft version of the SIGNAL text, and invited to comment. Any comments received are presented alongside the signal review.



The Signal Review Panel members and UMC staff

Key numbers

As of 1 July 2009, there were 4,759,960 ICSRs in VigiBase, collected from 1968. These reports contain 858,741 unique combinations, of which 117,487 have an associated IC025>0. During 2008, a mean of 113,046 combinations were entered into VigiBase each quarter. Of these, 2,521 (630 per quarter) were flagged during 2008 using the automated triage process. Combinations not reviewed previously were then assessed by the UMC's signal detection team.

Of the 2,521 combinations selected by the automated screening and triage processes, 372 (18%) were sent for detailed evaluation, resulting in the publication of 14 items in SIGNAL. These 14 assessments comprised four new drugs, two biological agents, one complementary medicine, and seven older conventional medicines. There was additionally one review of a drug-drug interaction.

Dissemination

Reviews from the Panel are occasionally published in the WHO Pharmaceuticals Newsletter. Contributions in 2008 included a review of thrombosis associated with the use of drotrecogin alfa in issue 5/6, and an overview of oseltamivir reports in issue 3. The Newsletter is available as an unrestricted document from the WHO website.⁴

A number of interesting recent signals were presented as posters at this year's International Society of Pharmacovigilance (ISoP) meeting in Reims, France. These signals were for statins and tendon rupture, montelukast and photosensitivity reactions, and serotonin syndrome following varenicline use.⁵



Staff at their meeting in Uppsala in October 2008.

Looking forward

Future developments planned for the signal process include a review of the triage algorithms in an attempt to improve the 'success rate' of the initial process for selecting combinations for review. We would also like to incorporate other methodology developed by the UMC's Research Department, including duplicate detection, automated extraction of known adverse reaction information from drug information references, and quality grading of reports. Since the primary audience for the SIGNAL document is the National Centres, we are interested in gathering more feedback from countries on what material in SIGNAL would be most relevant to their work.

The large set of reports available in VigiBase, together with the constant entry of new reports, requires the application of automated methods for effective data usage. However, the limited number of combinations sent for review, as well as the small number of articles finally presented in SIGNAL, emphasise the importance of detailed clinical review of potential new signals.

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2. Ståhl M et al. *Pharmacoepi Drug Safety* 2004; 13(6): 355-363.
3. Lindquist M. *Drug Safety* 2007; 30(7): 635-637.
4. <http://www.who.int/medicines/publications/newsletter/en/index.html>
5. *Drug Safety* 2009; 32(10); signals are abstracts 125, 126, and 133, text extraction is abstract 135.

Members of the UMC Signal Review Panel:

Dr Ariel E Arias, Canada	Prof P O Lundberg, Sweden
Dr Joanne Barnes, New Zealand	Dr Jens Lundgren, Denmark
Ms Anna-Lena Berggren, Sweden	Dr M Laurie Mashford, Australia
Mr Maximiliano Bergman, Argentina	Dr John McEwen, Australia
Prof Gunnar Boman, Sweden	Dr Ronald H B Meyboom, Netherlands
Dr Ian Boyd, Australia	Dr Ed Napke, Canada
Dra Mabel Burger, Uruguay	Prof Tamás L Paál, Hungary
Prof Alfonso Carvajal, Spain	Dr Martin Pfeiffer, Germany
Dr David W J Clark, New Zealand	Dr Robert Pless, Canada
Dr Anita Conforti, Italy	Dr Alain Rohan, USA
Dr Ana Maria Corrêa Nunes, Portugal	Dr Emilio J Sanz, Spain
Prof Dr Andrew Czeizel, Hungary	Dr Ruth Savage, New Zealand
Prof Richard Day, Australia	Dr Saad Shakir, United Kingdom
Prof Peter de Smet, Netherlands	Dr Debbie Shaw, United Kingdom
Dr P Murali Doraiswamy, USA	Mr Ivan Stockley, United Kingdom
Prof Edzard Ernst, United Kingdom	Dr Michael Tatley, New Zealand
Dr Rick Fraunfelder, USA	Dr Mary Teeling, Ireland
Ms Birgitta Grundmark, Sweden	Dr Ingrid Trolin, Sweden
Dr Pär Hallberg, Sweden	Prof Kiichiro Tsutani, Japan
Dr Kenneth Hartigan-Go, Philippines	Prof Giampaolo Velo, Italy
Dr Staffan Hägg, Sweden	Dr Anthony Wong, Brazil
Prof Peter Jacobs, South Africa	Dr Qun-Ying Yue, Sweden
Dr Sylvia Kardaun, Netherlands	
Ms Anne Kiuru, Sweden	The UMC signal detection team:
Prof Milan Kriska, Slovakia	Richard Hill (team leader)
Dr Nilima Kshirsagar, India	Maria Tengstrand
Prof Michael Langman, United Kingdom	Jeanette Johansson
	Helena Sköld
	Anders Viklund

'Monitoring Medicines' agreement signed

Sten Olsson

A project entitled 'Monitoring Medicines' has been set up following an agreement between the European Commission (EC) and the UMC which came into force on 1 September 2009. The project, running for 42 months, will be funded by the Seventh Framework Programme (FP-7) of the Research Directorate of the Commission.



Dr Shanthi Pal

The success in reaching the agreement is to a great extent the result of the initiative, persistence and hard work of Dr Shanthi Pal at WHO-QSM, Geneva. In early 2007, responding to a call for coordination projects from FP-7 on Patient Safety Research Networks, Shanthi Pal wrote a draft proposal focusing on four different themes relevant to patient safety:

- Strengthening consumer reporting
- Pharmacovigilance centres collecting problems related to inappropriate drug use (medication errors)
- Better use of existing global pharmacovigilance data through advanced data mining
- Developing active and passive pharmacovigilance systems to address national drug safety priorities.

Relevant partners were invited to join a consortium to meet the goals set out in the draft plan. The UMC was invited to become the coordinating partner, since WHO, for policy reasons, cannot fulfil this role. The full proposal, entitled 'Optimizing drug safety monitoring to enhance patient safety and achieve better health outcomes', was submitted to the EC in September 2007. The following partners are involved in the project:

- ◆ Uppsala Monitoring Centre (coordinator)
- ◆ World Health Organization
- ◆ Medical Products Agency, Sweden
- ◆ Lareb foundation, the Netherlands
- ◆ National Patient Safety Agency, United Kingdom
- ◆ Poison Control and Pharmacovigilance Centre, Morocco
- ◆ Copenhagen HIV Programme, Denmark
- ◆ Elliot Brown Consulting Limited, United Kingdom
- ◆ Zuellig Family Foundation, the Philippines
- ◆ University of Ghana Medical School
- ◆ Pharmacy and Poisons Board, Kenya

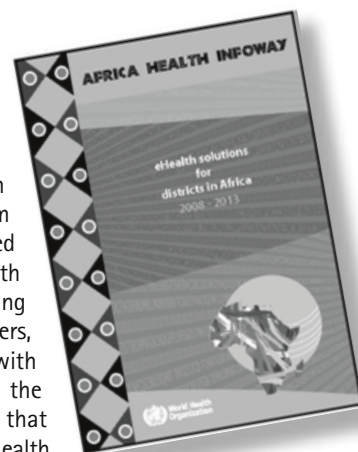
After an extensive project review process undertaken by the EC, the 'Monitoring Medicines' consortium was invited in March 2008 to initiate a formal negotiation with the EC with the aim of signing a grant agreement. The negotiation process was protracted, partly due to complex high-level legal discussions between WHO and the EC. Finally Ralph Edwards was able to sign the agreement with the Commission on behalf of the consortium, before he retired on the day

it entered into force. Project coordinator at the UMC is Sten Olsson, who will work closely with Shanthi Pal in the implementation of the project. Readers of *Uppsala Reports* and visitors to the UMC website will be regularly updated on progress of this project. We expect that it will lead to considerable methodological development in pharmacovigilance, benefitting patient safety around the globe.

Africa Health Infoway and VigiFlow®

Africa Health Infoway is a partnership between the World Health Organization, the International Telecommunication Union (ITU), the African Union, and other public and private sector stakeholders. The aim is to offer electronic information sources and tools to the healthcare sector in African countries. Services are targeted towards health workers, district health managers, policy-makers, health managers and the general public. The current project runs for a period of 5 years, 2008–2013, delivering broadband connectivity to global information, and capacity building through integrated systems to capture, use and exchange health information.

In March 2009, the Africa Health Infoway initiative was presented to the WHO Advisory Committee on Medicine Safety (ACSoMP). A request was made by ACSoMP that VigiFlow, the adverse reaction case management system developed by the UMC, be offered as a service through Africa Health Infoway. A joint WHO – ITU meeting was held at WHO headquarters, Geneva on 22 September 2009, with the aim of presenting some of the major WHO health initiatives that would benefit from the Africa Health Infoway Initiative. Sten Olsson from the UMC was invited to briefly present the WHO International Drug Monitoring Programme, the functionalities of VigiFlow and the benefits of having broadband access to the internet in African countries.



A high-level agreement between WHO and ITU regarding the Africa Health Infoway is likely to be signed very soon. Six African countries have been selected for a first roll-out of technical installations for broadband provision. We hope that this project will have a major impact on the accessibility to VigiFlow for many of the African members of the WHO International Drug Monitoring Programme. Limited internet access is a bottleneck for effective case management for many national pharmacovigilance centres, reporting to VigiBase and information exchange with other partners.

Pharmacovigilance for Panama

Mariano Madurga

"Pharmacovigilance in practice and monitoring of adverse reactions" was held at the University of Panama from 12 to 14 August 2009. This activity, framed as a complementary part of the "Specialisation Programme in Pharmacotherapy and Medicines Clinical Management, promotion 2009-2010", was organized by the Vice-Rector for Research and Graduate Studies at the University of Panama, through the "Centro de Investigación e Información de Medicamentos y Tóxicos", CIIMET (www.ciimet.org) under the direction of Professor Hildauro Acosta de Patiño.

Dr Victor Serrano (*Caja de Seguro Social*, Panama) opened with a lecture on "Pharmacovigilance: Challenges and Opportunities". An international team of speakers followed: Dr Claudia Vacca (*Universidad Nacional de Colombia*) presented Latin-American experiences in pharmacovigilance, and activities by different healthcare professionals to prevent ADRs; Dr Ismary Alfonso (*Centro para el Desarrollo de la Farmacoepidemiología*, CDF, Cuba) spoke on pharmacovigilance in primary care and specialised care in hospitals, dermatological adverse reactions, neurological and psychiatric disorders caused by medications, and adverse reactions to cardiovascular drugs; Dr Julio Toro (Panama) explored frequent ADRs with antimicrobials. Hildauro Acosta de Patiño presented the results of the national pharmacovigilance system audit which took place in 2006-2007 and a 5-year action plan.

Sessions addressed issues such as ADRs in newborns, drug-related blood dyscrasias, national pharmacovigilance actions since 1998, the establishment of regional centres and drug-induced liver diseases. Dr Rebecca Fallas of the Latin-American pharmaceutical laboratories (*FEDEFARMA*) spoke about pharmacovigilance activities of pharmaceutical companies, and Dr Mariano Madurga (Spanish Agency of Medicines and Healthcare Products, *AEMPS*) gave an international perspective, with ADR monitoring methodology, causality relationship and signal detection, action plans of national pharmacovigilance systems, the WHO Programme for International Drug Monitoring, regional networks (including the EU), vaccine and biotechnological products safety, good pharmacovigilance practices and activities of the pharmaceutical industry.



The speakers and organisers of the Panama meeting.

In a magnificent auditorium of the University of Panama, 80 professionals attended, including 31 students from the Specialisation Programme and healthcare professionals working as general practitioners, those in anaesthesiology, internal medicine and haematology, pharmacists from the regulatory area of the Ministry of Health, community pharmacists, and hospital pharmacists from public health institutions (Social Security Fund), and university professors in medicine and pharmacy. Pharmacists and medical doctors from several regions around Panama also attended.

This was an exciting education and training activity for pharmacovigilance professionals and institutions that demonstrated how pharmacovigilance is a collaborative activity which gains much from true sharing and networking.

Communicating Risk in Pharmacovigilance

Sten Olsson

The national pharmacovigilance centre of Croatia organized an international conference in Zadar, Croatia, on 1 – 2 October 2009 on communicating risk. Speakers had been invited to represent perspectives from WHO/UMC, regulatory authorities, multinational and regional pharmaceutical industry. Presentations of communication practices from the regulatory side were made by Viola Macoli -Šarin, Croatia, Mick Foy, UK, Nele Mathijis, Belgium, Marija Petronijevi, Serbia and Niamh Arthur, Ireland. The role and communication challenges of WHO/UMC were discussed by Sten Olsson. Industry perspectives on information to prescribers and patients were given by Michele Bartolini, Roche, Helmut Oberender, Bayer, Natasha Nasteva, Alkaloid, Vladimir Sužnjevi, Genzyme, and Tatjana Ajher Djuretek, Belupo.



Participants at the Zadar conference

It became evident that communication efforts have increased and improved considerably from both regulators and industry since the Erice Declaration on Communicating Drug Safety Information was published in 1997. Evidence of improved outcomes in terms of safer use of medicines and lower incidence of drug-related problems in healthcare are however lacking. Calls were made for further research in methodology to enhance the impact of current activities or to suggest new methods. Proposals were made that rational use of medicines needs to form part of the interactions of sales representatives from the Marketing Authorization Holders with healthcare practitioners, especially in the field of pharmacovigilance. This would entail a change in the approach of such representatives from solely a sales role to one able to impart scientific data to health workers.

Looking at data sources in Providence

Richard Hill and Ola Caster report

The 25th ICPE meeting, from 16th–19th August, in Providence, Rhode Island, had the usual very full programme, with five sessions of oral presentations running simultaneously, and up to seven simultaneous symposia. In addition there were six 'Pre-Conference Educational Sessions'. Compared with previous meetings, there was less of a focus on the methodological and statistical issues with observational studies.



Ola Caster, with moderators Andrej Czarnecki and M Miles Braun.

The underlying theme of the conference was the use of longitudinal data sources and related issues, such as how and when to pool different sources; whether to focus on hypothesis generation, strengthening, or testing; and whether one can actually do all of those things based on the same data.

Benefit-risk

Topics with a lower profile were benefit-risk assessment (there was, however a pre-conference session on *Comparative Effectiveness Research*), and medicines in children. Lloyd Sansom, Chair of Australia's Pharmaceutical Benefits Advisory Committee, emphasised that comparative effectiveness information is key to making policy decisions around medicines. However, there were fewer presentations looking at both safety research and comparative effectiveness research simultaneously.

Signal detection

Not much was presented on 'traditional' signal detection, except the symposium on CIOMS VIII and our own presentations. Although based on clinical trial rather than ICSR data, Stephen Evans presented interesting work on how to make use of ADR groupings in safety data analysis. His approach was a slight simplification of earlier work by Scott and Donald Berry that yielded somewhat different results.

Psychotropics

The session *Psychotropics in the Elderly*, included interesting presentations of database studies of serious ADRs associated with antipsychotic use in the elderly, one looking at events leading to hospital admission and the other at events in nursing home residents. Another on safety of psychotropics had one presentation of a propensity score-matched cohort study from a US claims database looking at suicide risk of antidepressants, which also included a depressed unmedicated group and a general population group for comparison. A nested case-control study in the GPRD examining the risk of self-harm and suicidal behaviour associated with antiepileptic use in epilepsy was presented.

UMC contributions

We both gave presentations to a packed room in the *Early detection in pharmacovigilance* section. Richard talked about implications on signal detection from the choice of underlying terminology and Ola on findings from regression-based data mining; both were warmly received. Ralph Edwards was part of a symposium on CIOMS VIII, together with June Raine and Manfred Hauben. Ralph also chaired a lunchtime session on what to do with signals from longitudinal data.

The UMC had posters on an evaluation of our signal work and a study into NSAIDs dosage in children. The UMC also had an exhibition booth which included demonstrations of Vigibase searches.

FDA work

A presentation in the *Early detection in pharmacovigilance* session from the FDA assessed consumer and healthcare professional reports for presence of essential data elements as well as clinical adequacy. There was also a presentation of weekly sequential analysis of data from the CDC's Vaccine Safety Datalink. This was an exercise in signal strengthening, and resulted in a single signal confirmation (febrile seizure following MMRV).



Richard Hill in the ISPE poster sessions

A major plenary on Wednesday featured the FDA's Sentinel Initiative Project. Miriam Sturkenboom also spoke on the EU-ADR (formerly ALERT) project. Many important views were shared between the two:

- there will be no centralized databases; rather, networks and the idea of 'analytical hubs' that are fed sufficient statistics computed from the individual databases (all in the interest of privacy).
- there is a clear focus on signal strengthening, not on signal detection, prompted by a concern that false positive findings may occur, and uncertainty on what to do with them in terms of communication and follow-up. This concern, together with issues of harmonizing different medical terminologies, was also cited as a reason for only looking at certain events.

Richard Platt from Observational Medical Outcomes Partnership talked about the scientific side, mainly the vaccine surveillance programme. Their method is based on the very same approach of looking at predefined events.

Pharmacists of the world prepare!

Bruce Hugman

Ghanaian drums and dancers on the steps of the National Theatre welcomed participants to the meetings of the Commonwealth Pharmacists Association (CPA) and the Pharmaceutical Society of Ghana (PSGH) in Accra, Ghana, 3-9 August this year. It was a colourful and exuberant beginning to a lively and stimulating series of professional discussions and memorable social events.

The theme of the CPA conference was: *Managing threats and crises: the vital role of pharmacy in an unstable world*. The topics ranged from the threats of pandemic disease and medication error, to natural and man-made disasters of all kinds. The conference examined the extent to which the pharmacy profession was informed, skilled and alert in the face of so many threats to human health and welfare – and the ways in which it could contribute to the reduction of threats, the prevention of disasters and the management of crises. An outcome of the meeting was a powerful communiqué (see p18), calling for a new and radical role for pharmacists throughout the world, engaged with their patients and customers in a true partnership in the face of hardships and dangers.



Blood pressure checks for local people.

health advice and so on. Necessary medicines (that may be prescribed by pharmacists), for instance against malaria, common colds and worm infections, are provided by sponsoring pharmaceutical companies. The health outreach programme was obviously very



Dr Anarfi Asamoah Baah of WHO, after giving an exhilarating speech in Accra

In true Ghanaian style, the welcome was warm, the entertainment memorable (including a performance by the exceptionally talented National Dance Company), the hospitality generous and the music loud. Alex Dodoo, re-elected President of PSGH, was widely complimented on his organising team's remarkable achievement of managing more than 1,500 delegates so efficiently. The Vice-President of Ghana and the Minister for Health were among the VIP guests who appeared impressed and pledged their support for the development of the profession.



Qualified pharmacists check the medical history of those who came

popular, judging from the large number of people who assembled at the stands asking for tests and professional advice. A disc-jockey with his powerful music equipment brought the atmosphere of a communal festival to the event. Health provision need not be boring!

Health Outreach

Sten Olsson

The Pharmaceutical Society of Ghana (PSGH) regularly organizes 'health outreach' activities for its members in a place selected in order to benefit the disadvantaged. This year a health outreach day took place in a municipality with the confusing name of Dar es Salaam, near the Ghanaian capital Accra, as part of the conference of the Commonwealth Pharmaceutical Association (CPA).

Foreign guests attending the CPA also took part in the outreach day. PSGH members offered citizens in the local community free health checks, with blood pressure and blood sugar measurements, general



High demand for health advice at the Accra outreach day

Communiqué

Issued by the 10th Commonwealth Pharmacists' Association meeting, Accra, Ghana 5-9 August 2009

Conference theme: *Managing Threats and Crises: The vital role of pharmacy in an unstable world*

- Natural and man-made threats and crises and failures of systems are increasingly common features of the modern world.¹ Many of them and the dangers they pose have radical and damaging effects on the health and welfare of often large populations, with children particularly exposed, especially in developing countries.
- Deficiencies and inequalities in human rights and in the provision of basic resources, services and opportunities² contribute significantly to global disease and premature death.

The CPA recognises the burden of suffering and the multiple deprivations of millions of the world's population, and the threats to which they, and some groups in particular,³ are vulnerable. Pharmacists, distributed widely throughout the continents, and in some of the remotest places, are especially well-placed to perceive and assess the risks and to contribute to their management or reduction.

Pharmacists of the Commonwealth call upon their colleague professionals throughout the world:

1. To be alert to the specific current and potential threats to the health, welfare and safety of their patients and communities; to become advocates for positive change; to collaborate with others, locally, nationally and internationally in the alleviation of suffering and the anticipation and prevention of crises.
2. To take part in collaborative planning for the reduction of risk and for the management of disasters and crises, especially those that are current and continuous, and those which can be plausibly predicted.^{4,5}
3. To be compassionate professionals, far beyond the basic roles of drug retailers and dispensers,⁶ actively committed to understanding their patients and local communities and the multiple risks and needs which affect their health, happiness, welfare and safety.
4. To work actively with patients and communities to improve health-related behaviour and health in general, through effective one-to-one relationships, outreach activities, education, public health initiatives, campaigns, community development, advocacy and other means.
5. In recognition of the particular threats to the welfare and survival of children, and of global commitments to this cause, to work actively to ensure progressive realisation of the full rights of children, including the right of access to healthcare and to appropriate, high quality essential medicines.^{7,8}

These vivid and high-priority opportunities and challenges are being met only partly and incompletely, if at all, in most parts of the world.

Pharmacists, who are closely in touch with the majority of all patients and their communities, are in a unique position to change things for the better. Pharmacists in industry bear key responsibility for providing safe, efficacious and affordable, quality medicines. In their daily relationships and activities, and in developing their vision of a better world, all pharmacists should take leadership in many aspects of reducing risk and improving health throughout the Commonwealth and beyond.

This communiqué had the unanimous support of the large international audience present at the meeting.

Accra, Ghana

¹ TB, HIV/AIDS, malaria, pandemic viral infections, cancer, heart disease; lifestyle diseases (e.g. diabetes, hypertension, obesity); tobacco use; extreme weather events, natural disasters; control of counterfeit and illegal drug trafficking; unregulated use of medicines. Globalisation poses challenges but also offers opportunities.

² Shortages of food, water, shelter; poor sanitation; lack of education; lack of access to healthcare services and medicines; unemployment. Pharmacists in the Commonwealth reaffirm their commitment to the Universal Declaration of Human rights.

³ Pregnant women, children, the elderly.

⁴ Diseases: malaria, HIV/AIDS, TB, diabetes, obesity; behaviour: safe sex, compliant medication use, rational use of drugs (especially antibiotics),

disease vector control; issues: counterfeit and sub-standard medicines, medication error, infant and maternal mortality, drug resistance; events: flooding, wild fires, earthquakes, tsunamis.

⁵ E.g.: stockpiling of appropriate medicines, vaccines, surgical and other supplies; drills and training in disaster response; preparation of refuges and safe-havens.

⁶ While noting that pharmacists bear primary responsibility for meeting the medicine-related needs of populations.

⁷ Children need access to age-appropriate dosage forms of medicines.

⁸ Health systems are encouraged to remove financial barriers limiting access to healthcare and medicines, for all children.

Recorded Presentations

In order to share some of the teaching available on UMC courses, video recordings of four presentations given at the 2009 Uppsala training course may be viewed via the following link with the Uppsala University website: <http://media.medfarm.uu.se/flvplayer/umc09>

How to build an effective pharmacovigilance system

Pia Caduff-Janosa - Swissmedic

Pharmacovigilance in Public Health Programmes

Shanthi Pal - WHO

Patient safety problems related to drug counterfeiting

Toumi Amor - (IMPACT) WHO

Policies, norms and standards for the safety of medicines

Shanthi Pal

Clinical Biostatistics

Ola Caster

The 30th International Society for Clinical Biostatistics conference in Prague, Czech Republic, last August, focused on the design and analysis of clinical trials.

From the point of view of pharmacovigilance the most interesting session was that on *Regulatory Affairs*, where prominent statisticians acknowledged the need to consider post-marketing data such as claims databases, electronic health records (EHRs), and ICSRs. Frank Rockhold (GSK), one of the original authors of the ICH E9 document ('Statistical Principles for Clinical Trials'), and Robert O'Neill (FDA) were among the speakers. The former noted that biostatisticians need to seriously move into signal detection and benefit-risk modelling and recognized the potential usefulness of post-marketing data sources. Robert O'Neill discussed the prospective use of the FDA sentinel network, as well as ICSRs.

A keynote speech by Mark Buyse proposed a method for translating clinical relevant endpoints into statistically more sensitive endpoints. The core of this proposal was carrying out pairwise comparisons between the patients in one group with the patients in another group.

Ola Caster attended on behalf of the UMC, presenting a poster on a regression method to aid signal detection, and making an oral presentation on an algorithm to automatically extract ADR information from free text.

The organizers offered a major social programme that much enhanced the overall impression of the conference, culminating in a conference dinner at Kaiserstein Palace.

Rheumatology conference

Kristina Star, one of the Drug Safety Analysts in the UMC Research department, spoke at the 37th congress of the German Society of Rheumatology (with the Association for Orthopaedic Rheumatology and German Society of Paediatric Rheumatology) on 23–26 September in Köln. She gave a presentation on the UMC's process of detecting signals and an overview of recent VigiBase data reported for children.

Training for South-East Asia

Cecilia Biriell and Elki Sollenbring

From time to time WHO organizes pharmacovigilance training courses in WHO regions. Such a five-day training course was organized by WHO Headquarters in co-operation with WHO South-East Asian regional office (SEARO) from 28 September to 2 October 2009.

The course was held in Colombo, Sri Lanka and attended by around 25 participants from eight countries: Thailand, Indonesia, Sri Lanka, India, Nepal, Myanmar, Maldives and Bhutan. The level of pharmacovigilance programmes in the region varies a lot, from Thailand which has a well-developed programme with 22 regional

centres and 38,000 reports a year, to the Maldives and Myanmar where pharmacovigilance programmes have not yet been set up.

The five days covered all aspects of pharmacovigilance, from key definitions in pharmacovigilance to the development of country-specific action plans and there was a lot to learn for everyone. The course was opened by the Minister of Healthcare and Nutrition of Sri Lanka, Dr Nimal Siripala De Silva, and in the newspaper the following day we could read that the minister wants to substantially increase the health budget, but unfortunately nothing was mentioned about pharmacovigilance.



Elki Sollenbring from UMC instructing Dr Jumeylath Beygam and Mr Mohamed Fazeen from the Maldives in VigiFlow

The course was organized by Mary Couper and Mitsuko Imai of WHO-HQ in co-operation with Dr Krisantha Weerasuriya of SEARO, and included a panel of facilitators: Professor Nilima Kshirsagar gave her expertise in drug surveillance in leishmaniasis programmes, and local experts Professor Rohini Fernandopulle, Dr Shalini Sri Ranganthan and Dr Pryadarshani Galappatthy talked about various aspects of pharmacovigilance relevant to countries in the South Asian region.

The course included three interactive sessions on entry of cases into VigiFlow, causality assessment and country specific action plans. All three sessions created great interest and lively discussions in the working groups. It was clear that sustainable financing of the pharmacovigilance programmes is a problem in many of the countries.

Elki Sollenbring and Cecilia Biriell from UMC lead the hands-on training on VigiFlow after an introduction of the system, and also of WHO-ART and WHO Drug Dictionary. Ken Hartigan-Go led discussions on some educational cases for causality assessment where participants came up with many alternative explanations to the causes of the reactions and therefore the assessment.

The course covered many more topics: pharmacovigilance in Public Health Programmes, pharmacovigilance in vaccines programmes and adverse events associated with traditional medicines. Participants came away from the course filled with new knowledge to be included in the development of country-specific action plans for the next few years.

The programme included not only the intensive pharmacovigilance training but also social activities organised by the personnel of the WHO South-East Asian regional office. Participants could sample Sri Lankan dishes while enjoying Sri Lankan music and dance at the welcome reception while the farewell party at the beach consisted of a delicious dinner and dancing to guitar music.

The detective director

Sten Olsson poses some questions to Marie Lindquist, the UMC's new Director

You have served the UMC for many years. What attracted you to apply for the Director's post?

Marie Lindquist: I can't think of a more interesting and challenging job! I've spent my professional life helping UMC develop from its quiet beginnings, and it seems the most natural step to take up the ultimate challenge. I want to use my competence and experience to help the UMC grow and flourish in the future. I just hope I'll be the leader UMC and our part of the WHO Programme deserve!

Has it been a dream for you to be the leader of an organisation?

Not for its own sake, no. But I do like to influence events, shape policy, make decisions and take the lead when I can. Leadership is nothing without good people to work with and that's what makes the UMC such a positive place to have such responsibility.

What is for you the most challenging aspect of becoming UMC Director?

To find the right balance between stability and innovation and flexibility. If we want to continue to influence the future direction for pharmacovigilance and patient safety, we must not only adapt to change, but also be in the front-line and lead and manage change.

...and the most inspirational?

I'm privileged to have been chosen to lead a unique organisation with a wonderful team of competent and dedicated people. UMC's vision of helping to safeguard patients around the world is itself inspirational.

If pharmacovigilance and the UMC had not come your way, what is likely to have become your profession?

Probably an architect: I want to plan, design, create beautiful, lasting things which are useful. That's something we can do at the UMC too.

Have you got any heroes, role models or other people, historic or living, who have inspired you in your professional career?

Unlike many teenagers, I never really worshipped or idolised celebrities when I was young, nor do I now, but I have always admired Katherine Hepburn and other strong, competent and witty women who have shown that it is the person that counts, not the gender. Professionally, I have been inspired by and tried to learn from dedicated pioneers like David Finney, Beje Wiholm and Ralph Edwards – and a fictional master detective: Sherlock Holmes! There are many others that I could name, but I would also like to say that I am motivated, and moved, by the thought of all those modest people who never hit the limelight but who struggle, sometimes against hard opposition, and do things that they believe in.

Is there any decision you have taken in your professional career that you regret in hindsight?

No, I don't think so. Others might feel that experience in other work areas would have been a good move for me, but I don't really feel that myself.

Do you have any personality characteristics that most people do not know about (and you are prepared to disclose)?

I'm a romantic with a sentimental streak; basically a shy person but I feel things very intensely even though, I think, some see me as a cool character. I get very angry and frustrated when technical equipment doesn't work (connecting my TV and DVD player was a nightmare!); the appalling language and lack of intelligible instructions in many user manuals and help texts can sometimes drive me crazy.

What relaxes you when you try not to think of work?

While not thinking about work is one of my main personal challenges, I love music and can lose myself there: playing my favourite pieces loud in the car; singing alto in Mozart's Requiem, playing Handel's Zadok the Priest. I also find it relaxing to go for a brisk walk on a cold, crisp day; getting my hands dirty in the garden; stroking my cats; and I love to

look after my home and care for my family and friends. Being a mother and grandmother is a great source of joy!

What makes you laugh and why?

I'm amused by human foibles and absurdities and by humour which is based on witty and intelligent observation of people. I do like the understated, ironic tone of what I think is typical English humour; and the video 'Rachmaninov had big hands' with the musical comedy duo Igudesman & Joo (available on the internet) is an example of something that makes me laugh!

What do you think you'll be doing professionally ten years from now?

I really don't know! I'm not a career person in the sense of thinking where I'll move next. My real ambition is to contribute something of lasting value to society and the individuals within it, whatever the role. I want to continue in my current job as long as I am the right person for the UMC, and as long I am good at what I do.

Thank you, Marie!



The WHO-DD's content management team

Elki Sollenbring

The WHO Drug Dictionaries are a part of the WHO Individual Case Safety Report database – VigiBase, and comprise an extensive source of medicinal product information. In drug safety surveillance the Dictionaries are used to identify drug names, their therapeutic use and active ingredients from all over the world. The Dictionaries contain data from 1968 onwards. The content originates mostly from national reference books of drug names sent to the UMC from the National Centres and IMS Health. As of June 2009 the WHO Drug Dictionaries (combined) contained 211,457 unique names out of 1,578,212 different products and trade names. The principal customers are pharmaceutical companies, clinical research organizations and drug regulatory authorities.

The Drug Dictionaries content management team consists of: Carin Ellene, Elki Sollenbring and Malin Jakobsson, all MSc graduates in pharmacy and Camilla Westerberg and Malin Zaar, pharmacists. Carin, Camilla and Malin Jakobsson are the main coders of the medicinal products received via the UMC's collaboration with IMS Health and the national reference sources, and as a result, hundreds of new products are added to every release of the WHO-DD.

The coding process includes entering the active ingredients according to INN (International Non-proprietary Name system), verifying the product names, and assigning ATC codes. Elki is responsible for the coding of traditional remedies and she also assists senior specialist Mohamed Farah in the production of the Herbal ATC index. Malin Zaar is currently involved in designing the Chinese Drug Dictionary, a dictionary containing products found in China, including trade



Camilla Westerberg, Carin Ellene, Malin Zaar, Malin Jakobsson, Elki Sollenbring

names in Chinese characters and pinyin. If inconsistencies are found in the Dictionaries, they are followed up and changes to the Dictionaries are released in March every year, to keep up the quality of the world's most comprehensive database of medicinal products information.

All National Centres within the WHO Programme can have access to the WHO Drug Dictionary in different ways, the most direct being via VigiFlow (contact info@who-umc.org).

Publications news

Recent publications from the UMC include:

Meyboom RHB, Star K, Bate J, Savage R, Edwards IR.

Correspondence: TNF- α Inhibitors and Leukaemia: International Pharmacovigilance Reports.

Drug Safety, 2008, 31(5): 445-447.

Savage RL, Kunac DL, Johansson J.

Appraising the post-marketing safety of medicines : A description of national and international pharmacovigilance with a focus on medicines used in chronic pain.

Current Anaesthesia & Critical Care, 2009; (20): 215-220.

Strandell J, Bate A, Hägg S, Edwards IR.

Rhabdomyolysis a result of azithromycin and statins: an unrecognized interaction.

British Journal of Clinical Pharmacology, 2009; 68(3):427-34.

Edwards IR.

Editorial. The good old drugs!

Drug Safety, 2009; 32(4):271-3.

Edwards IR, Lindquist M.

Editorial. Understanding and communicating key concepts in risk management: what do we mean by benefit and risk?

Drug Safety, 2009; 32(6):449-52.

Edwards IR.

Editorial. Outliers and patients with adverse drug reactions.

Drug Safety, 2009; 32(8):623-4.

PharmacoEpi & Risk Management

The PharmacoEpi & Risk Management Newsletter has reached its third edition. Produced in France by the MAPI Trust, details can be found at www.prmnewsletter.org.

Issue 3 includes articles on 'New FDA signalling and surveillance initiatives', 'Management of cardiovascular risk potential for a new oral contraceptive', and 'Chronic pain management registry to be launched in the United States'.

Visitors

From August 31 to September 4, **Adwoa Bentsi-Enchill** from WHO-IVB (WHO's Department of Immunization, Vaccines and Biologicals) in Geneva, along with **Nevil Fouad** and **Muhammad Nour**, both from HIT/ISM, at the WHO Eastern Mediterranean Regional Office, Cairo (EMRO), visited the UMC. In a number of meetings the various tasks relating to the development/support and analysis of the database for the Global Network for Post-marketing Surveillance of Newly Pre-qualified Vaccines were discussed.

On 3rd of September the UMC had the pleasure of receiving three visitors from the **Library of the Swedish Medicinal Products Agency (MPA)**. They were Pia Bagge, Weldu Tseggai and Anders Forsberg who came to learn more about the UMC activities, terminologies and dictionaries. Both Elki Sollenbring and Cecilia Biriell presented an overview of the activities, the WHO Drug Dictionary and WHO-ART.



Jerry Labadie, Nevil Fouad, Sten Olsson, Adwoa Bentsi-Enchill, Muhammad Nour

New staff

Sara-Lisa Fors

Sara-Lisa joined the UMC in August 2008 on a short-term contract, working with the WHO Drug Dictionary. Later she joined the Reporting team, a position which has now become permanent, and involves supporting member countries in their reporting to the WHO database (VigiBase). She also codes information originating from ICSR reports into the Drug Dictionary.

Born, raised and educated in Uppsala, after graduating with a Bachelor of Science in Pharmacy in 2007 Sara-Lisa worked at a pharmacy in Gävle, about 100 km north of Uppsala. She then spent a year at the Swedish Drug Information call centre, Apoteket Kundcentrum before arriving at the UMC. "I am very glad that I got this opportunity; it turned out to be a nice place to work at, and I really enjoy meeting people from all over the world!"

Outside work Sara-Lisa is a regular gym user, and is also currently taking evening classes to improve her Finnish: "this is a language I learnt to speak a little thanks to my Finnish mother. Once or twice a year I go to Pori in Finland to spend time in our summer house and to visit my relatives".



New UMC staff: (from left) Carin Ellene, Camilla Westerberg and Sara-Lisa Fors

Camilla Westerberg

Camilla, originally from Örebro, moved to study pharmacy at Linköping University. "I had been working in a pharmacy at the end of secondary school and thought it seemed like a pleasant place to work where you got the opportunity to help people. I decided that this was my future career." Camilla graduated from Linköping in 2006 with a Bachelor of Science in Pharmacy degree. Following graduation she lived in Uppsala for a year, taking a course in gender studies and further pharmacy courses at Uppsala University.

"My first full-time job was in a pharmacy back in Örebro; then I came to the UMC in the autumn of 2008. The first impression was that it was a pleasant place to work where you also got the opportunity to make a contribution to safer drug use in a more global way. My current post is a content coder in the Drug Dictionaries team."

"I'm currently fully occupied in my spare time decorating my apartment, but I also like artistic painting and reading."

Carin Ellene

Carin is from the coastal town of Sundsvall and moved to Uppsala in 1998 to study. After three semesters of biology, she decided to change course, and graduated in 2005 with a Master of Science degree in pharmacy.

"After this I worked at pharmacies in Uppsala – a great learning experience, but not what I wanted to do for the rest of my life. During university studies I had the opportunity to visit the UMC and learn about its activities. When I heard that the UMC was looking for pharmacists, I didn't hesitate to apply." Carin now works in the Drug Dictionary team. "My main task is to enter new products into the dictionary, mainly from the IMS data. Although enjoyable, it can be quite challenging, and I feel that my experience from working in pharmacies is very useful."

When not working, she enjoys time with her family. "I have two children, 6 and 2 years old, so spare time include things like playing Nintendo Wii and building Lego houses".

COURSES & CONFERENCES

DATES	TITLE	PLACE	ORGANISER/CONTACT
5-7 November 2009	Sixth International Meeting of Pharmacovigilance	Bogotá, Colombia	Universidad Nacional de Colombia, Av. Carrera 30 No. 45-03, Bogotá, Edif. 476, Oficina 20, Tel: +57-1- 3165000 x15629
11-12 November 2009	Case narrative writing for reporting adverse events	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
16-18 November 2009	2nd DIA Conference on Signal Detection and Data Mining	New York, USA	DIA Phone: +1-215-442-6158 E-mail: Ellen.Diegel@diahome.org
17-18 November 2009	Latest Developments in Pharmacovigilance	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
18-19 November 2009	Pharmacovigilance in products subject to licensing agreements	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
18-20 November 2009	Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing	Paris, France	DIA Europe Tel.: +41 61 225 51 51 Fax: +41 61 225 51 52 E-mail: diaeurope@diaeurope.org
20-22 November 2009	Annual conference of society of Pharmacovigilance of India (SOPi)	Sirsa (Haryana), India	SOPi Professor K C Singhal E-mail: vc@nimsr.com
23-24 November 2009	Adverse Event Reporting & Pharmacovigilance	London, UK	Pharmaceutical Training International Tel: +44 (0)20 7017 7481 E-mail: registration@pti-europe.co.uk www.pti-europe.co.uk/adr
3-4 December 2009	Pharmacovigilance planning and risk management	Southampton, UK	DSRU Tel: +44 (0)23 8040 8621 E-mail: jan.phillips@dsru.org ; www.dsru.org/
3-4 December 2009	Best Practice in Phase IV Clinical & Observational Research	Prague, Czech Republic	NextLevel Pharma Tel: +421 (0)2 3266 0382, E-mail: erikav@nextlevelpharma.com; www.nextlevelpharma.com/
7 December 2009	Introduction to Signal Detection and Data Mining in Pharmacovigilance	Basel, Switzerland	DIA Europe Tel.: +41 61 225 51 51 Fax: +41 61 225 51 52 E-mail: diaeurope@diaeurope.org
10 December 2009	Writing Successful Pharmacovigilance Risk Management Plans	London, UK	Smi Conferences www.smi-online.co.uk/
14-16 December 2009	Pharmacovigilance	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
10-14 January 2010	DIA Annual Conference for Contemporary Pharmacovigilance and Risk Management Strategies	Washington DC, USA	Drug Information Association Tel: +1 (215) 442 6100 Fax: +1 (215) 442 6199 E-mail: dia@diahome.org www.diahome.org
18-19 March 2010	Basic pharmacovigilance course	Hong Kong	International Society of Pharmacovigilance www.isoonline.org
20-21 March 2010	Advanced pharmacovigilance course	Hong Kong	International Society of Pharmacovigilance www.isoonline.org



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