

MUR68



Meetings in China | Completeness | 10 million

Eastern Mediterranean Declaration | Forms for CPD



Marie Lindquist
Director
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Centre

Last week I found a handwritten letter in the mailbox. It was from my granddaughter. Five years old she has just discovered the joys of reading and writing, and in her new-found enthusiasm had decided to send grandma a message. She wrote: "Hello and Merry Christmas. Now all mosquitoes and hedgehogs have gone for their winter sleep and all mice, bears and bumblebees too. Greetings from L."

Holding the letter in my hand, I found I could not stop smiling. Being a Swede, I am very familiar with the dark and gloomy December weather up here in the north, but I never get quite used to it. In a few sentences, this little girl had managed to evoke a wonderful picture in my head, not only of animals neatly tucked away, hibernating somewhere out there in nature; but also of the inherent promise of an awakening coming in the spring.

It is not only the absence of light that can make me feel gloomy sometimes. Looking back at 2014, I think there are good reasons to be concerned about what is going on in the world. I'm thinking not only in terms of what seems like an increasing amount of natural disasters around the globe, but also the level of misery caused by humans. In spite of history that should have taught us that aggression does not solve conflicts, we still have countries that are ravaged by war and political violence; and even though recent years have seen fantastic technological and scientific advance, still there are many, many places on earth where access to healthy food, effective healthcare, appropriate shelter, clean water and a functioning infrastructure are only a dream; and where endemic disease is not a worrying possibility, but an everyday reality.

To make matters worse, the consequences of natural disasters are often aggravated by human inability to deal with them swiftly and appropriately. The Ebola outbreak is just one example where the international community should have been much quicker in providing resources to help those in the affected countries deal with the acute emergency, and stop the disease from spreading. And what are we doing to support the people in Liberia, Guinea and Sierra Leone now, when ebola is still not fully contained, and the economies of their countries are stretched to the very limits?

But all is not dark, far from it. People sharing the same purpose and vision can, and do, get together to fight injustice and to correct mistakes. Pharmacovigilance, though it does not have the kudos and immediacy of epidemics and major events, addresses critical issues of public health and patient safety everywhere. One of the privileges of being part of the global pharmacovigilance network is to experience what can be achieved when people have each put their minds and hearts into improving the lives of fellow humans. It is heart-warming to think about the strong professional, and personal, bonds that have been formed between people from all over the world; these bonds, I'm sure, are crucial to our ability, step by step, to change the world towards it being a better place for all of us.

Pursuing that vision in the years to come, we should put our collective efforts into improvements in some key areas:

- *Develop the knowledge basis that is needed to support good therapeutic decision-making*
 - ◆ *Facilitate access to, and use of clinically relevant information, from spontaneous reports, but also from new sources and types of data – such as studies, electronic health records, patient-generated data, quality registers*
 - ◆ *Integrate pharmacovigilance knowledge in clinical decision support systems*
- *Measure and show evidence of the impact of our work on morbidity, mortality and healthcare costs, to convince decision-makers to invest the necessary funds in the development of pharmacovigilance*
- *Establish productive partnerships and collaborations to make pharmacovigilance an integral part of healthcare and develop holistic patient-centred approaches to better prevent harm to patients taking medicines.*

Looking ahead, I trust that the inherent promise of an awakening New Year will be the energiser that helps us tackle the challenges ahead with enthusiasm and vigour. There is much to be done, and I look forward to working with you all in 2015. Let's make the best of it, together!

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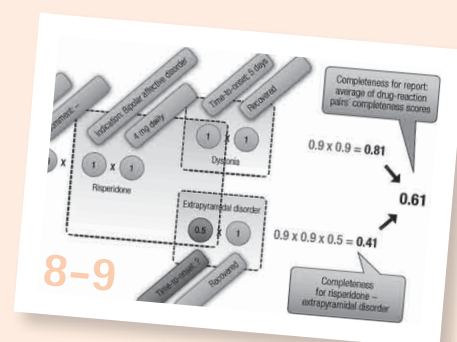


People and medicines

The WEB-RADR project, social media and mobile technologies.

Complete report

A case study on improving quality through analysis of completeness, plus updates on the UMC tool.



Tianjin

The WHO Programme then ISO meet in the Chinese city for their annual discussions.

A big adventure

The life and career of Mohamed Farah as he starts his retirement.



Welcome to Bhutan

Ngawang Dema

Bhutan is located in the Eastern Himalayas with its population of 0.74 million spread over 20 districts and a land area of 38,394 sq. km. As an element of Gross National Happiness, affordable and accessible health care is central to the public policy of Bhutan and free healthcare is provided to the entire Bhutanese population.

In order to control and regulate medicinal products in the Kingdom, a Medicines Act was passed in 2003 and a Drug Regulatory Authority (DRA) established in June 2004 to implement the Medicines Act and Bhutan Medicines Rules and Regulations.

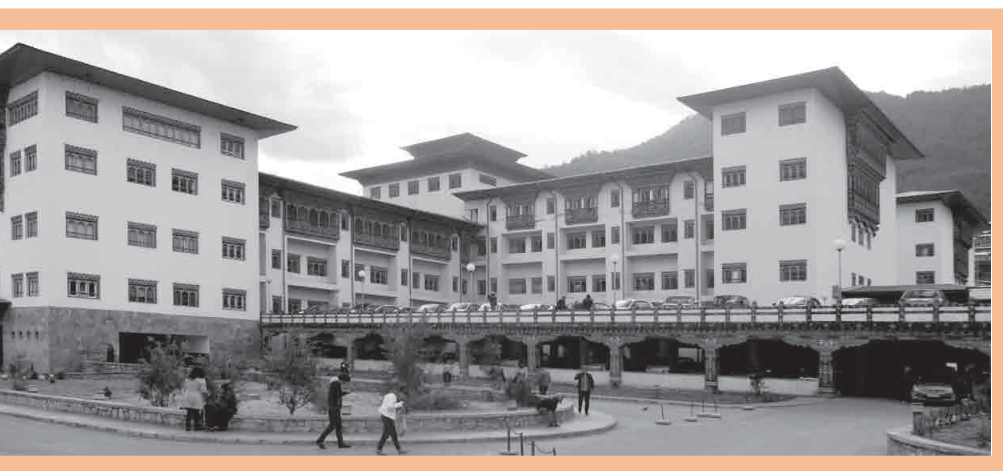
and the establishment of the DRA, pharmacovigilance activities such as sensitization programmes were introduced to pharmacy professionals via the Essential Drugs Programme under the Ministry of Health.

Increasing coverage

Post 2003, DRA is identified as the National Pharmacovigilance Centre headed by the first National Pharmacist of Bhutan, Mr. Sonam Dorji, with a staff strength of 24. Only two personnel in the Post-Marketing Control Division of DRA are engaged in planning and conducting pharmacovigilance activities.



Head of Bhutan national centre Sonam Dorji (front centre) and key personnel.



Pharmacovigilance centre at Jigme Dorji Wangchuck National Referral Hospital.

Separation

The Drug Regulatory Authority was detached from the Ministry of Health from 2008 as an autonomous agency in order to avoid conflicts of interest, since the Health Ministry is one of the major importers of medicines. Prior to 2003,

Up until 2012, it was the case that only pharmacy professionals were targeted for reporting of ADRs and hence there was under-reporting since this segment of professionals is only involved in handling

outpatients departments and missed the inpatient units (patients admitted to hospitals). In 2013 therefore, nurses were introduced to the ADR forms and in the near future DRA is considering incorporating the medical officers from hospital emergencies handling patients round the clock, in the pharmacovigilance activities.

Hopes for the future

Regional Pharmacovigilance Centres are identified in the Regional Hospitals where either reporting of ADRs or collection of ADR reports is managed by Focal Persons but at present universal causality assessment is an aspiration for our centres.

With Bhutan joining the WHO Programme for International Drug Monitoring in December 2014, and people getting trained from WHO-UMC organized training, DRA envisages an improved system of pharmacovigilance in Bhutan.

Another Asian country joins

Sten Olsson

Just after Bhutan was admitted to the WHO Programme, we also had the pleasure of receiving confirmation from the Safety and Vigilance department at WHO Geneva that the national pharmacovigilance centre of Bangladesh had met the requirements for admission. They submitted their first batch of adverse drug reaction case reports to the Global ICSR database, VigiBase, using the UMC's web-based ICSR management system VigiFlow.

Bangladesh and Bhutan were the latest two new WHO Programme members of 2014, and Bangladesh became the 120th member.

The Directorate General of Drug Administration in Bangladesh applied for membership of the WHO Programme for International Drug Monitoring in November 2013. The Head of the national pharmacovigilance centre in Bangladesh is Mr A. A. Salim Barami, based in the capital Dhaka. We hope to have fuller report on their activities in the future.

India to host 38th Annual Meeting

V. Kalaiselvan

Following the 2014 meeting of national pharmacovigilance centres in China preparations have started for 2015. Participating in the 2014 meeting widened our level of expanding pharmacovigilance in India. It was an excellent opportunity to assess the pharmacovigilance situation in my country and compare it with the current issues of global importance.

Welcome to India

It is a great honour and pleasure to welcome staff from national centres participating in the WHO Programme for International Drug Monitoring to New Delhi from 3-6th November 2015. The event will be organised locally by the Indian Pharmacopoeia Commission (IPC) under the 'Ministry of Health & Family Welfare, Government of India. IPC is functioning as National Coordinating Centre for Pharmacovigilance Programme of India (NCC-PvPI) to monitor the safety of drugs in the country. The WHO Country Office (India) is the partner in organizing this event.

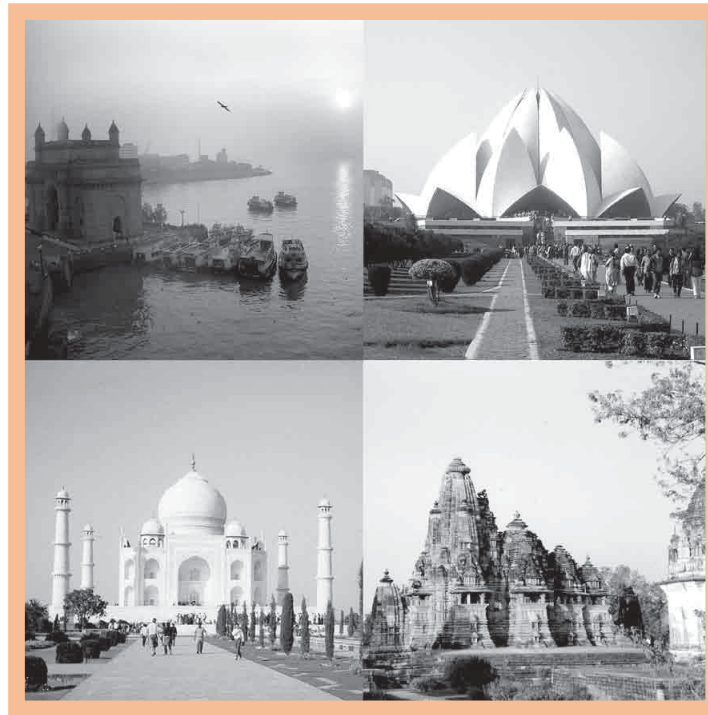
Riches of Delhi

The National Capital Territory of Delhi is one of the major industrial, financial and cultural centres of India. The city's rich cultural

heritage displays the legacy of many Indian empires that preceded the modern state. The Taj Mahal, a UNESCO World Heritage Site, is located just three hours away in Agra. The Rashtrapati Bhawan, Qutub Minar, Jantar Mantar, Red Fort, Humayun's Tomb and Jama Masjid are among other wonderful sights that lie within the city limits. Since we would like to make the event a memorable one, we plan to offer a one-day visit to the Taj Mahal on the 7th November 2015.

Keen anticipation

We feel certain that the 2015 WHO Programme meeting will bring together all the countries which have co-operated for the common task to promote medicines safety. Our thanks to WHO and the UMC team for giving us the opportunity to host the event. It's our pride and pleasure to welcome you all to India!



Welcome to India - clockwise from top left: Gateway of India, Mumbai; Lotus Temple, Delhi; Kandariya Mahadeva, Khajuraho; Taj Mahal, Agra.

10 Million ICSRs

Sten Olsson

We tend to celebrate even numbers, e.g. decade birthdays, but are they really significant? You can say that VigiBase is not much richer as a source of information on medicine related harm because it now has 10 million individual reports, rather than 9.9 million. The even numbers are more important because they invite us to stop for a while and to reflect. Reaching 10 million case reports in the global database testifies to the success of bringing countries from all over the world together with one common vision of preventing patient harm and to make them comply with WHO reporting requirements.

Global growth

The WHO Programme began with ten countries contributing to the international database in 1968 and today 120 countries do so. We have grown truly global. Moreover

the reporting rate from countries is increasing almost exponentially.

Asian progress

A significant change in the reporting pattern is that we have many Asian countries, e.g. China, Rep of Korea, Japan, India, Singapore, among the top ten contributors for 2014. Reporting from low- and middle-income countries is also increasing exponentially. VigiBase will consequently provide a picture of medicine related injuries that is closer to the global truth than before.

Differences in the data

With more representative data we should be able to reveal regional differences in the risk pattern of medicines being used in different settings and populations with different background risk factors. The representativeness and the quality of the information submitted

in this endeavour is as important as the numbers, but we do need the big numbers.

Keep reporting!!

Using mobile technologies

Magnus Wallberg

Three months into the WEB-RADR project a working group met in the new EMA offices at Canary Wharf in London. While 80 participants attended the meeting in person even more followed the event remotely via Adobe Connect. The focus of the workshop was to keep the WEB-RADR project on track and follow up on individual work packages. A project overview was presented by Andy Cochrane (Novartis).

What encourages reporting?

Before lunch the 'mobile reporting platform' covered by the WEB-RADR work packages 3a and 3b was discussed. Peter Mol (University Medical Center Groningen) and Raphael Van Eemeren (Amgen) reported on the work to identify barriers to reporting, evaluate patient willingness to report via mobile devices, and weigh up what functions would motivate use of reporting apps. The first patient survey had indicated that they and health professionals would be especially interested in getting up-to-date information on drugs they use and safety notifications from the authorities, plus having access to aggregated safety data.



WEB-RADR participants in London.

Carrie Pierce (Epidemico) presented the MedWatcher app built for US FDA (see box below right). Their aim is to use the existing MedWatcher app to build the more generic version for EU settings with the extra dimension of translations, different styling, medical dictionaries and other adaptations required by each EU country.

François Houyez (EURODIS) made a visionary presentation on what mobile reporting and smart devices in combination could bring when it comes to patient personal health data, in comparison to what a simple reporting app brings as of today.

Donald Singer (European Association for Clinical Pharmacology and Therapeutics) reported on a project in Rwanda where an online reporting form had been field tested. Many

more reports could be generated by simply educating the hospitals on the need for reporting while simultaneously providing them with a user-friendly online reporting tool. Donald also mentioned that the penetration of smart devices is increasing hugely in Africa, opening up possibilities for the global spread of what is achieved in the WEB-RADR project. HALMED (the Croatian agency) is among the project partners and the prospect of the infrastructure allowing mobile reporting directly to VigiFlow® (HALMED's ICSR management system) is encouraging, since many African countries also use VigiFlow.

Mining social media

After lunch we turned to work packages 2a and 2b – data mining of social media. Mining social media is a major undertaking but results so far are encouraging. There is a great need for natural language processing and duplicate detection methods to find interesting posts.

John Van Stekelenborg talked about not only how to mine social media streams but also what to do with the information retrieved. Using standard methods is a logical first step but it might be of interest to look into entirely new ways of assessing and looking at the data gathered.

Another question on information extracted from social media is how to handle the 'reports'. Should they be treated as 'normal' ICSRs or should they be analyzed differently? Who should be the owner of the data collected, and is it ethical to mine social media streams for safety information? Many questions were raised but with few answers: one big task for WEB-RADR is to find those answers.

Fabio Polverino (European Data Protection Supervisor) spoke on the concept of 'mHealth' ('Mobile Health'). He also explored the unclear definition of 'health data'. Does it cover personal training achievements collected from sport apps and heart frequency measures monitored by smart devices?

MedWatcher and MedWatcher Social

MedWatcher and MedWatcher Social are two tools developed by Epidemico in collaboration with FDA. MedWatcher is an app with functionality to allow patients to record medicines being taken and by doing so receive safety information about the drugs and report side effects. MedWatcher Social is an online tool that displays safety data that has been extracted from social media.

About WEB-RADR

The WEB-RADR (web Recognising ADRs) project is supported by the Innovative Medicines Initiative Joint Undertaking (IMI JU), for which financial resources come from the European Union's Seventh Framework Programme (FP7/2007–2013) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

WEB-RADR is working on delivering two key outcomes by September 2016:

- ◆ Develop a mobile application (app) that healthcare professionals and patients can use to report suspected adverse drug reactions.
- ◆ Assess the possibility for medicines regulators to provide accurate, timely and up-to-date information on medicines to patients, consumers, healthcare professionals and caregivers through the app.
- ◆ Explore the identification of potential safety issues with medicines from user comments in social media, taking into account personal data protection legislation.
- ◆ Develop recommendations for a policy framework for use of mobile technologies and social media in pharmacovigilance and the monitoring of the safety of medicines.

For more, go to web-radr.eu

Ethical aspects

At the end the workshop homed in on ethical considerations and data protection. Daniel K Sokol (UK) (who incidentally has a history as a hospital magician), identified the need for 'consent'. He highlighted the words 'Information, Voluntariness and Competence'. Does the patient have the information about what (s)he is participating in, and is it understood? Is it voluntary? For example, do you have to 'volunteer' to get something of value back (like a user community on the web) and does the patient have the competence to know what (s)he is agreeing to?

Finally the newly-launched WEB-RADR website was presented. The website has been developed by Epidemico and is intended to be the main hub for information about the project and its progress (see box above). And of course the WEB-RADR website is developed in a 'responsive' way so that it can be easily accessed also by mobile devices!

Third GVSI Meeting in Tianjin

Sten Olsson

This third annual meeting of Global Vaccine Safety Initiative (GVSI) stakeholders took place in Tianjin, China, on 13 – 14 October 2014. For the first time it was organized in direct association with the annual meeting of the WHO Programme for International Drug Monitoring which allowed many delegates to attend both meetings. Since the second day of the vaccine safety meeting was running in parallel with the pre-meeting of the medicine safety meeting, on the same floor of the conference venue, there were ample opportunities for professional and social interaction. The meeting assembled around 80 people from 25 countries.

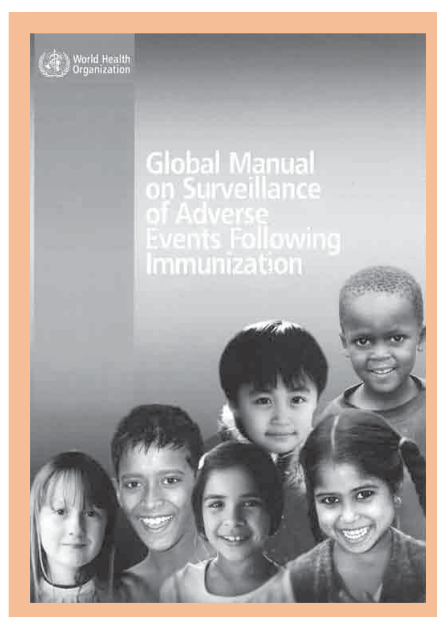
Launch of manual

The meeting started with a launching ceremony for the 'Global Manual on Surveillance of Adverse Events Following Immunization' (see image and www.who.int/vaccine_safety/publications/aeft_surveillance/en/). This document has been subjected to extensive international consultation prior to publication and is one of the products of the GVSI. Hopefully it will be widely used in national immunization programmes all over the world. The opening session also included a general overview of the achievements and output from the GVSI so far, presented by the WHO secretariat and the chairman of the GVSI planning group, Alex Dodo.

Experiences

The morning session of day one had three themes:

- Strengthening of AEFI surveillance systems, with presentations from Nepal and Tanzania
- Establishing collaboration between national regulatory authorities and immunization programmes for an effective vaccine safety surveillance



The new Global Manual.

system, including presentations from Chile and China

- Monitoring the safety of newly-introduced vaccines, with presentations on HPV vaccine from Brazil and Argentina.

In the afternoon the meeting learned how vaccine pharmacovigilance is being built in Africa, how a multi-country collaboration is established in Latin America for evaluation of vaccine safety signals and how the WHO European office has developed guidelines to manage communications in response to vaccine safety events. Presentations were also made on how causality assessment of AEFIs have been strengthened in the South Asia region and how national AEFI surveillance systems have been evaluated in the Western Pacific.

Updates and development projects

The second day started with an update from WHO on progress in the planning for deployment of Ebola virus vaccine in West Africa. A status report was also given from WHO on the fight against SSFFC (substandard/spurious/falsely-labelled/falsified/counterfeit) medicinal products. A report was also given from the Brighton Collaboration Viral Vector Vaccine Safety Working Group; this was of particular interest and relevance since Ebola vaccines are expected to be of this type.

Stakeholders

A status report was given from the CIOMS working group on vaccine safety, established to address Objective No 8 of the Global Vaccine Safety Blueprint, which refers to interactions between national governments, multinational agencies and manufacturers. On this topic perspectives were also given by GAVI (Global Alliance for Vaccines and Immunization) and some multinational and regional vaccine manufacturers.

Safety together

The final session was devoted to issues of collaboration on pharmacovigilance between public health programmes and national regulatory systems both on an international and national level. The objectives and activities of the WHO Safety and Vigilance unit (SAV), created in 2013, were set out, followed by the scope, structure and activities of the WHO Programme for International Drug Monitoring. Examples and good models for collaboration were then provided from the USA, Morocco, Croatia, Uganda and India.

Responding to vaccine related events

Sten Olsson

The WHO Regional Office for Europe recently published a guide providing informative strategies and tools to support effective communication planning in response to vaccine safety events. It is intended to be used by immunization programme managers and partners. The guide stresses how vaccine related events (VRE) is a wider concept than Adverse Events Following Immunization (AEFI). VRE are considered to also include :e.

- a new study or experimental data related to vaccines or immunizations
- a report in the press, or a local rumour about vaccines
- a temporary suspension of a vaccine
- a vaccine recall
- the replacement of a vaccine.

Among the different topics covered by the guide are media communication planning,

developing a message, selecting the medium, media skills, crisis handling and dealing with rumours. The 67-page document has 12 practical annexes and is published in English and Russian.

Go to <http://www.euro.who.int/en/home> and follow links to [health topics /publications /key publications](#)

Developing quality in Vietnam

Thuy Nguyen Phuong, Anh Nguyen Hoang, Hoa Nguyen Dang

Background

Vietnam joined the WHO Programme in 1999, but an independent National Drug Information & ADR Center was launched in 2009 and started to collect ICSRs on behalf of Drug Administration of Vietnam from 2010. In the period 2011–2013, the quantity of ICSRs in Vietnamese database has increased more than two-fold.

A large quantity database permits early signal detection and provides helpful information to clinical practice. However, a rapid quantitative increase does not always correlate with an increased quality of reports. Therefore, a comprehensive retrospective assessment on the overall quality of ICSRs in the national Vietnamese database was performed.

Method

All ICSRs which were received in the period of 2011–2013 were included in the research. Exclusion criteria were reports which were related to quality defects and non-medicine products. The UMC's *vigiGrade* tool was used to evaluate ICSR quality.¹ Twenty-one information fields on the Vietnam ADR reporting form were grouped into 10 dimensions with corresponding penalty factors as mentioned in *vigiGrade*. Reports with a completeness score (C) > 0.8 were classified as well-documented. Evaluation parameters included level in the national health system, way of filling in ADR forms (e-reporting or handwriting) and primary reporter (physicians, pharmacists, nurses); see *Table 1*.

Results

The total number of ICSRs added in the Vietnam pharmacovigilance database from 2011 to 2013 was 10,894 of which the reports

received during 2013 accounted for 50.1%. There were 38 reports related to sub-standard and non-medicine products (excluded from the study sample). Among the included ICSRs (n = 10,856), over three years 71.1% were well-documented (*Figure 1*). The most frequently missing information fields were dosage, indication, onset, and outcome.

C > 0.8) was higher than the average in *VigiBase™* (January 2012) (0.45 and 13% reports having C>0.8).¹ Central hospitals were more able to access updated knowledge and technology, but their average score is lower than provincial and district hospitals (0.82 vs 0.85) (*Table 1*).

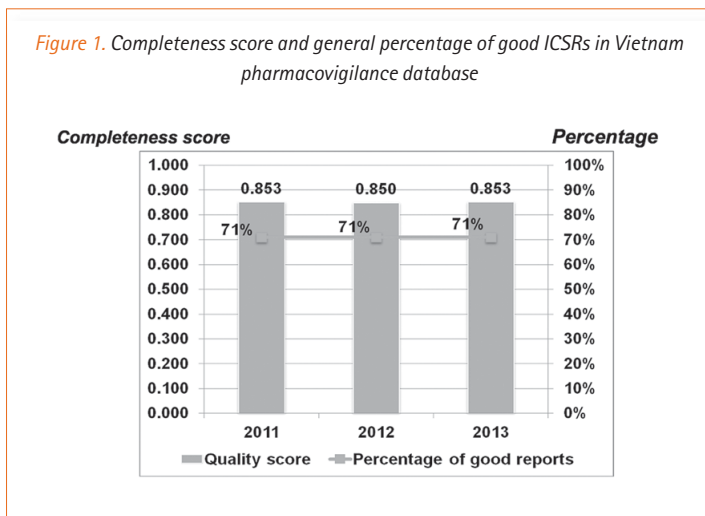
This figure raised a lot of suggestions and potential follow-up for the National DI & ADR Center to continuously promote ICSR quality. Not only the vertical level of hospitals but also the occupation of reporters affected quality of spontaneous reports. Physicians accounted for the highest proportion of ADR reports in Vietnam database (45.4%), followed by pharmacists (26.2%). However, pharmacists provided the greater percentage of good ICSRs (82.4%) as well as the highest average score (0.92) (*Table 1*). Therefore, it is important to strengthen the role of pharmacists in the

Vietnam reporting system as well as to spend more resources on improving the quality of ICSRs generated by physicians. The results showed that e-reporting or filling in ICSRs on a computer were important factors for provision of good ICSRs. The National DI & ADR Center should encourage healthcare workers to participate more actively in online reporting.

Conclusion and perspectives

This study has identified completeness score of ICSRs and factors that contributed to developing quality of ICSRs in Vietnamese database. These data will be used for development of a national training plan to promote ADR reporting in Vietnam.

¹ See full reference on page 9.



ICSRs reported by pharmacists had the best quality. ICSRs from central hospitals were identified as having a lower completeness score compared to provincial and district hospitals. Using a computer to fill in the reports provided better quality than handwritten (*Table 1*).

Discussion

Vietnam DI & ADR Center used at least four different methods to assess the quality of ICSRs. Among these approaches, *vigiGrade* has been chosen due to its convenience and advantages such as assessing more information fields, simple calculation, and detailed score ranges.

The average completeness score (0.85) and percentage of good ICSRs (71% reports having

Table 1. Several factors related to quality of ICSRs

Factors		Completeness score (±SD)	% of good ICSRs (C>0.8)
Level in health system	Central level	0.82 ± 0.25	67.6% (n= 1 534)
	Provincial/district level	0.85 ± 0.23	71.7% (n= 9 322)
Type of filling ICSRs	By handwriting	0.84 ± 0.24	69.2% (n= 9 514)
	By computer	0.93 ± 0.16	84.8% (n= 1 342)
Reporters	Physicians	0.85 ± 0.22	68.9% (n= 4 926)
	Pharmacists	0.92 ± 0.17	82.4% (n= 2 844)
	Nurses	0.87 ± 0.21	72.4% (n= 2 022)
	Others (assistants, technicians)	0.63 ± 0.33	47.9% (n= 1 064)

Completeness score improved

Therese Lundin

A new, improved version of Completeness score is currently being released and sent out to national pharmacovigilance centres in the WHO Programme. The method, now called *vigiGrade*TM Completeness score, is updated to even better measure the quality of Individual Case Safety Reports (ICSRs).

Updates

The Completeness score is a measure of the amount of clinically relevant information on ICSRs as they appear in *VigiBase*[®]. It is calculated from a number of different parameters, including time-to-onset, indication, patient age and reaction outcome.

In the updated Completeness score, the new parameter dosage is also included since this is judged to be particularly relevant for clinical case assessment. In addition, the weightings of the different parameters on the total score have been adjusted. For example, the penalty for case reports lacking reaction outcome information is 30% in the new version, compared to 15% in the old version.

Applications

The Completeness score can be used to visualize where clinically highly relevant information is missing on case reports, as a first step to improve quality. The method has

been used to identify issues in the export of ICSR data, to improve ADR report forms where relevant fields are missing, and to track effects of quality improvement work.

Read more about *vigiGrade* in the *Drug Safety* article by the UMC Research department.¹

References

1. Tomas Bergvall, G. Niklas Norén, Marie Lindquist. *vigiGrade: A Tool to Identify Well-Documented Individual Case Reports and Highlight systematic Data Quality Issues*, *Drug Safety* 2013, 37(1), pp. 65-77.

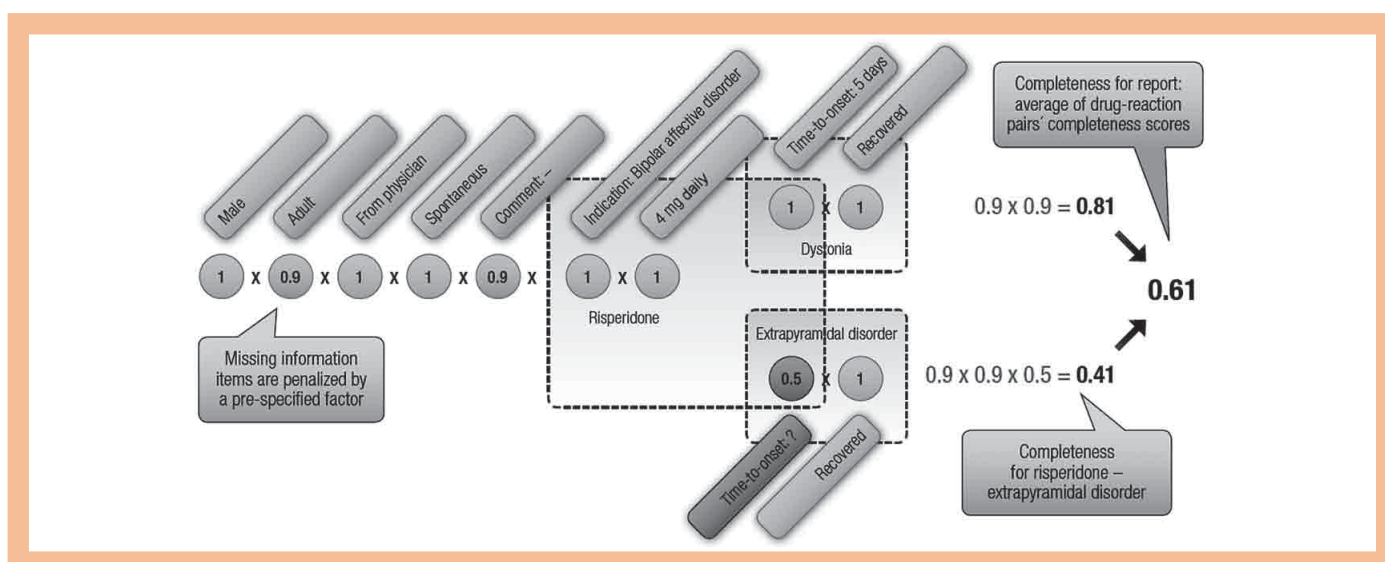


Diagram showing an example of how the *vigiGrade* Completeness score is calculated for a report.

VigiLyze gets noticed

Monica Plöen

Outside the small world of pharmacovigilance one of the UMC's software services to national centres has been noticed in the wider sphere of software applications.

We were thrilled that *VigiLyze*TM was chosen as one of the ten finalists for the national inUse UX awards – a competition focusing on good user experiences in digital solutions.

The finalists ranged from apps to new systems, and were aimed at both public to private settings – all chosen because of their clear focus on the benefit to both users and business.

Sadly we did not come out on top at the awards evening in Stockholm, but it is great that our area of work is being recognized outside our immediate stakeholders.

In the latest improvements, ATC codes are now included in *VigiLyze*, and we will continue to enhance it, working with our national centres colleagues.



At the ceremony –

Monica, Ellen Ekerling (UMC consultant), Thomas, with Anders behind.

Building Eastern Mediterranean collaboration

Raja Benkirane

The first Eastern Mediterranean Region (EMR) / Arab pharmacovigilance meeting was held at the Centre Anti Poison et de Pharmacovigilance du Maroc, WHO Collaborating Centre for Pharmacovigilance in Rabat from the 22nd to the 27th September 2014. This inaugural encounter was held in collaboration with the World Health Organization. The purpose of this meeting was to interact, exchange information, implement and reinforce national pharmacovigilance activities in Eastern Mediterranean and Arab countries and to define an action plan for their development. Welcoming remarks were given by the Moroccan Minister of Health, Professor Houcine El Ouardi.

There were 183 experts from 28 countries, including ten Arab countries and countries from the Eastern Mediterranean Region. The participants represented national pharmacovigilance centres, Marketing Authorization Holders (MAH), WHO Geneva, the Arab League as well as universities, the Council for International Organizations of Medical Sciences (CIOMS), WHO Collaborating Centres and the Uppsala Monitoring Centre.

Plenary programme

Plenary sessions covered eight themes: The role of WHO Collaborating Centres and the status of pharmacovigilance systems in EMR/Arab countries, Risk minimization measures, Database management and signal detection, Integration of vigilances in a single system ('global vigilance'), Strengthening vaccine vigilance, Medication errors management, Pharmacovigilance in industry, and Pharmacovigilance in clinical practice.

and definitions, risk minimization plans, and strengthening national vaccine vigilance.

From this body of work, the conference recommended:

Status of pharmacovigilance systems in EMR/Arab countries

- to encourage more countries to join the WHO Programme
- to monitor annually the situation and evolution of pharmacovigilance activities in the region.

Global vigilance

- to sustain the concept for an integrated vigilance system
- to establish/reinforce local regulations
- to build a global vigilance system in countries where a pharmacovigilance centre does not exist
- to harmonize and coordinate between all systems to centralize reports in a national centre in countries where the pharmacovigilance already exists.

Risk minimization

- to address targeted, specific and adapted action plans
- to encourage inter-country collaboration for improving risk management plans applicability
- to set up locally-adapted indicators.

Arab guidelines

- to create a widely-based steering committee to monitor and evaluate the Arab guideline implementation and develop key performance indicators

Harmonizing terminology and definitions in Arabic

- to acknowledge the common terms used in pharmacovigilance harmonization
- to publish and widely disseminate these terms.

Training and capacity building

- to identify regional experts in all areas (causality assessment, preventability assessment, signal detection, risk minimization)
- to organize an annual course on pharmacovigilance for all stakeholders with contributions from regional and international experts
- to organize practical training for pharmacovigilance centre staff in advanced countries
- to foster the technical support of UMC and WHO-CC Rabat in pharmacovigilance activities.

Networking

- to develop a network for timely exchange of information between Arab/EMR states and to discuss crisis management
- to hold a periodic regional meeting on pharmacovigilance
- to conduct multi-centre studies on common safety issues.

Rabat Declaration for Pharmacovigilance in the Eastern Mediterranean Region and Arab countries

The meeting participants issued a Declaration which built on the recommendations from the sessions. This concentrated on key outcomes from the meeting related to assessment of pharmacovigilance in the region, strengthening collaboration, establishing a steering committee on the Arab guidelines, and calls for additional resources. Integrating pharmacovigilance in public health programmes, the commitment of WHO and its Collaborating Centres, and encouraging the important role of the drug manufacturers as a key partner for pharmacovigilance systems also featured in the Declaration. It also called for better infrastructures, human and financial resources, and a legal basis to develop an integrated system of pharmacovigilance for health products.

The full Declaration may be accessed via <http://capm.ma/>



Some of the participants in the first Eastern Mediterranean Region and Arab meeting in Rabat.

Group recommendations

In addition to these plenaries, four working groups discussed integrated pharmacovigilance systems, harmonizing terminology

- to support countries in its implementation
- to emphasize the role of pharmacovigilance centres in the document.

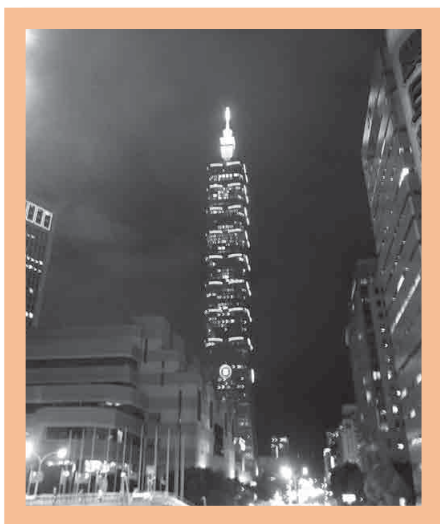
ICPE enters its 4th decade

Ola Caster

The International Society of Pharmacoepidemiology held its 30th anniversary annual meeting, ICPE, in Taipei, Taiwan, at the end of October. This was the first time ever the meeting was placed outside of North America or Europe, and our hosts certainly put a tremendous effort into making it a memorable one.

Familiar vs. New

Placed in a modern convention centre just a stone's throw away from the world-famous Taipei 101 tower, this ICPE offered a scientific programme with many familiar elements. As always, results from recent observational drug-effect studies were given ample space together with methodological advancements in pharmaco-epidemiology. However, some more unconventional and emerging topics had also been allowed onto the agenda. For example, an entire plenary session was devoted to the use of patient-centred information in pharmacoepidemiology, and the various symposia collectively covered issues ranging from adverse drug reaction tracking in social media to pharmacovigilance in emerging countries.



Taipei 101.

Former President's view

Owing to its location, this meeting attracted quite an unusual demographic composition by ICPE standards, with almost half of the participants based in Asian countries. Clearly though, lots of familiar faces were to be seen as well. A personal highlight was the keynote presentation delivered by one of those long timers, former president of the society,



Mats Persson and Ola Caster with fellow ICPE delegates at the conference dinner.

Professor Bert Leufkens. His most interesting point, in my view, was that pharmaco-epidemiology must adapt to be able to handle exposure as a social construct: already now, exposure at the population and individual level is heavily dependent on factors largely unrelated to science, such as politics, economics, culture, as well as human behaviour and interaction, whether face-to-face or virtual.

UMC taking part

As has been the case for several years running, UMC was represented at ICPE both from the commercial and the scientific side. With respect to the latter, two oral presentations were given by UMC staff, complemented by several posters covering important topics such as mining of electronic health records and benefit-risk assessment. One of the oral presentations provided an overview of UMC's novel method to support signal detection, *vigiRank*, as part of the meeting's sole session on pharmacovigilance methodology. (For more information on *vigiRank*, please see Uppsala Reports 67.) The other described UMC's role in supporting pharmacovigilance activities in low- and middle income countries, and so formed a valuable contribution to the symposium on pharmacovigilance in emerging countries mentioned previously.

Out of the ordinary

The conference was well organised and ran almost as smoothly as the remarkably efficient Taipei subway system. A clear highlight was the gala dinner, which took place at the stunning Grand Hotel. Not only were attendees overwhelmed by a seemingly ceaseless flow of delicious Taiwanese cuisine, but the entertainment too was something out of the ordinary. A highly energetic and powerful group of young male drummers was followed by a

display of Taiwanese opera by the performance group Ming Hwa Yuan. Specially for ICPE, this famous ensemble performed a rare show outside its own venue.

Looking towards 2018

Whereas the relay baton has now been handed over to Boston, the host city of next year's ICPE, the conference will return to Asia in 2018. Based on the generosity and commitment of our Taipei hosts, I am certain that lots of this year's participants are excited about the opportunity to return to the East for another pharmaco-epidemiology festival.

Emerging Countries symposium

Syed Rizwanuddin Ahmad

A symposium on pharmacovigilance at ICPE drew attention to the special needs of low- and middle-income countries (LMIC). Syed Rizwanuddin Ahmad, an independent pharmacovigilance consultant who organized the session gave an overview of pharmacovigilance systems in LMIC with particular emphasis on how areas of immediate need such as defining and addressing the scope, human resource needs, information sharing, and sustainability, are being tackled. David Lee (MSH) stated that pharmacovigilance is a shared responsibility and requires both passive and active approaches to monitor safe use of products; and a commitment to public health.

Elisabeth Ludeman (USAID) presented a comparative analysis of systems in five Asian countries that found that across these countries their status was strongest in the area of policy, laws, regulation, and governance, but weakest in risk assessment and evaluation. Chioma Ejekam from Nigeria shared the ground reality that unavailability of reporting forms and lack of standard operating procedure was an important barrier to ADR reporting, in addition to need for training and capacity building. Ola Caster (UMC) described the different ways the UMC supports LMIC in training, capacity building, and technical assistance.

WHO Programme in Tianjin

Alem Zekarias

China was the host country for the 2014 meeting of national centres in the World Health Organization (WHO) Programme for International Drug Monitoring. It was the 37th annual meeting WHO has organized since the start in 1978.

Between 14–17th October, the China Food and Drug Administration (CFDA) and WHO welcomed around 120 representatives from 50 countries covering all regions of the world to Tianjin, a port city in north-eastern China. The conference venue, where most delegates were staying, was conveniently situated in the centre of the city.

Pre-meeting

The meeting started on Tuesday October 14th with a pre-meeting for the national centres in the WHO Programme organized by the Uppsala Monitoring Centre (UMC). It offered an opportunity for all national centre delegates to engage in discussions and workshops focusing on operational issues in pharmacovigilance and patient safety. This was a great chance for both new and old member countries to participate and contribute based on their own experiences.

The day was attended by 100 representatives and included both presentations and interactive workshops. In addition to speakers from UMC presenting topics such as 'Developing a positive reporting culture' and 'The role of vigiRank in Signal detection' external speakers were invited. Gerald Dal Pan from US-FDA held an interactive session about regulatory aspects of pharmacovigilance, Mick Foy from the UK Medicines and Healthcare Products Regulatory Authority presented '50 years Anniversary of the Yellow Card', and Pui Ling Lee from Health Sciences Authority in Singapore discussed her centre's experience of pharmacovigilance.

Inspiring and educational

The main meeting on 15–17 October opened with Vice Minister Wu Zhen from CFDA welcoming us, followed by introductory words from Dr Clive Ondari and Dr Shanthi Pal of WHO. This was an inspiring start of three interactive, exciting and educational days covering different essential topics presented by a range of presenters from different parts of the world.

The meeting had customary sets of working groups where the participants could choose from eight topics and join together to

discuss them and make recommendations that were then presented on the final day.

In the final session Dr V Kalaiselvan, on behalf of the Indian National Pharmacovigilance Centre, and with the support of a welcoming video, invited the WHO Programme members to New Delhi for the 2015 meeting.

Brunei Darussalam reflections



Asma A'tiyah Haji Abdul Hamid, Head of Drug and Poison Information Section

The National Centres meeting of the WHO Programme is a marked event in the calendar of member countries as it brings together key people around the world to discuss major issues in pharmacovigilance.

For me, joining this National Centres meeting after being away for many years was like going home. I wondered who would be there. Would I see familiar faces like Marie Lindquist, Shanthi Pal, Bruce Hugman, Sten Olsson and Geoffrey Bowring who have played significant roles during my training in pharmacovigilance and supporting Brunei Darussalam ADR Monitoring Centre? I was also excited to visit China as I had never been there before.

Upon arrival at the Holiday Inn Tianjin Riverside Hotel, I was struck by the breathtaking view of the Tianjin Eye near the hotel, overlooking the Hai River, a symbol of many positive experiences in China.

Food for thought

We started with a pre-meeting tutorial; after registering, my colleague and I were

warmly welcomed by UMC staff. The tutorial provided food for thought on improving my own country's pharmacovigilance system. Case studies on the topic 'Developing a positive reporting culture' and examples of Adverse Drug Reaction (ADR) forms were circulated, and gave insights into different countries' pharmacovigilance systems. Besides that, UMC representatives presented updated information on product offerings and current developments.

On to the WHO meeting

Next day the WHO annual national centres meeting began with the official opening ceremony. Despite the language barrier, I felt greatly welcomed by the CFDA. Dr Clive Ondari, coordinator Safety and Vigilance at WHO then explained recent reforms at WHO. A plenary, update sessions and working group discussions completed the day; the second day followed a similar format while the last day was all plenaries, a presentation from India and the closing ceremony.

Enriching group work

After listening to all the inspiring speakers, I felt encouraged by what I had learned. I thoroughly enjoyed the meeting which provided the opportunity to learn and share the updated knowledge. The most enriching experience was the working group sessions, in particular on evaluating benefit–risk assessment of drug regulatory decisions, where many factors were found to affect local decisions. These sessions encouraged animated discussions with other member countries, bringing a mutual sense of belonging and understanding in striving towards a similar goal to safeguard the safety of the public. The meeting also strengthened the bond among the various countries for existing and future project collaborations. Building relationships is vital to enhance notification of safety issues among member countries. Last but not least, I felt that the



A plenary session in progress.

meeting was well-organised and successful. A wonderful experience for me to meet familiar faces and making new friends.

Thoughts from Cape Verde



Djamila Reis, Head of National Pharmacovigilance Centre, Cape Verde

Expectations

The preparation of the agenda for the national centres meeting is a huge challenge: balancing the interests of different degrees of experience and technical development between pharmacovigilance centres.

My expectation of participation in the WHO Programme's annual meeting was to find an inclusive, shared space, no matter the degree of development of each participant's pharmacovigilance system, and without neglecting the imperative of being a high-level scientific space.

The meeting

The meeting proved fruitful, and useful information in many areas was emphasized. Sharing experiences and good practice, and scientific updates to strengthen the network were prominent.

The meeting kicked off with motivational speeches by the hosts and WHO, reporting back from the 36th annual meeting by Dr Shanthi Pal and explaining the role of the four WHO Collaborating Centres; Uppsala (Sweden), Accra (Ghana), Rabat (Morocco) and the new centre in the Netherlands, at Lareb.



Vivek Kalaiselvan, Mohamed Farah, Alem Zekarias.

The three days included updates on reports and reporting statistics from the WHO Programme along with the theme of training activities and capacity-building in pharmacovigilance. This provided a broad overview

and identified ways to access continuing training for national centres staff. Other pragmatic and relevant topics related to the collection and evaluation of problems beyond adverse drug reactions, the benefits of investing in pharmacovigilance, the safety of herbal medicines 10 years on from WHO's guidelines, open access to the WHO database, causality assessment of adverse events following immunization, and integrating pharmacovigilance in curricula. There was an opportunity to get know the size, complexity and evolution of the pharmacovigilance system in China.

From a personal perspective and the reality of pharmacovigilance in Cape Verde, I was particularly keen to hear how to improve the quality of individual case safety reports. The evolution of the quality of notifications for specific national centres, beyond the utility of analysis of activity indicators, gave us motivation to increase the number, frequency and quality of notifications.

At other times, working groups allowed very participative debate that was then reported to the plenary. The subjects were all relevant and reflected current issues of running a national centre. Working groups were:

- Challenges and opportunities in facilitating collaboration between public health programmes and national centres
- Global information sharing during medical-related crisis
- Adapting international decision to place settings/context when evaluating benefit/risk assessment in drug regulatory decisions
- The role of pharmacovigilance centres in systematic data collection of drug exposure during pregnancy
- Providing information to help consumers understand risks versus benefits with medicines
- Relevance and approaches of signal detection in low- and middle-income settings
- The added value of patient reporting and involvement of civil society in pharmacovigilance
- Signal detection in vaccines.

The possibility of networking is an intangible aspect but probably the one with the greatest potential impact on the functioning of the centres. Unfortunately, it is the result with



Vice Minister Wu Zhen during the Opening Ceremony.

the greatest weakness in terms of durability. Vital in such a meeting is the quality, care and efficiency around all aspects of the meeting organization. To the CFDA administration and the WHO team: congratulations and thank you.

Impact and future activities

Immense perspectives for training, unlimited possibilities of sharing best practice and learning from others' experience and numerous adjustments after recommendations were received. The dilemma is identifying priorities against a backdrop of tight finance and at a centre where a lot is still to be done.

How to ensure we keep in contact? How do we follow up the intentions of sharing best practices and discussion of joint projects or common problems? We are all responsible, but I would challenge the WHO Collaborating Centres to promote the operation of working groups with a specific theme or project through virtual meetings and to ensure a more continuous operation of the network. Together we can do a lot more and better for the patient safety.

ISoP serves a Chinese feast

Daniele Sartori

After previous sorties from its European cradle the International Society of Pharmacovigilance gathered in China: Tianjin on the north east seaboard. This metropolis, counting more inhabitants than the whole of Sweden, benefits from the recent Chinese technological advancements: a thirty-minute maglev glide links it to the capital, Beijing. The joyful cracking of fireworks resonates in the distance, carrying news of marriages, over the Hai, through high-rise buildings and among the old British, French and Italian concessions.



Professor Ian Wong, one of the 2014 organizers, in Tianjin.

Hors d'oeuvres

On the 20th of October Tianjin hosted the opening ceremony for the 14th ISoP meeting. Some of the attendees however had registered to attend one of the three pre-courses the day before: many chose to delve deep into the usefulness of network meta-analyses in evaluating interventions in an indirect fashion, others learned how to address new issues in reporting, with emphasis on consumer reports; some participants took part in what felt more like a group chat about communication in pharmacovigilance than a formal course.

The main course

Over 200 professionals attended the main conference. There was a relatively low attendance this year; on the bright side, faces became familiar after a day at the luxurious Holiday Inn Riverside Hotel, allowing for more solid networking opportunities. As in previous ISoP meetings, two daily parallel sessions made us choose among topics such as: pharmacogenomics, signal detection and the use of social media to identify safety issues; discovery,

recognition and management of specific adverse drug reactions affecting a specific organ (liver and skin) or targeted populations (children, the elderly, women).

Some highlights

Juhaeri Juaeri from Sanofi, USA, introduced the audience to an evaluation of the reliability of the methods used in web-based signal detection. The query log database from Microsoft Bing was used as a tool to conduct web-based signal detection using different methods and comparing them to a standard: the FDA Adverse Event Reporting System (FAERS). These methods revealed low sensitivity as well as specificity; low predictive values were accompanied by high negative predictive values.

Erroneous administration of medications was put into the current Chinese social context by Dayou Wang, from Fudan University, providing cultural background to the reluctance of reporting events associated with it. When admitting a mistake is not only a stain on one's professional life but also frowned upon by those around, medication error reporting becomes a burden.

This year ISoP members were introduced to the 'special interest group on risk communication', formed in 2013 and introduced to us by Priya Bahri of the European Medicines Agency. The group aims at closing the distance between decision-makers in risk minimization and professionals or patients by incorporating evidence-based communication practices in pharmacovigilance.

UMC offerings

The UMC was well represented in Tianjin, and the Research section presented six examples of recent work: *A sum greater than its parts – joining information sources for improved pharmacovigilance* (Tomas Bergvall), *A novel process to capture safety signals in spontaneous reports on children* (Kristina Star), *Why can't a woman be more like a man?* (Pia Caduff), *A signal based on spontaneous reports of convulsions in association with finasteride* (Daniele Sartori), *Varenicline and abnormal sleep-related events* (Pia Caduff), and *Key features of medication error reporting in VigiBase* (Kristina Juhlin). The latter presentation competed in the (unexpected) Junior Pharmacovigilantes competition, ultimately won by Wallis Lau, from Hong Kong.

Posters

The first prize was for a poster on the Association between oral fluoroquinolone

use and the development of retinal detachment (Hong Kong), second prize was on High-dose methotrexate: drug-drug interaction and toxicity (Nantes, France) and third on the Value of patient reporting in signal generation (from Accra, Ghana). A UMC poster from Johan Ellenius considered Development and evaluation of an algorithm for named entity recognition of drugs in global pharmacovigilance. The poster area was strategically near the main entrances to the conference rooms and the coffee service, ensuring maximum attendance.

...and for dessert

On the social side a sumptuous gala dinner consisting of traditional dishes from all over China was served in the Grand Ball Room. A quartet of strings, far different to violins and cellos, delighted the guests, who would have wished the night to have lasted a little longer. The show continued with a young artist conveying picturesque images by gracefully manipulating fine sand.



Traditional and modern in Tianjin.

Forms and Newsletters for CPD

Niamh Arthur

At the annual National Centres meeting in Tianjin in October, a presentation on the use of the Irish national drug safety bulletin and adverse reaction report forms for continuing professional development (CPD) was made; this article further describes these activities.

Resources

The Health Products Regulatory Authority (HPRA) has worked with the Irish Academy of Continuing Medical Education (iaCME) which is an independent provider of accredited on-line CPD resources for healthcare professionals. These resources, available free of charge to healthcare professionals, include training/educational modules on adverse reaction reporting, and the HPRA *Drug Safety Newsletter* (DSN). This provides a useful stimulus for practice-based CPD, while reinforcing important safety updates for medicines and increasing the potential impact and influence on professional practice with a view to achieving meaningful patient outcomes.

Accredited CPD

iaCME is an independent provider of accredited CPD, established and run by innovative Irish healthcare professionals (two pharmacists and a doctor) who have considerable experience in the area of pharmacovigilance, quality management and CPD, producing accredited online resources in Ireland since 2011. These e-learning resources utilise a variety of Web 2.0 technologies and apply the latest professional learning concepts.

The module on adverse reaction reporting includes a screencast in the training materials that follows the entry of details in the HPRA online report form. This module also includes a link to a short YouTube video which illustrates the various roles in the pharmacovigilance process, including those of the marketing authorisation holder, national and EU regulatory bodies and the WHO (<http://www.youtube.com/watch?v=NeR8pen1T5M>).

Tailored for accreditation

The overall focus of the modules based on the DSN is on reducing risks to patient safety by applying learning from new and emerging safety information as highlighted in each edition. iaCME formats the content and adapts it to an appropriate template on the iaCME Learning Environment to make it more engaging, and provides additional resources to explore individual topics in a more practice-focused way for those who wish to do so. The modules are accredited and structured to equip healthcare professionals with evidence of engaging with relevant CPD.

Accredited by the Irish College of General Practitioners (ICGP), modules are worth 0.5 'external' CME credits for the medical profession. The CPD Model for Pharmacists in Ireland is not credits based. However, consequent to accreditation by the ICGP, the DSN modules fall into the category of 'formal learning' as defined by the Irish Institute of Pharmacy (IIOF). The modules involve a four step process **Read**, **Evaluate**, **Discuss** (optional) and **Document**. Reading and Evaluating are self explanatory. Online discussion forums provide an opportunity for peer learning through sharing ideas/experiences or asking questions. Documentation includes an evaluation to automatically generate a certificate to validate awarding of credits (doctors) and to

Irish Pharmacy News, issued to all registered pharmacists, reinforcing the availability and use of these resources, as well as providing a further opportunity to learn and evaluate the impact of the regulatory updates on their practice.

Feedback on the use of the modules has been extremely positive, with increasing usage over time and a substantial proportion of regular users. Work has started on the development of podcasts, with consideration of the feasibility and usefulness of providing either a single podcast for each DSN edition, or bite-sized podcasts on each topic covered in the DSN. Expansion into other areas, including nursing and undergraduate education, is also underway.



provide evidence of formal learning (for pharmacists/nurses). (Certificates can be printed and/or saved and also remain available on the Learning Environment.) Furthermore and most importantly, however, the modules also include tools and templates – specific to each DSN – to support reflection on individual practice in order to identify and record actions to minimise risks to patient safety in individual practices. Personal blogspace also facilitates reflection and recording. Tools made available in this way offer opportunities for additional CPD credits – 'Internal CME' for doctors and 'informal learning' for pharmacists.

Informing practitioners

Regular articles on the DSN CPD modules have also been published in the monthly

Agency support

The HPRA supports the use of these modules for CPD purposes and has contributed to the review of the individual modules prior to their release, which has been an important step in allowing HPRA to highlight aspects of particular regulatory concern, or to reinforce advice based on reporting trends, issues giving rise to frequent questions etc. The modules are hosted on iaCME's website, accessible free of charge to healthcare professionals and are also available via a dedicated link from the HPRA website.

Further information is available from <http://learn.iaCME.ie/> and <https://www.hpra.ie/homepage/stakeholders/healthcare-professionals>

Steady steps in pharmacovigilance

Magaly Tito Yépez

For years countries in Latin America and the Caribbean have seen the need to implement pharmacovigilance systems, and Peru is no exception. In 1999 the 'Dirección General de Medicamentos Insumos y Drogas' (DIGEMID) created the Peruvian pharmacovigilance system and began intensive activities both sensitizing adverse drug reaction (ADR) notification from health professionals and pharma companies as well as encouraging the decentralization of pharmacovigilance work through regional and institutional reference centres.

A partnership was initiated with the main national health care strategies (immunization, HIV-AIDS and tuberculosis) to boost notification rates. Despite this, high under-reporting of ADRs is evident, due to unfamiliarity with their importance, the weak ADR reporting culture and lack of a legal framework. Although this is not a good position, it is a reality for many countries in this region.



International guests and Peruvian centre staff.

Coordinated, consistent efforts

The Pan American Network for Drug Regulatory Harmonization (PANDRH) is an initiative of the national regulatory authorities within the region and the Pan American Health Organization (PAHO), which supports the processes of pharmaceutical regulatory harmonization in the Americas within the framework of national and sub-regional health policies, while recognizing pre-existing asymmetries. PANDRH coordinates a network of focal points through virtual meetings which exchange pharmacovigilance information between countries with the aim of strengthening and developing pharmaco-

vigilance and forming proposals for regulatory harmonization that promote safety and rational use of drugs. During the last 10 years PANDRH has supported an international meeting to advance technical, scientific and regulatory agreements in pharmacovigilance.

Lima the host

On 6-7 November Peru hosted the 'XI International Pharmacovigilance Meeting of the Americas'. The event was organized by DIGEMID with the support of PAHO. It was preceded by two other meetings, the first aimed to conduct a situational analysis of pharmacovigilance in Peru and gathered professionals responsible for the regional and institutional reference centres. The second was for members of PANDRH, who had the opportunity to discuss technical documents and normative aspects of pharmacovigilance, and included a signal detection session run by UMC staff.

The main meeting gathered 346 health professionals from all regions of Peru, and from other countries: Colombia, Mexico, Chile, Argentina, Costa Rica, Paraguay, Uruguay, El Salvador, Barbados, plus Sweden, Canada, Spain and the United States. The focus was development and strengthening pharmacovigilance in the Americas. This was achieved thanks to speakers with extensive experience and expertise, among others, José Luis Castro, Pamela Bravo (PAHO/WHO), Elki Sollenbring, Paula Alvarado and Pia Caduff (UMC), Gloria Giraldo (Health Canada), Mariano Madurga (Spain), Gerald Dal Pan (US FDA), María del Carmen Becerril Martínez (COFEPRIS, México), Andres Brandolini (ANMAT, Argentina), Andrés Luna (INVIMA, Colombia), Carmen Lobos Saldías (ANAMED-ISP, Chile), Maryam Hinds (Barbados), Magaly Tito Yépez (DIGEMID, Perú), Gladys Turpo Mamani (Dirección General de Epidemiología, Perú) and María Esther Castillo Díaz (Instituto Nacional del Niño, Perú).

Impact of regional efforts

"At a time when the pharmacovigilance legislation in Peru is strengthening, the topics discussed on Risk Management Plans, Communication and Risk Management, Effective Communications, Crises Communication and International Pharmacovigilance system by inspiring speakers like Gerald Dal Pan, Mariano Madurga, Gloria Giraldo and Paula Alvarado and Elki Sollenbring, motivated the audience's interest and greatly contributed to the development of pharmacovigilance in the region." said Dr Silvia Alvarez Martell, DIGEMID. "The participation of representatives of centres in Colombia, Chile, Mexico, Barbados, Peru and

Canada, highlighted the progress and development of patient's safety in the Americas", Dr Alvarez concluded.



Hands-on signal detection: Colombia, Mexico, Paraguay, Costa Rica and Spain.

Topics covered risks associated with drugs, detection and communication of medication errors, pharmacovigilance of biological and biotechnological products, clinical investigation and post-commercialization studies related to drug safety, experiences of work with other national health programmes, identification of gaps in pharmacovigilance and the role of pharmacovigilance in pharmaceutical policies.

Two poster prizes were awarded from around 36 posters presented covering different pharmacovigilance projects undertaken in different regions of Peru and other Latin American countries.

Moving forward

The meeting allowed the development of health professionals' skills and the exchange of experiences between countries with similar circumstances struggling to strengthen pharmacovigilance in order to offer effective, safe and quality drugs for their populations.

Peru has a deep commitment to this task. Annually we receive around 6,000 ICSRs but we know that does not reflect our reality, and we are working on strategies to improve the situation. Meetings with our main contacts to identify problems and the principal limitations related to pharmacovigilance activities are on-going. Implementation of means to facilitate notification will take time, but we are progressing and will reach the goal where all drugs sold in our country are safe for our people.

Magaly Tito Yépez is Team leader for pharmaco-epidemiology and pharmacovigilance at DIGEMID

A secondment in Barcelona

Elki Sollenbring

Within UMC's Global Services I am responsible for support to Latin American and Caribbean countries in many aspects of pharmacovigilance. Some of these countries are new in setting up a pharmacovigilance centre while others have a well-established centre but still need our support. It is vital for UMC staff to see the processes and routines at a centre in person; how they work and how they manage different situations. We have a lot of theoretical information but to see the reality helps us to understand and support national centres better.

Spanish system

The Spanish pharmacovigilance system consists of a National Centre and seventeen autonomous Regional Centres (RC). It is a well-established and functioning pharmacovigilance system, and Spain has been a member of the WHO Programme for International Drug Monitoring since 1983.

Region within a hospital

The Foundation Catalan Institute of Pharmacology (FICF – in Spanish 'Fundación Instituto Catalan de Farmacología') is located at the Clinical Pharmacology Department of Vall de Hebron university hospital. FICF is part of the hospital, as well as being affiliated to the Barcelona Autonomous University (Universitat Autònoma de Barcelona). The FICF has four sections: pharmacovigilance, pharmacoepidemiology, therapeutic queries, and pharmacology in primary health care. The RC of Catalunya is run by the pharmacovigilance section of FICF.



A final office lunch for Elki in Barcelona.

This Catalunya centre is the oldest in Spain, founded in 1982. Since it has been a pioneer in the development of the system in Spain I was recommended to undertake a secondment there. (If you are wondering "why she didn't visit the national centre instead?" it is because in Spain the national centre doesn't have the same reporting and analysis processes as a regional centre.)

The experiences in Barcelona were excellent. I worked within a great team with two experienced and fabulous pharmacologists, Gloria Cereza and Nuria Garcia. I also had interactions with a wonderful group of pharmacologists, pharmacoepidemiologists, nurses, IT people, secretaries, and of course the leaders of the centre.

The regular work

During my two month stay I was engaged in different activities such as registering and assessing ICSRs, through the detailed processes of receiving, registering and entering the ICSR into FEDRA (Farmacovigilancia Española, Datos de Reacciones Adversas – the national Spanish database), as well as retrieving ICSR information from FEDRA and going through the signal detection process.

I made a presentation about WHO/UMC work for the staff of the division and went through Vigilyze for colleagues. Since the intention was to be involved as much as I could, I tried to participate in different activities to understand the work of other sections and be updated on important activities/topics around medicines.

The national centre

I also visited the national centre in Madrid for two days. I gave WHO/UMC presentations for their staff and for the pharmacovigilance technical committee group. I then participated as an observer during the technical committee meeting where the 17 autonomous regional centres met. During this day they present and discuss potential signals that some of the regions have detected and also discuss other important topics related to their network. This was an intensive and very educational session.

I also joined senior staff as an observer on a visit to a hospital where they were presenting an introduction on pharmacovigilance. I am really grateful to the staff of the regional and national centres for their patience and for sharing their knowledge and experience with me. It was an invaluable experience!

Potential in East Africa

Alex Dodoo & Haggard Hilda Ampadu

Zanzibar is a semi-autonomous country which, with Tanzania, forms the United Republic of Tanzania. Zanzibar consists of several small islands and two large ones, namely Unguja (often referred to simply as Zanzibar) and Pemba. As part of the United Republic of Tanzania, its government works closely with that of Tanzania but it is

important to note that Zanzibar is semi-autonomous with its own President and Ministers of State. Within the East African Community (EAC), it is one of the six Partner States, the others being Tanzania, Burundi, Kenya, Rwanda and Uganda.



Courtesy call on Minister of Health.

L-R: Mr Nassir Buheti, Ms. Hilda H. Ampadu, Dr Mohammed Samba, Honourable Rashid Seif Suleiman, Minister of Health and Prof Alex Dodoo.

A country visit to Zanzibar was undertaken from 14–17 September 2014 by the WHO Programme with financial support from the Uppsala Monitoring Centre, in collaboration with the WHO Collaborating Centre for Advocacy and Training in Pharmacovigilance as well as the WHO Headquarters, Geneva.

Medicines regulation

The Zanzibar Food, Drugs and Cosmetics Board (ZFDB) is the national regulatory body for controlling the quality, safety and effectiveness of medicines, herbal remedies, medical devices, foods and cosmetics. It is a semi-autonomous body of the Ministry of Health and Social Welfare and became operational in its current form on 1 January 2007.

Its mission is "To protect and promote public health by ensuring quality and safety of food, medicines, cosmetics and medical devices", and its vision "To provide the best regulatory services of food, medicines and cosmetics in Zanzibar by 2020".

The National Centre for Pharmacovigilance is within the Department of Medicines and Cosmetics. It has two full-time staff members responsible for all activities relating to the regulation of medicines and cosmetics including pharmacovigilance and medicines information.

Pharmacovigilance

Pharmacovigilance in Zanzibar started formally in 2003, with the National Malaria Control Programme as the entry point. The focus then was on antimalarials, spurred by the switch of treatment from chloroquine and sulfadoxine-pyrimethamine to artemisinin-combination therapy. In 2007 all

pharmacovigilance activities moved to the ZFDB which is now the National Pharmacovigilance Centre. From 2007, the focus shifted from antimalarials to all products – vaccines, herbal remedies, traditional medicines, allopathic medicines, blood products, as well as cosmetics. The quality of products in circulation on the market as well as spurious, substandard, falsified, falsely-labelled and counterfeit medical products (SSFFCs) is covered.

Since 2007 Zanzibar has been an Associate Member of the WHO Programme. It has a national ADR reporting form and a National ADR Advisory Committee, though the committee has not been active for a while. Zanzibar is an active participant in the Regulation and Harmonization Programme of the EAC (www.mrh.eac.int). The goal of the EAC programme is to harmonize registration systems within EAC to facilitate access to safe, efficacious and quality essential medicines.

Visit activities

During our visit we worked with local colleagues to

1. assess the pharmacovigilance situation, using WHO indicators
2. identify gaps in the pharmacovigilance system
3. provide support for Zanzibar to become full members of the WHO Programme
4. undertake advocacy to senior government officials.

Observations

Zanzibar is well prepared for full membership of the WHO Programme, having a national centre located within the ZFDB and being active in EAC harmonization efforts. The centre recognizes the principle of leveraging resources from its neighbours and collaborators. Cordial and conducive relationships have been established with the WHO-CC in Accra, and an active relationship with the whole WHO Programme including WHO Headquarters, WHO-AFRO, the UMC and the WHO Collaborating Centre for Pharmacovigilance in Rabat, Morocco should follow.

We were delighted to see Zanzibar represented at the WHO Programme meeting last October, and look forward to further collaboration and involvement with our colleagues.

Reporting and rights in Oman

Almed Al Harbi

Oman started adverse drug reaction monitoring in 1993 and became a member

of the WHO Programme in 1994. Spontaneous reporting was initiated by health care professionals in both public and private sectors following a ministerial order issued by the Under-Secretary for Health Affairs.



Publicising patients' rights.

Reporting rates were low to begin with. Under-reporting prevailed until 2006 when we started routine awareness workshops at regional level. A minimum of three workshops per year in three different regions was the norm. Participation from private sector also improved after we arranged separate workshops. Significant progress came with the introduction of flex boards in private pharmacies. These boards spread awareness by listing the rights of a patient in both English and the local language. This also encouraged patients to report their concerns to the pharmacists.[see box] The quarterly report of the adverse drug reactions gave statistics on total number of reports, broken down by region and institution, creating a sense of responsibility and competition among the reporters, who wanted their institution / province / region to appear there. In addition the names of the top ten individual reporters were published in the annual report in our Pharmaceutical Newsletter.

All these measures increased reporting from around 500 in the database (2005) to more than 2,000 (end of 2013). Reports from the private sector increased from 1 or 2 to 20 by 2012 and 63 by 2013.

Oman has also set out the patient's rights when medicine is dispensed:

1. To know my medicine, how and when to use, dose, expected adverse drug reaction (ADR) and where to store.
2. To get the usage instruction written clearly on the pack of the medicine.
3. To discuss with the pharmacist any issues related to my medicines and to inform him about other medicines I am on.

4. To inform the pharmacist about any adverse effect that I might suffer as a result of using medicines and ask him/her to fill in ADR form and send it to Ministry of Health.

SOPICON 2014

Ruth Savage

The 14th Annual Conference of the Society of Pharmacovigilance, India & International Symposium on Safe Medicine and Safe Patient was held at Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh on 1-3 December 2014. The conference included 120 presentations, posters, and guest lectures as well as the two annual orations. Two paediatricians, Dr Noel Cranswick of the Australian Paediatric Pharmacology Research Unit, Melbourne, Australia, delivering the John Autian oration, and Dr Anurag Tomar of Jaipur, reminded us of the burden of adverse reactions in children and the paucity of evidence for the safe use of medicines in this age group.

Dr Cranswick noted that progress was being made through the inclusion of paediatric plans in drug development legislation and the evolution of paediatric formularies. Dr Tomar promoted active drug surveillance in this age group and the need for Indian data. 'Another Perspective in Pharmacovigilance' was the title of the KC Singhal oration delivered by Professor Eugene van Puijenbroek of Lareb, the Netherlands, in which he discussed the ADR information that patients find important, as revealed through their reports. This was very relevant since the Pharmacovigilance Programme of India has recently released its Consumer Side Effects reporting form.

Other presentations included evidence of the diligent investigation and promotion of pharmacovigilance awareness by regional Adverse Reaction Monitoring Centres (AMCs); novel ways of ADR reporting; risk management; and a look into the future of personalised medicine through pharmaco-metabolomics. It was a pleasure also to see the high standard of student work which included well-documented single case reports, investigation of practice safety and formal studies covering both traditional and modern medicines.

A conference highlight was an evening visit to the Ibn Sina Academy of Medieval Medicine and Sciences led by Dr Syed Ziaur Rahman, Organising Secretary of SOPICON 2014.

Journal of Pharmacovigilance and Drug Safety (Official Publication of Society of Pharmacovigilance, India) Volume 11, No 5; 2014 (Conference Supplement Issue). (ISSN 0972-8899.)

Recent UMC visitors

Alessio Gasparotto

Alessio worked as a pharmacist in Italy after his degree and always had patient safety as his first priority. This led him to a postgraduate course in pharmacovigilance at the University of Verona.



"One of the most important things that I learned is that pharmacovigilance includes different aspects not only related to the medicine – for example how to communicate with all the people and not only professionals, and as a pharmacist this is very important. Here at the UMC I had the possibility to participate in the signal detection and work with the causality assessment. I was honoured to be a part of the UMC even if only for a few months. I think this place is very special for its history and for the effort that the people here put in to preserve our health. I wish to thank the UMC staff who have welcomed me like a part of this great family;

also I would like to thank staff at the University of Verona who made this possible."

Jakob Sahlström

Jakob is an MSc student in Engineering Physics at Uppsala University with a focus on scientific computing and machine learning. From mid-September 2014 for three months he worked on his Master thesis at the UMC office.

"When I read the description of the suggested thesis project – 'Automatic de-identification of free text narratives on individual case reports of suspected adverse drug reactions' – I thought, to help saving lives using technologies in my area of interest, now that's interesting!"



"During my time at the UMC I developed a platform for analyzing free text, primarily finding and erasing names of places and

dates that could potentially identify patients. It enables state-of-the-art statistical models to be used in combination with handcrafted rules including tools for evaluating and visualizing the results. The platform can be applied to more than just de-identification and I hope that it will be used more at the UMC Research department."

"I have learned more than I could imagine during my time at the UMC, surrounded by nice and competent people facing interesting challenges every day."



The President of the International Society of Pharmacovigilance Hervé Le Louet made a short visit to the UMC in December, during which he discussed membership of the UMC's Signal Review Panel and met with Director Marie Lindquist and UMC Research staff.

Expecting the Worst in Chinese

A Chinese translation of the UMC's powerful guide to crisis management 'Expecting the Worst' has just been published.

This project has been a collaboration between the UMC (principally Dr Zhurong Liu) and staff at the Institute of Executive Development of the China FDA. Staff appointed by the Institute in Beijing have taken Bruce Hugman's text and translated it, with cross-checking and proofing undertaken by the UMC's team.

The book, about anticipating, preventing and managing medicinal product crises, will be obtainable from the Institute, and further details about this will be published soon.

We are proud that another edition of this major crisis management publication is now available, and look forward to receiving feedback as it becomes more widely disseminated.



Two sample chapters from Expecting the Worst (2nd edition) are available in print-protected format to show examples of the book's content from the UMC website. Chapters 1 (Introduction) and 2 (The Framework for Planning) may be viewed in pdf format. Go to the Publications section > UMC Material – and look for Expecting the Worst.

UMC on YouTube

Uppsala Monitoring Centre has launched its YouTube Channel.

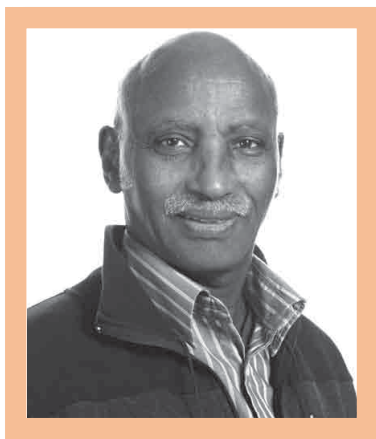
In this online video platform you will be able to access training, lectures and other pharmacovigilance materials.

<https://www.youtube.com/channel/UC1Sm0Uue6noAWVY4P2JEIjw>

Click, subscribe and keep an eye on this channel!

Mohamed bows out

Geoffrey Bowring



Mohamed Farah is a familiar face for many who know the UMC and its work over the last two decades. He was born and grew up in what was then the Italian Trust Territory of Somaliland. Having obtained his Teaching Diploma, from 1966 Mohamed held posts in secondary schools in Bullo Barde, Qoryoley and Mogadishu, teaching several subjects, mainly mathematics. Several quirks of fate took him from there on a very different path.

A big ceremony

In 1972 Mohamed was chosen to organize a form of 'mass game', a backdrop where a field of children stationed on one side of the Mogadishu Football Stadium spelled messages to the grandstand: "3,000 school children, each holding a large book with pages of block colours synchronized their movements so that when seen as a whole, huge pictures were created presenting ideological messages praising the October 1969 Revolution in Somalia". The ceremony, in the presence of Haile Selassie of Ethiopia, Julius Nyerere of Tanzania, Jaafar Nimeiry of Sudan and Marien Ngouabi of the Republic of the Congo went well and following this Mohamed was given the opportunity to

further study so-called mass games in the People's Republic of China.

From Games to Chemistry

Mohamed arrived in China in 1973 and began Chinese language studies. While in Beijing undertaking these classes he met with many of the non-Chinese in the capital, including George Bush senior and his wife Barbara, at the Friendship Hotel / Restaurant / Shop. At this time however, he decided to change direction and was granted leave to study organic chemistry.

He therefore began a Bachelor's degree in 1974 at Tianjin Nankai University, the only non-Chinese in his class. There he met his fellow students, and his room-mate Dh. D Kong Jianshe. Communication with his classmates was severely restricted and he had to take virtually all meals with the handful of other non-Chinese at the university. He was aware though of the personal trials and liaisons of the students in such an environment. The teaching resources were very limited, with few books and most classes consisting of learning from a blackboard.

Towards the end of the upheavals of the Cultural Revolution, his experiences and observations as an outsider in China were almost unique and eye-opening. He had many opportunities to witness the way of life in a large provincial city in the 1970s. He was living in Tianjin at the time of the 1976 Tangshan earthquake, which resulted in him and some others being moved to Beijing for over a year.

He continued his studies with a Master of Science in Organic Chemistry at Tsinghua University in Beijing from 1980-1981. During this period he also acted as mentor to

thirteen other Somalis who had come to Beijing for further education.

Plants

On his return to Somalia, during the 1980s Mohamed began to take a serious interest in traditional medicines and the properties of the ingredients used in them, some of which were toxic to humans. Eventually he initiated joint herbal research work between several Faculties: Chemistry, Medicine and Botany. Collaboration commenced between Italian professors of organic chemistry at Mogadishu University and staff in the Faculty of Chemistry, funded by the Swedish government. The group located a traditional healer who was illiterate but became involved as an expert in the properties of plants used in herbal medicines.



Mohamed and some of his fellow classmates by the Summer Palace lake in Beijing, 1970s.

In 1982 he went to Uppsala for the first time, undertook herbals studies, and commenced a doctoral thesis (entitled *Isolation and identification of pharmacologically active compounds from plants used in Somali traditional medicine*) which he obtained in 1991.

His first paper on herbal medicines (*Volatile Mono- and Sesquiterpeneoids from Kleinia Pendula*) was published in 1987 by which time he was living semi-permanently in Uppsala.



Mohamed with his classmates; in front of the Nankai faculty building in the mid 1970s, and in the same place, November 2014.

The same year while in Somalia collecting plant samples with a Swedish professor and three doctoral students near the intersection of the borders with Kenya and Ethiopia, the security situation deteriorated such that he needed to get out. He returned to the capital, being stopped by heavily armed combatants en route, but managed to help his guests to safety, before he himself returned to Sweden a couple of months later. His family only escaped on the final Aeroflot flight to leave Mogadishu two years later.

Settling at UMC

Mohamed started working at the Uppsala Monitoring Centre in January 1995. In December of his first year at the Centre he attended the annual national centres meeting in Bangkok. After that first meeting he made many good friends at pharmacovigilance centres in the WHO Programme.

At the UMC he has been responsible for development of the principles of herbal nomenclature and classification that is now the backbone of the WHO Herbal Drug Dictionary, including an application of the WHO ATC classification system to herbal medicines. His extensive work on plant nomenclature resulted in several scientific papers on the topic and a UMC book entitled 'Accepted Scientific Names of Therapeutic Plants – and their synonyms'. His personality and language skills made him a very important asset to the organization, particularly when



Professor Xhang, Mohamed Farah, Mr Kong Jian Shi.

taking care of foreign visitors or lecturing on botanical nomenclature and safety of herbal medicines in countries around the world. Over the years he learnt to encompass the diverse Somali, Italian, English, Arabic, Chinese and Swedish languages!

China again

Mohamed went back to China on UMC work with Ralph Edwards twice in the 1990s. Then in 2014, as part of the UMC delegation to the 37th WHO Programme meeting in China, Mohamed returned to Beijing and Tianjin. With some help he had traced most of his classmates from the 1970s, and the result was "the biggest, most inclusive and most fascinating reunion in my life, not only that, but also meeting my Professor Zhang in

Tianjin, who had been at my side throughout my time in Tianjin and Beijing".

"One of my most memorable experiences on the trip was that I was invited to attend a conference in Beijing. For the occasion, I discussed with my room-mate, and we went to his mother's house because she was a seamstress and during my student years in China was able to take my measurements and made a traditional Chinese shirt for me. In those days, specialty clothing was hard to buy. Forty years on, China has developed at a remarkable speed. Today, one can find and buy anything."

The photos of then and now give some indication of the reunions; "I'm so happy that I was able to reunite with old classmates and friends again and to take a picture at the same place where we stood about 40 years ago".

At home

All his six children have graduated in the natural sciences. He has seven grandchildren, and one of his aims in his retirement is to help the local children in the flats where he lives on the outskirts of Uppsala with their homework, although he will also continue as a consultant for the UMC.

Mohamed is a warm and friendly man with many fascinating life experiences. He has some amazing stories to tell, which we can only touch on here.

ISoP honours Cheng Jinghua

I Ralph Edwards

Cheng ('John') has worked tirelessly for pharmacovigilance in China from the mid 1980s. He only stopped working a couple of years ago, and he is 81 years old. He was the Chief Pharmacist at Ditan Hospital, Beijing, and introduced pharmacovigilance to that hospital. His time there was memorable for warning of the use of Ketoconazole and fatal liver failure, when used for the trivial indication of fingernail fungal infection; conducting public promotion of drug safety in nearby parks at the weekends; and working with his hospital colleagues to increase awareness of adverse reactions to traditional treatments as well as to 'western' pharmaceuticals.

He took a fellowship in pharmacovigilance in New Zealand from 1988-1989. That was the turbulent time of the Tiananmen Square confrontation. In spite of concerns about all the unrest, Cheng's aim was clearly stated to me at the time, "I want to bring drug safety

to the whole of China". Pursuing this goal, he organised the first national ADR Conference in Beijing with 300 participants. His great wish has been fulfilled now that the CFDA annually manages ~1.5 million ICSRs with 37 regional ADR centres.

After initiating the ADR meetings, he worked on his other important initiative: the creation of the Chinese 'ADR Journal'. This was his constant preoccupation until he retired: but he still keeps close contact with the Journal. He is pictured (centre) in the photo, with his successors on the Editorial Board, and me. Cheng received an Honorary ISoP membership at their 2014 Tianjin meeting.

One of the most modest people, he said of his time in pharmacovigilance, "I wanted to do good things in drug safety, but not for me". I asked him, "What are you happy about?" He replied, "I'm pleased that nearly all

pharmacists know about drug safety" I asked, "What are you not pleased about?" His reply: "I have not been able to convince doctors that pharmacovigilance is very important".

Neither have the rest of us!



Introducing new faces

Steve Roan, born in Brisbane, Australia, has lived in Uppsala for 11 years, having spent three years in London. "I have had numerous jobs in a variety of industries. My career started at 15 as a lifeguard at a public swimming pool. When not saving lives I was emptying rubbish bins, cutting the lawn or serving ice cream. From high school I started a trade, and after four years became an electrician. After one too many synapse-altering electrical shocks I decided on a career change and studied to become a nurse with an interest in neurology.

In London I moved into clinical research, managing pain studies and ending within the CRO industry in Phase I research. I stayed in CROs for ten years in business development. At the UMC, I am Customer Relations Team Manager and my role is to support staff who conduct webinars and User Group meetings internationally to meet customer needs and satisfaction.

On a personal level I enjoy swimming, surfing, running at the beach, all of which are a challenge in Sweden."

Rebecca Chandler was born and raised in Chattanooga, Tennessee. However, her medical education led her to many states in the USA: medical school in Georgia, internal medicine in Missouri and infectious diseases in Oregon. "Having met a visiting German scientist during these years, family commitments led me to Uppsala in 2008 and I worked at the Swedish Medical Products Agency as a Clinical Safety Assessor. During my six years at MPA, I evaluated numerous periodic safety reports and risk management plans for marketed products, such as vaccines, antiretrovirals, TNF alpha blockers and bisphosphonates. The H1N1-Pandemrix experience solidified my dedication to pharmacovigilance and particularly vaccine safety."

Rebecca joins the Research team to provide clinical input to signal detection strategies as well as signal assessment. She will also be involved in training.

"Outside the office, I am wife and mamma to three children; I like to consider myself a 'foodie' and I love folk music."

Eva Sundman was born in Kalmar, south-eastern Sweden and moved to study at Stockholm University where she received a BSc in Human Resource Management and Labour Law in 1992. "Since 1993 I have lived in Uppsala worked as an HR Manager in the Life Science industry and a consultant helping small- and mid-sized companies with HR issues.

In August 2013 I started as a HR consultant at UMC. In June 2014 I assumed a permanent position as the Head of Human Resources to

"I married a Swedish man who loves sailing and we have one daughter. With my brother I inherited a keen interest in cuisine; while the rest of my family were cooking French and Japanese dishes, we were good at tasting!"

Daniele Sartori is a pharmacy graduate from the University of Pavia, Italy. He joined the UMC in September 2013 as an intern, via a post-graduate programme offered by the University of Verona, and a year later was interviewed for a position as Research Pharmacist. He has been responsible for editing the Signal Document, communicating with external reviewers and performing custom searches in VigiBase®. In the next few months he will be involved in signal detection sprints and research projects.

"What I love about working in the Research Section is the incredible room for expressing your own creativity. There are always new tweaks, new improvements anyone can contribute to and talks

on how to do so either arise in casual conversation or scheduled weekly 'fikas'. A bit of me: I enjoy reading, travelling, cooking and photography."

Sara Hult grew up in Ljusdal, a small town in Hälsingland. When she was 20 she decided to move to Uppsala and study, where she obtained her MSc in Pharmaceutical Biosciences. "I have previously worked at UMC as a consultant but am now a permanent employee as a Research Pharmacist. I am responsible for Custom Searches; these consist of retrieval of VigiBase data for external customers such as pharmaceutical companies and national centres. I am also involved in the signal detection process, production of the SIGNAL document, dealings with the review panel and other projects within Research.

When not working, I like to spend time with my family and friends. I enjoy travelling and being out in the nature, but also just relaxing at home, watching a movie or doing some reading or knitting."



Sara, Steve, Rebecca, Eva and Daniele; Yoko (inset, with Missy Tyrefors).

develop human resources strategies, processes and policies and provide professional operational HR support. I also serve as a visiting lecturer at Uppsala University for several weeks a year, with a focus on labour law. In my spare time I am a dedicated chilli grower and recently made chilli jam for the first time."

Yoko Yoshimoto Tyrefors was born in Osaka, Japan and graduated from Kobe College, starting work at Saab Scania International and Diplomat Sales: a first encounter with Sweden. She moved to Genzyme, and has since stayed in the field of life sciences. "As Commercial Operations Director for a Swedish CRO, I was responsible for sales and marketing in Japan, identifying business opportunities and converting them to sales and high customer retention. I have a BA and MCom and published a book with my professor based on my empirical studies, 'International management and corporate culture'. At UMC, I function as Key Account sales representative for Japan and coordinate activities with a focus on sales and customer relations."

DATES	TITLE	PLACE	ORGANISER/CONTACT
5–6 February 2015	Annual Pharmacovigilance and Risk Management Strategies Summit	Berlin, Germany	Vonlanthen Group Tel +49 303 187 95 78 E-mail : AlexanderNorman@vonlanthengroup.com
16–28 February 2015	First Asia Pacific pharmacovigilance training course	Mysore, India	JSS University, UMC E-mail: pvtraining@jssuni.edu.in
18 February (training), 19 February 2015	PROTECT Symposium	London, UK	European Medicines Agency www.imi-protect.eu/
25–26 February 2015	Back to Basics in Pharmacovigilance	Southampton, UK	Drug Safety Research Unit Tel: +44 (0)23 8040 8621 www.dsru.org/trainingcourses E-mail: jan.phillips@dsru.org
11–12 March 2015	EU Regulations and Guidelines for Pharmacovigilance	Southampton, UK	Drug Safety Research Unit (See above for contact details)
16–18 March 2015	Advanced Pharmacovigilance	London, UK	Management Forum Ltd Tel: +44 (0)1483 730008 www.management-forum.co.uk E-mail: registrations@management-forum.co.uk
23–27 March 2015	Data Management for Regulatory Affairs and Public Health	Accra, Ghana	WHO Collaborating Centre for Advocacy & Training in Pharmacovigilance www.who-pvafrika.org E-mail: training@who-pvafrika.org
26–28 March 2015	Basics in pharmacovigilance and new developments	São Paulo, Brazil	ANVISA and ISO P Latin America Chapter www.isoonline.org E-mail: administration@isoonline.org
11–14 April 2015	ISPE Mid-Year Meeting	Bordeaux, France	International Society for Pharmacoepidemiology (ISPE) www.pharmacoepi.org
13–15 April 2015	DIA EuroMeeting 2015 : Innovation, Demand, Access and Patient Safety	Paris, France	DIA Europe www.diahome.org/en-GB/Meetings-and-Training/
20–22 April 2015	International Meyler course in Pharmacovigilance	's-Hertogenbosch, The Netherlands	Lareb www.lareb.nl/WHOCC
23–24 April 2015	Lareb conference on patient reporting: Current perspectives and future possibilities	Leiden, the Netherlands	Lareb (See above for contact details)
18–29 May 2015	17 th International Pharmacovigilance Training Course	Uppsala, Sweden	Uppsala Monitoring Centre www.who-umc.org
20–21 May 2015	Global Regulatory Pharmacovigilance Environment	Hammersmith, London, UK	Drug Safety Research Unit (See above for contact details)
1–12 June 2015	9 ^{ème} Cours Francophone de Pharmacovigilance	Rabat, Morocco	Centre Anti Poison et de Pharmacovigilance du Maroc www.capm.ma/
1–19 June 2015	The WHO Collaborating Centre Vaccine Pharmacovigilance Fellowship	Accra, Ghana	WHO Collaborating Centre for Advocacy & Training in Pharmacovigilance (See above for contact details)
9–11 June 2015	Signal Detection Conference	London, UK	Drug Safety Research Unit (See above for contact details)
24–26 June 2015	Medical Aspects of Adverse Drug Reactions	Southampton, UK	Drug Safety Research Unit (See above for contact details)
22–26 August 2015	31 st Annual Conference ICPE	Boston MA, USA	International Society for Pharmacoepidemiology (ISPE) www.pharmacoepi.org
14 September – 9 October 2015	The WHO Collaborating Centre Pharmacovigilance Fellowship	Accra, Ghana	WHO Collaborating Centre for Advocacy & Training in Pharmacovigilance (See above for contact details)
27–30 October 2015	ISoP 2015 Annual Meeting	Prague, Czech Republic	International Society of Pharmacovigilance www.isoonline.org E-mail: administration@isoonline.org
25–27 November 2015	2 nd African Society of Pharmacovigilance (ASoP) conference 'Pharmacovigilance In Africa : New Methods, New Opportunities, New Challenges'	Accra, Ghana	ASOP 2014 www.asop2014.com



The Uppsala Monitoring Centre (UMC) is a not-for-profit foundation and an independent centre of scientific excellence in the area of pharmacovigilance and patient safety. We provide essential research, reference, data resources and know-how for national pharmacovigilance centres, regulatory agencies, health professionals, researchers and the pharmaceutical industry round the world.

Many of our services and products have been developed as a result of our responsibility – as a World Health Organization Collaborating Centre – for managing the WHO pharmacovigilance network of over 120 countries and the WHO global individual case safety report database, VigiBase®. A core function is the screening and analysis of data with the aim of detecting potential issues of public health importance in relation to the use and safety of medicines. Other services include technical and scientific support to WHO and its member countries, and provision of tools, such as VigilYZe™ and VigiFlow®, for data entry, management, retrieval and analysis.

Our main commercially available products are the family of international WHO Drug Dictionaries, used by most major pharmaceutical companies and CROs.

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