MAPPING the HERBAL JUNGLE

Bhutan’s PV progress • Uppsala Health Summit • Big data and causal dispositionalism • Managing MEs • Social media campaign • Better signal detection with vigiRank
**Director’s message**

After my father died last year, I thought a lot about him and the role he played, and still plays, in my life. One of the most important things he taught me was that it is who you are as a person that matters – not where you come from, how you look, or what position you have in the world. And he never made me feel that there were things I couldn’t do because I was a girl, not a boy. I know that I was different from boys, physically, but I never felt branded negatively as the ‘weaker sex’. Only much later did I fully appreciate how fortunate I was to be able to grow up thinking of myself primarily as a person, a human being who also happened to be a girl.

My view of a good world is where all of us are being seen, and valued, as the unique individuals we are. A world where we are appreciated in all our complexity, and where our choices are made based on ability and interest, not a category or label that we have been assigned by others.

Our ability to quickly categorise things around us is a basic instinct, a survival mechanism, and it was essential in a time when the ability to quickly identify danger was a matter of life or death. By classifying and grouping things, we make a complex reality more manageable. The problem is if we categorise in a way that is confining and excluding, and reduces reality too much.

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R. Edwards, “Lives with complexity and buy data”, Uppsala Reports 78, p. 28


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Editor-in-Chief Paula Allegrini, Editors Anders Hedin, Maria Lindquist & Geoffrey Dowling. Editorial committee supported by branch of multidisciplinary pharmacovigilance experts. Production: UMC Global Communications Design: Daniel Hansson, Zellout, Sweden. Content Illustration: Delux. Contact: Uppsala Monitoring Centre, Box 1051, S-751 40 Uppsala, Sweden info@who-umc.org +46 18 65 60 40 Web: www.who-umc.org

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ETIOPIA FIRST TO USE UPDATED VIGIFLOW

In October 2017, the first version of the renewed VigiFlow was launched, and Ethiopia became the first country to go live with the new system.

The launch prompted UMC staff to visit Addis Ababa and the national pharmacovigilance centre (NC) in the Ethiopia Food, Medicine and Health Care Administration and Control Authority (EFMAGCA), with the aim to train local personnel as well as to collect feedback for future VigiFlow training materials. VigiFlow is used by more than 70 countries and the new version will gradually be rolled out to all of them throughout this year. UMC will contact each national centre to set up a timetable to start using the new version.

Since on-site visits to all users are not feasible, the Ethiopia experience and feedback from EFMAGCA will be of great value when UMC prepares VigiFlow training materials, for example webinars, to be used by national centres.

ATC/DDD Toolkit a gold standard for drug utilisation studies

Since 1996, the World Health Organization endorses the Anatomic Therapeutic Chemical (ATC) and Defined Daily Dose (DDD) methodology as the gold standard for drug utilisation monitoring and research. The Toolkit and relevant resources are available online.

The WHO Collaborating Centre for Drug Statistics Methodology in Oslo, Norway, developed the manual for the ATC/DDD Toolkit together with the WHO International Working Group for Drug Statistics Methodology. The WHO Medicines Safety group created the ATC/DDD online Toolkit, and the first version of it went live on WHO’s website in March 2017. The Toolkit was created to be a comprehensive and user-friendly online resource for anyone interested in undertaking drug utilisation studies. It contains guidance on how to set up and use the international ATC/DDD methodology.

This methodology facilitates the presentation and comparison of drug consumption statistics at international, national, and regional levels irrespective of differences in nomenclature (both branded and generic), packing sizes, pricing, and customary dosages. Such methodology is useful for valid presentation and comparison of drug utilisation within and across countries to support better outcomes and quality use of medicines.

These kinds of studies are important because although medicines can provide substantial benefits they have the potential to harm patients, which can result in substantial costs. The level of expenditure on medicines varies between countries and it is important to be able to understand the patterns of use – for example, the types of medicines used and their quantity. Drug utilisation studies are essential for monitoring these patterns and trends, and for understanding their impact on the efficiency with which health outcomes are gained.

Explore the Toolkit online

Through 10 chapters, the Toolkit will lead the user from the basics of the ATC/DDD methodology and its applications, to how to set up a drug utilisation study. Users can test their skills on the ATC/DDD methodology through the online quiz, and expand their knowledge through the literature recommended in the application. They can also sign up for the annual courses organised by the WHO Collaborating Centre for Drug Statistics Methodology.

Test how much you know about the Toolkit with this quiz!

www.who.int/medicines/regulation/medicines-safety/toolkit
Learning

Asian and African pharmacovigilantes train in India

For the fourth year in a row, UMC joined forces with India’s JSS University to train pharmacovigilance professionals from the Asia Pacific and African regions.

In February, 32 participants from 12 countries gathered in India for the 4th Asia Pacific Pharmacovigilance Training Course. The course, hosted by the JSS College of Pharmacy in Mysore, India, has been jointly organised by Uppsala Monitoring Centre and JSS University every year since 2015. It is modelled on UMC’s two-week long International Pharmacovigilance Training Course in Uppsala, Sweden – taking place for the 20th time this year.

Although the Indian course was designed to develop pharmacovigilance knowledge and skills in the Asia Pacific region, recent years have seen an increasing number of participants from African countries. This year, more than a third of trainees came from Africa. Most participants worked for national pharmacovigilance centres, with a few representatives from pharmaceutical companies, hospitals and academia.

“This course gives a platform for people from different countries to come together,” said Dr G Parthasarathi, dean for Global Engagement at JSS University and course coordinator. “Participants get to know each other personally and professionally, and learn from each other. That will be of great value to them. I’m sure they will treasure this and it will help us a lot.”

Lectures were delivered by UMC and JSS staff, and by external speakers from India’s Monitoring Centre for Strengthening Pharmacovigilance Practices, who was a speaker at the meeting, pointed out that signal detection with a moderate number of reports should start with qualitative methods. But producing potential signals is only the means to an end, Amina Alsharh from the Saudi Food and Drug Authority (SFDA) will improve signal detection, whereas in other national centres case assessors undertake the entire process, from causality to signal evaluation.

“This course has been very beneficial to me,” said Ms Chrissy Chulu, a pharmacist from the Pharmacy Medicines and Poisons Board in Malawi. “What I learned here – especially concerning medication errors and causality assessment – will definitely increase the scope of pharmacovigilance in our country. So this is the message I’m taking back home: we are going to work on this and it will help us a lot.”

In recent years, several Arab countries have developed robust processes to capture adverse drug reaction (ADR) data. A general trend in the region is devolving the collection of reports of adverse events to a more local level. The total of Vigibase reports coming from the region now exceeds 70,000 and with their expanding national databases, countries have been thinking about ways to make use of their data. When the Arab Countries Pharmacovigilance Network met in Saudi Arabia in October 2017, the investigation of safety issues was a general theme throughout the agenda. Signal detection practices across the region differ from country to country. In Saudi Arabia, a specialised team does the signal detection, whereas in other national centres case assessors undertake the entire process, from causality to signal evaluation.

The next UMC pharmacovigilance training course takes place in Uppsala, Sweden, on 21 May–1 June 2018.

Advancing signal detection in Arabic countries

In an effort to put pharmacovigilance data to greater use, members of the Arab Pharmacovigilance Network exchanged notes on signal detection practices at their second regional meeting in Riyadh.

In recent years, several Arab countries have developed robust processes to capture adverse drug reaction (ADR) data. A general trend in the region is devolving the collection of reports of adverse events to a more local level. The total of Vigibase reports coming from the region now exceed 70,000 and with their expanding national databases, countries have been thinking about ways to make use of their data. When the Arab Countries Pharmacovigilance Network met in Saudi Arabia in October 2017, the investigation of safety issues was a general theme throughout the agenda. Signal detection practices across the region differ from country to country. In Saudi Arabia, a specialised team does the signal detection, whereas in other national centres case assessors undertake the entire process, from causality to signal evaluation.

Dr Amina Tibsaa from Morocco’s WHO Collaborating Centre for Strengthening Pharmacovigilance Practices, who was a speaker at the meeting, pointed out that signal detection with a moderate number of reports should start with qualitative methods. But producing potential signals is only the means to an end. Amina Alsharh from the Saudi Food and Drug Authority (SFDA) will improve signal detection, whereas in other national centres case assessors undertake the entire process, from causality to signal evaluation.

Dr Adel Alhaif from the Saudi Food and Drug Authority. Photo: SFDA

national ADR database and media screening. Of the signals generated, known ones are excluded and the remainder are then ranked with an in-house signal prioritisation tool. Further investigation follows, sometimes by external reviewers, and ultimately regulatory action, if needed. In the near future, the Saudi Food and Drug Authority (SFDA) will improve signal dissemination and collaborate with academic institutions.

“We will increase the communication of signals. You will start to see more signals in our newsletters locally and globally. We are also planning to increase our collaboration with research centres and universities. They could help refine or strengthen our signals by doing cohort studies,” said Mohammed Fouda, head of the Signal Detection Section at SFDA, in his presentation.

The Arab Good Vigilance Practice Guidelines state that, while national medicines authorities are responsible for monitoring safety issues emerging from their databases, market authorisation holders are liable for signal detection and validation for their products. Several representatives from pharmaceutical companies were present at the meeting and were eager to learn more about signal detection and subsequent investigations.

Many agreed that there is a need to increase competence in signal detection in authorities and industry alike. Though few had seen Uppsala Monitoring Centre’s online course on signal detection and causality assessment, it was a well-received initiative. Spontaneous reporting databases were recognised as a useful resource for signal generation, as were epidemiological methods for further investigation of signal hypotheses. Following the main meeting, a workshop explaining fundamental concepts in pharmacoepidemiology generated considerable attention.

Meanwhile, many Arab countries do not operate national pharmacovigilance programmes at all. At the meeting, pharmacovigilance proponents from Kuwait and Lebanon told their stories about the emerging interest to establish pharmaco- vigilance systems in their countries.

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WHO PIDM

The African continent was well represented at the meeting, with over half of the attendees from the WHO African Region. Uganda has one of the more mature medicines monitoring systems in East Africa, an analysis of five key components of a regulatory system has shown. Recent developments have included the launch of online adverse drug reaction (ADR) reporting, implementation of targeted spontaneous reporting – which could be applied in all public health programmes, such as tuberculosis – and improved relationships with marketing authorisation holders (MAHs). A law has been passed to mandate MAHs for generics to nominate a person responsible for pharmacovigilance, which should increase reports.

To sustain its work, Uganda’s National Drug Authority (NDA) is sponsoring staff to undertake postgraduate studies. Individual presentations at the meeting furthered the attendees’ knowledge of activities in Uganda, with talks on the incidence of ADRs in anti-malarial treatment; on toxicity due to kanamycin in multi-drug-resistant tuberculosis; and on anaemia and their quality is low. The Sierra Leone national pharmacovigilance centre confirmed the intensive training given to doctors, nurses and pharmacists in the country, although their quality is low. The Sierra Leone centre, for example, receives reports from three regions of the country, with reporting methods not necessarily suited to their setting, and their low capacity to analyse data. Moreover, few LMICs authorize reports to signals received – most replicate what is done by more established authorities. This strategy fails when new medicines with limited safety data are introduced on a large scale.

A Project Smart Surveillance project, launched by WHO and BMGF, addressed the audience. Most LMICs, she said, can collect data and upload reports to VigiBase, the WHO global database of individual case safety reports (ICSRs), and are clearly motivated to improve their pharmacovigilance systems. Concerns relate to the continued changes to the reporting formats in these countries, with reporting methods not necessarily suited to their setting, and their low capacity to analyse data. Moreover, few LMICs authorize reports to signals received – most replicate what is done by more established authorities. This strategy fails when new medicines with limited safety data are introduced on a large scale.

The ‘Project Smart Surveillance’, launched by WHO and BMGF, aims to help LMICs identity, assess, and manage risks associated with new medical products, and to improve pharmacovigilance post-marketing surveillance. According to Dr Preston, the value of this sub-regional approach is evident in providing a database, analytical tools to countries that do not have them, and offering staff and technical support.

“Most LMICs can collect data and upload reports to VigiBase, and are motivated to improve their pharmacovigilance systems.”

Dr Charlie Prestan, an advisor at the Pan American Health Organization (PAHO), spoke about the difficulties of medicines regulation in the small, low-resourced states of the Caribbean Community (CARECOM). The region covers a population of 70 million, where some states have no regulatory authority, and few monitor drug safety and quality. A Caribbean Regulatory System (CRS) aims to reduce the reliance on reference authorities, and also targets pharmacovigilance and post-marketing surveillance. According to Dr Prestan, the value of this sub-regional approach is evident in providing a database, analytical tools to countries that do not have them, and offering staff and technical support.

Meanwhile, the national pharmacovigilance centre in Guyana gave a round-up of recent advances in patient reporting and implementation of new technologies in ADR reporting. Their mobile app, launched in 2016, was featured on national TV news, boosting patient reporting. Campaigns have progressively lifted the reporting rate, especially from patients. Future plans include a closed IT system for health professionals, offering two-way communication, integrated with familiar clinical and hospital IT systems, thus allowing more direct reporting.

Tomas Bergvall and Dr Rebecca Chandler from UMC presented progress made in method development studies, research into medicines use data, and making better use of narratives in case safety reports – while respecting patient confidentiality – to make more detail available. Dr Chandler described two signal-detection exercises. One aimed at probing reports from patients, in collaboration with Lareb in the Netherlands. The other looked at covariates of individual attributes to see how VigiBase could be used for identifying risk groups of patients with an increased propensity to a given effect. At the end Christoph Küng, Head of Division at Swissmedic, announced that the 2018 meeting, celebrating 50 years of the WHO Programme for International Drug Monitoring, would take place in Geneva, Switzerland, where WHO is headquartered, from 5–8 November 2018.

The African Medicines Regulatory Harmonisation (AMRH) is advancing the creation of an African Medical Agency, with a pharmacovigilance advisory group. The AMRH, she said, was established in 2014, with the African Medicines Regulatory Harmonisation committee for medical agencies. In 2012 it approved a strategic plan, with work progressing on the establishment of an African Medicines Regulatory Harmonisation committee for medical agencies.

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See you in Switzerland in November!

The WHO Programme for International Drug Monitoring will host representatives of national pharmacovigilance centres at its 41st Annual Meeting in Geneva on 5–8 November 2018, when the programme also celebrates its 50th anniversary.

The International Society of Pharmacovigilance holds its 18th annual meeting in Geneva on 11–14 November. Register online: www.isps2018geneva.org
BHUTAN’S CLIMB TO MEDICINES SAFETY

The outlook is good for pharmacovigilance to progress upwards in Bhutan, Ms Tshering Choden, one of the country’s five pharmacovigilance professionals, tells Uppsala Reports in this Q&A.

WHAT ARE THE CHALLENGES TO PHARMACOVIGILANCE IN BHUTAN AND WHAT CAN BE DONE ABOUT IT?

Being a small country, one constraint in Bhutan is that we have too few professionals. Right now there are approximately 50 pharmacists in the country. I wish there would be more. If we had more professionals who knew about the safety of medicines, we could expand pharmacovigilance activities in our hospitals, so having pharmacy professionals in hospitals is essential – they know what to do and have a knowledge of pharmacovigilance and adverse drug reactions (ADRs).

We have to build capacity with good education – we need more people to be trained in pharmacovigilance, and not only pharmacists. Fortunately, we only focused on training pharmacy professionals, but if we want to have a good system in place in Bhutan, we should train all healthcare professionals, starting with nurses and doctors. We’re now in the process of training all health workers – nurses, doctors, pharmacists, pharmacy technicians and related assistance – in all hospitals and primary health-care units in Bhutan, on the importance of reporting ADRs, how to fill the forms, and where to send them.

If we had more manpower I think we could make everyone report adverse effects. We could reach each household and learn about their knowledge of pharmacovigilance, and also talk to our healthcare professionals to check their knowledge of medicines safety. If we were all committed it would be really easy for us to report ADRs, and we could strengthen pharmacovigilance activities in hospitals.

HOW ARE YOU WORKING TO IMPROVE PHARMACOVIGILANCE AT YOUR HOSPITAL?

One of the challenges we face at the Eastern Regional Referral Hospital is that most people have been unaware of pharmacovigilance. They didn’t think it’s necessary to report ADRs because it’s already written in the package leaflets – they think it’s in the nature of the drug to cause the reaction.

However, there is a big shift. Patients should know what pharmacovigilance means, what the effects of medicines are, and that there won’t be any pharmacological effect without any side effects. And for healthcare professionals it’s essential to know about pharmacovigilance so that they don’t report the ADRs. Under-reporting is one of the biggest problems in under-developed countries. To encourage my colleagues to report, we made an awareness in my centre to report ADRs, and they have to submit a minimum of three reports. We have free access to all the reporting forms in the hospital. I have distributed reporting forms to all the wards and explained to the staff how to report, what to write, and how they can submit, and most of the staff in my hospital are aware of ADRs now.

WHY DO YOU THINK IT’S IMPORTANT TO SPREAD AWARENESS OF MEDICINES SAFETY?

 Awareness of pharmacovigilance is very important because safety comes first in treatment. Without knowing the safety of the drug, we cannot treat the patient. Patients should know what pharmacovigilance means, what the effects of medicines are, and that there won’t be any pharmacological effect without any side effects. And for healthcare professionals it’s essential to know about pharmacovigilance so that they don’t report the ADRs. Under-reporting is one of the biggest problems in under-developed countries. To encourage my colleagues to report, we made an awareness in my centre to report ADRs, and they have to submit a minimum of three reports. We have free access to all the reporting forms in the hospital. I have distributed reporting forms to all the wards and explained to the staff how to report, what to write, and how they can submit, and most of the staff in my hospital are aware of ADRs now.

WHAT’S NEXT FOR MEDICINES SAFETY IN BHUTAN?

Bhutan has a very young pharmacovigilance system, so we are moving at our own pace to develop and to get our own place established for pharmacovigilance in the Ministry of Health. Everything needs time to fall into place. We are not in a hurry, we are not being so ambitious, but we are working on it. We are trying to strengthen the pharmacovigilance system in Bhutan.

Who is Tshering Choden?

Tshering Choden is a hospital pharmacist at one of Bhutan’s three regional pharmacovigilance centres, the Eastern Regional Referral Hospital in Monggar. She is the pharmacovigilance contact person and has been a driving force behind increasing the amount of adverse drug reaction reports submitted at the hospital.

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Updates

FIP pulls in the crowds and calls for change

Robotics dispensing is just one among many challenges reshaping the pharmacy profession as it negotiates the transition from a supply function to a priority of patient care. This year’s FIP meeting explored the soul of pharmacy and how pharmacists should envisage and build their future.

More than 2,500 people from 90 countries poured into Seoul in September 2017 for the 77th annual meeting of the International Pharmaceutical Federation (FIP, Fédération Internationale Pharmaceutique). With its theme of “The soul of pharmacy”, it had a strong philosophical thread, but there was also the usual packed daily programme of vivid reports, updates, and workshops showcasing the vision and the methods to achieve that transformation.

A rich agenda and stern parameters

Speakers presented information about new apps, film and video projects, adventurous graphics, and many other vital innovations. The chief at Google Health reminded everyone that attention spans were shrinking and that time available to grab attention on a digital device was now maybe as low as four seconds; three seconds the limit waiting for a website to load. Of 160,000 health apps available today, 36 account for around half of downloads, many of them quickly abandoned. There is current research to expand the reach of the four billion people not currently connected to the internet.

Healthcare, this man from the frontiers pointed out, does not compare well in terms of innovation and excitement with driving or online shopping, doctors and pharmacists are inevitably subject to unflattering comparisons.

Visionary pharmacists with soul clearly have an immense contribution to make in addressing multiple problems in all regions and countries of the world. The old paradigm of passive retailing and dispensing has to be transformed into dynamic, innovative, empathetic engagement with patients and communities, through mould-breaking technology and courageous personal effort. In Seoul, FIP was showcasing the vision and the methods to achieve that transformation.

The workshops were organised by the Centre of Regulatory Excellence (CoRE) at the Duke-NUS Medical School in Singapore. Part of CoRE’s mission is to establish regional platforms and networks that will help boost skills and enhance collaboration in the ASEAN and Asia-Pacific region. To that end, the group organised two-day pharmacovigilance training workshops in Laos and Cambodia.

The three main topics at the training sessions were protecting public health through pharmacovigilance, engaging stakeholders to improve adverse drug reaction (ADR) reporting, and risk management planning. The workshops began with an introductory presentation on the topic, followed by an interactive session where participants discussed the challenges they face and brainstormed solutions suited to their own settings.

The introductory presentation was given by Adena Lim, the deputy director of the Vigilance and Compliance Branch within the Health Sciences Authority (HSA) in Singapore. She emphasised the crucial role that pharmacovigilance plays in protecting public health, and gave an overview of the work that transformed Singapore’s ADR unit from the small operation it was when it started in 1993, to the multi-functional division it is today.

UMC’s pharmacovigilance officer Deliana Aboka next talked about best practices for engaging stakeholders in improving ADR reporting. She underlined the importance of reporting and its societal impact, and also the benefits of optimising the workflow of ADR-report collection.

The second day had a presentation by Dr Debrah, Christophe Delahaye, Board and Executive Committee member of the International Society of Pharmacovigilance (ISoP) and regional head of Pharmacovigilance Policy with Bayer. Dr Delahaye showcased a prototype mobile application designed as a risk-minimisation tool, offering information to the public on appropriate drug use, among other things.

The overall aim of the workshops was to strengthen the capacity of the national pharmacovigilance centres, promote policy innovation, and enable positive changes through raising awareness about the importance of drug safety and ADR reporting among healthcare professionals.

At the event held in Laos’s capital Vientiane, about 20 participants from the national pharmacovigilance centre and various public health programmes attended. The country has a population of almost 7 million and became a full member of the WHO Programme for International Drug Monitoring in 2015.

In Phnom Penh, Cambodia’s capital, the workshop was ceremonially opened by Dr Dr Vu Van, the director general for health of the Cambodian Ministry of Health. She addressed the 80 participants with emphasis on the important role they play in protecting the population’s health and she encouraged all to contribute to pharmacovigilance in their settings. Many of the attendees were medical doctors practising outside the capital.

The future of both countries lies in strengthening their pharmacovigilance structures and increasing their competence and capacity for analysing their own national data.

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FIP www.fip.org
Pier Health Resource Centres
www.phr.ca

FIP Centennial Declaration 2012
Pharmacists and pharmaceutical scientists accept responsibility and accountability for improving global health and patient health outcomes by designing, producing, distributing, and responsible use of medicines. Society can contribute to these objectives by supporting the advancement of pharmacy practice and the pharmaceutical sciences.

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Two days of medicines safety in Laos and Cambodia

Aiming to bolster pharmacovigilance competences in the Asian region, Singaporean CoRE invited UMC to take part in workshops on medicines safety in Laos and Cambodia in August 2017.

Pharmacists and pharmaceutical scientists accept responsibility and accountability for improving global health and patient health outcomes by designing, producing, distributing, and responsible use of medicines. Society can contribute to these objectives by supporting the advancement of pharmacy practice and the pharmaceutical sciences.

Learning
Dialogue

SUMMIT 2018: CARE FOR CANCER

At Uppsala Health Summit in Uppsala, Sweden on 14–15 June, international experts will gather to discuss how to provide better care for an increasing number of cancer patients and cancer survivors globally.

THANKS TO ADVANCES in treatment options, the chances of surviving cancer are better than ever before. However, cancer incidence is increasing and new forms of therapy are expensive. As a result, resource management and priority setting face major challenges. How can we ensure equitable access to diagnosis and treatment?

Each year, more than 8 million people worldwide die from cancer, and over 17 million people receive a cancer diagnosis. The number of new cases is projected to rise dramatically in the coming decades, especially in low- and middle-income countries, as a result of lifestyle factors such as smoking and poor diets, as well as chronic infectious disease. Already today, 70% of all cancer deaths occur in low-income countries where cancers are typically detected late and treatment options are few.

In May 2017, the World Health Assembly adopted a resolution on cancer, requesting member states to develop national cancer plans, including prevention, and access to screening, diagnosis, treatment, and care.

Uppsala Health Summit will bring together a broad spectrum of expertise in the cancer community from across the globe, including scientists, private sector representatives, healthcare professionals, NGOs, and policy-makers. The meeting aims to put in motion a constructive dialogue and identify proposals on how to implement opportunities from science and innovation for more equal therapeutic access and better patient outcomes globally.

“Prevention by promoting a healthy personal lifestyle and reducing harmful external exposure is of course extremely important, but can only solve part of the problem,” said Prof Lars Holmberg, Chairman of the Uppsala Health Summit Programme Committee.

“We also need to face the tough questions that arise with the fast-growing need for treatment and care. It’s time to agree on guidelines and priorities that reflect the recent scientific advances, for example the opportunities around data, and work out ways we can make them benefit the individual patient,” he said.

THE WORKSHOPS WILL address a broad set of critical topics, including biomarker development, precision medicine, drug repositioning, and how to prepare healthcare systems for more cancer survivors. The latter is the subject for the workshop prepared by a group led by Uppsala Monitoring Centre’s Dr Birgitta Grundmark, oncologist and a member of UMC’s research team.

“Worldwide, the number of cancer survivors is growing as access to efficient diagnostics and treatments improves. While this is a very positive trend, we also know that adverse effects both from the treatments and from the disease itself may appear later in life,” Dr Grundmark said.

“New Medicines and Vaccines: Monitor Safety and Ensure Access”

In the first episode of UMC’s podcast, Dr Chandler draws on the UHS workshop to discuss pharmacovigilance in public health emergencies, issues of real-time safety surveillance, and public trust.

“IWe need to prepare and improve national health systems’ handling of this. Experiences from childhood cancer survivors will form the starting point for the discussions in this workshop.”

“How we improve care and treatment for children living with cancer today is one of the cross-cutting issues that will be an integral part of each workshop, along with patient involvement, equal care and global perspectives.

“As always at Uppsala Health Summit, a plenary programme will guide and inspire the workshop dialogues. Confirmed speakers in plenary sessions include Dr Mariângela Simão, WHO assistant director-general for Drug Access, Vaccines and Pharmaceuticals; Prof Max Parkin of the Nuffield Department of Population Health, University of Oxford and the African Cancer Registry Network; and Prof Arnie Parashrumit of the Tata Memorial Centre, Mumbai.

UMC at Uppsala Health Summit 2017

Uppsala Monitoring Centre partnered with UHS for last year’s summit on the topic of “Tackling Infectious Disease Threats - Prevent, detect, respond with a One Health approach.” There, UMC’s Dr Rebecca Chandler hosted a workshop titled “New Medicines and Vaccines: Monitor Safety in Emergency Situations.”

UMC’s new podcast!

In the first episode of UMC’s podcast, Dr Chandler draws on the UHS workshops to discuss pharmacovigilance in public health emergencies, issues of real-time safety surveillance, and public trust.

www.soundcloud.com/uppsalamonitoringcentre

UPPSALA HEALTH SUMMIT 2018: CARE FOR CANCER

At Uppsala Health Summit in Uppsala, Sweden on 14–15 June, international experts will gather to discuss how to provide better care for an increasing number of cancer patients and cancer survivors globally.
MORE THAN 100 people in Belgium were prescribed slimming pills containing fang ji, a traditional Chinese medicine (TCM), in 1998. Severe nephropathy ensued, with most patients requiring dialysis. The clinic had dispensed the wrong product, unaware that ‘fang ji’ refers to TCM drugs derived from two different plants: Stephania tetrandra and Aristolochia fangchi. Subsequent reports demonstrated the same substitution had occurred in other countries. Ambiguity of herbal drug names is surprisingly widespread, the same ‘fang ji’ being associated with drugs derived from at least 18 plants with differing chemistries. Failing to deal with this ambiguity in labelling, regulation, and quality control clearly has serious health consequences.

Growing international use and trade in herbal products increases the urgency for professionals to address this issue. Pharmacovigilance professionals need accurate names for plant-based products to undertake effective signal analysis. Similarly, clinical trials must know which plant-derived drugs are taken by participants. Those writing monographs or framing regulations must be precise as to which plant is intended, and be aware of all its possible synonyms if they are to locate all relevant publications and adverse reaction records. Unambiguous labelling of plant materials and health records is the first step towards safer use and more effective authentication and quality control.

DIVERSITY OF MEDICINAL PLANTS

An astonishing number of medicinal plants are used worldwide, and international trade in herbal drugs and plant-based food supplements is growing. WHO estimated that the trade in TCM products alone was worth US$83 billion in 2012, and report that 90% of Germans use herbals. Although most formal healthcare systems continue to neglect them, a few countries are now integrating ‘traditional’ plant-based drugs into mainstream medicine, particularly to treat chronic conditions. Millions of people, especially in rural communities in parts of Africa, Asia and South America, nevertheless rely on traditional remedies for their primary healthcare needs.

Knowing exactly how many medicinal plants are used is complicated, as most plants are known by multiple names, causing double counting. In their 2017 State of the World’s Plants report, Kew Gardens, a botanical research institute managing global taxonomic references, provided a reliable lower limit of 28,187 medicinal species cited in approximately 150 major pharmacopoeias and medicinal references. This study also showed that only 16% of medicinal species are under regulatory control, despite the popularity of herbal remedies. Indeed, the number of species described within pharmacopoeias fell during the 20th century, with the Brazilian Pharmacopoeia, for example, citing 196 plants in 1926 but only 11 in 1996. Similar trends occur in European pharmacopoeias, despite recent inclusion of TCM plants. Why should this be? Several reasons exist. Some herbals simply fell out of favour as more targeted drugs became available. Gathering the scientific evidence required of modern monographs can also be a challenge when working with herbals, which are more complex than pharmaceutical drugs and consist of multiple chemicals with multiple potential targets. Nevertheless, such drugs often remain in widespread use despite their removal from pharmacopoeias.

“Inconsistent use of names for medicinal plants and plant-based drugs can have serious health consequences and impede efforts to analyse adverse reactions to herbal medicines. Kew Gardens’ Medicinal Plant Names Services enables scientific rigour in the regulation, coding, and use of herbals.”

“Only 16% of medicinal species are under regulatory control, despite the popularity of herbal remedies.”

Stephania tetrandra. A diuretic. Full scientific name: S. tetrandra S. Moore.

Aristolochia fangchi. Used to treat a number of conditions, but causing nephropathy when used at the concentration required of S. tetrandra. Full scientific name: A. fangchi Y.C.Wu ex L.D.Chow & S.M.Hwang.

Decocting pieces from A. cimicifuga. Photo: © Yulin Lin

Feature

Feature

Inconsistent use of names for medicinal plants and plant-based drugs can have serious health consequences and impede efforts to analyse adverse reactions to herbal medicines. Kew Gardens’ Medicinal Plant Names Services enables scientific rigour in the regulation, coding, and use of herbals.
THE PLANT-NAME JUNGLE

Plants and the drugs derived from them are referred to using common, pharmaceutical or scientific names. Common names like ‘ginger’ are part of everyday speech; they vary from place to place and their meanings may change over time. A plant called ‘yarrow’ in some places is referred to as ‘maidenhair’ or ‘sowbread’ elsewhere (synonyms). A name like ‘bluebell’ may refer to one species in England and another in Scotland (homonyms). The multiplicity of names and their inconsistent use across countries and disciplines cause considerable confusion.

Pharmacopoeias offer detailed technical descriptions of how to prepare herbal drugs and should be precise about which plant to use. Sadly, this is not always the case. Some pharmacopoeias use common names, and many others employ pharmaceutical names—often confusingly written in Latin—indicating the plant part or the preparation to be used (e.g. ginseng radix rubra). Pharmaceutical names are under no formal control and are often confusingly written in Latin—indicating the plant part or the preparation to be used (e.g. ginseng radix rubra).

The multiplicity of names is a problem for everyone, including patients, who might use the wrong plant, for example, or the preparation to be used (e.g. ginseng radix rubra). Pharmaceutical names are often confusingly written in Latin—indicating the plant part or the preparation to be used (e.g. ginseng radix rubra).

THE SOLUTION

New’s Medicinal Plant Names Services (MPNS) addressed this confusion by capturing all pharmaceutical, common and scientific names employed for herbal drugs in 150 major medical references, regulatory data sets and pharmacopoeias. Each name was mapped to Kew’s botanical references to extract the current scientific name and all synonyms for each plant. MPNS can thus reliably count species and make links to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other.

Overall, MPNS is facilitating effective international collaboration between Kew and Uppsala Monitoring Centre was reinvigorated by MPNS. For each of the approximately 4,000 different scientific plant names in the WHODrug dictionary, MPNS provided spelling corrections, the family name and the currently preferred scientific name and synonyms. This highlighted plants stored within VigiBase, the WHO global database of individual case safety reports, for herbal drugs in 150 major medical references, regulatory data sets and pharmacopoeias. Each name was mapped to Kew’s botanical references to extract the current scientific name and all synonyms for each plant. MPNS can thus reliably count species and make links to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other. The automatic validation saved effort, whilst increasing integrity and currency of plant data under multiple names, and enabled these to be linked to each other.
Feature

Oman takes steps towards safer herbal medicines

In September 2017, a workshop on the regulation of herbal medicines was held in Oman. The event aimed to enhance herbovigilance measures in the country, to ensure safe, effective and good-quality herbal products on the Omani market.

"The Oman Ministry of Health has become concerned with the use of herbal remedies and recognised the need for herbovigilance."
BETTER SIGNAL DETECTION WITH VIGIRANK

By factoring in the content and quality – not just the quantity – of adverse drug reaction reports, UMC’s vigiRank algorithm reliably flags potential signals for further investigation.

SIGNAL DETECTION is at the core of Uppsala Monitoring Centre’s mission, and scientific development in this area remains one of the organisation’s hallmarks. The most recent UMC contribution to statistical signal detection in pharmacovigilance is vigiRank. Developed in 2014, vigiRank is a statistical method whose primary function is to help prioritise drug–adverse reaction pairs (or drug–drug–adverse reaction triplets) before manual clinical assessment. At UMC, such automatic first-pass screening of data in VigiBase, the WHO global database of individual case safety reports, was previously driven by disproportionality analysis – specifically, by one of its four common measures, the Information Component (IC). A large number of organisations worldwide employ disproportionality analysis for this purpose.

The major limitation, however, is that disproportionality relies solely on reporting frequencies: it counts reports for a given drug–adverse reaction pair, and compares that to an expected number. In contrast, vigiRank considers also the content of individual reports, and so better resembles the clinical assessment it is intended to support. For each drug–adverse reaction pair, vigiRank assesses five strength-of-evidence components: completeness, recency, disproportionality, availability of case narratives, and geographical spread. Moreover, while disproportionality analysis works as a hard filter – returning an unranked selection of drug–adverse reaction pairs to assess clinically – vigiRank provides a priority listing that can be followed from the top down, as far as resources permit.

When vigiRank was developed, its performance was first evaluated on a set of unranked selection of drug–adverse reaction pairs to assess clinically – vigiRank provides a priority listing that can be followed from the top down, as far as resources permit.

In a study published in Pharmacoepidemiology and Drug Safety in August 2017, the UMC research team compared the first batch of drug–adverse reaction pairs prioritised by vigiRank in 2014, to an earlier dataset from the era of disproportionality analysis, selected with the same criteria. Of all the drug–adverse reaction pairs that were assessed, about 3% of those flagged by vigiRank turned out to be signals, compared to a mere 1% of those selected with the IC alone. In other words, vigiRank is more efficient than disproportionality alone at flagging potential signals in VigiBase. As a natural but improved successor of disproportionality, vigiRank remains the fundament of automatic prioritisation in UMC’s routine signal detection operations before clinical assessment. Reports or drug–adverse reaction pairs can be arbitrarily filtered to focus on specific subsets, and this is what UMC regularly does in its so-called ‘signal detection sprints’. Previous sprints have focused, for example, on paediatric drugs, vaccines, patient reports, and regions of interest (Africa, Asia, Latin America). So far, vigiRank has not been routinely available outside UMC. However, the algorithm is described in detail in a freely accessible scientific publication. The current implementation is tailored to VigiBase, and use in another database may require adaptations. UMC continuously strives to improve its services to the pharmacovigilance community, particularly for members of the WHO Programme for International Drug Monitoring. Concrete plans to increase support to local signal detection efforts within VigiLyze – UMC’s search and analysis tool for VigiBase – are now taking shape, and there may be a role there for vigiRank. UMC hopes member countries will join in this exciting development.

How does vigiRank work?

For each drug–adverse reaction pair, vigiRank computes a score based on these five components (in order of importance). The higher the score, the more likely the pair is to constitute a safety signal.

1. Completeness
   How many informative reports are there for the drug–adverse reaction pair? This is calculated with UMC’s Information Component (IC) measure of disproportionality.

2. Recency
   How many reports for this drug–adverse reaction pair were submitted in the last three years?

3. Disproportionality
   Has the drug–adverse reaction pair been reported more often than expected? This is calculated with the Information Component (IC) measure of disproportionality.

4. Case narratives
   How many reports contain free-text case narratives?

5. Geographical spread
   How many countries have reported this drug–adverse reaction pair?
Brazilian hospital’s early action system prevents medication errors

At the Hospital Estadual Sumaré, extra safety measures have been established to avoid medication errors, and an ME-prevention method based on the principles of signal detection is being investigated.

“HES staff are studying whether the methodology used to conduct signal detection in pharmaco-vigilance could be used for ‘signal detection’ to prevent medication errors in hospitals.”

The Hospital Estadual Sumaré (HES) is one of the hospitals of the University of Campinas (Unicamp), a public university in the state of São Paulo, Brazil. The hospital was opened in September 2000, and it is an important centre for education and in-service training for students from the School of Medical Sciences.

HES was the first public hospital in Brazil to be certified with a higher grade in the Brazilian accreditation system for healthcare units, and the first hospital outside of the state capitals to be certified by the healthcare standards organisation Accreditation Canada, again at a higher level. Quality management is an important part of the hospital’s institutional culture. Following a recommendation by the regulatory authority of São Paulo, a pharmacovigilance commission was established in 2003 at the hospital, formed by a physician, a nurse, and a pharmacist. From the beginning, medication errors (MEs) were recognised as a specific issue that must be assessed separately from notifications related to suspected adverse drug reactions. Thus, several policies have been developed over the years, in order to reduce MEs at the hospital.

For each phase of the medicine-handling process – starting with purchase of products, through storage, prescription, drug dispensing from pharmacists, and finally drug administration – there are certain actions and safety measures that must be taken. For example, the qualification of suppliers is checked at the purchasing phase; ‘high alert’ drugs such as adrenaline and anesthetics are marked with a red label in the storage phase, and medicines are also sorted in a colour scheme by expiration date; the prescription phase calls for the use of standard prescriptions made according to medical protocols; and so on.

One action in particular should be highlighted: the prescription system for antimicrobial prophylaxis in surgery. There is a prescription protocol, but the physicians’ rate of compliance with it was low – less than 50% – until 2011. The problem was that they were asked to prescribe using the drug name, but as doctors usually work in two or more hospitals and each institution has its own protocol, inconsistencies occurred. At HES, a system was created where the physicians should prescribe the name of the medical procedure instead, for example cholecystectomy, which resulted in 100% compliance with the protocol.

Two years ago, staff at HES discussed the introduction of a method to identify a risk and take early action to prevent MEs. This question is relevant because the assessment of the database is usually done by analysing the most frequent events. Focusing on this point, a pilot study was conducted, which became a research project.

In this project – which is still ongoing – HES staff are studying whether the methodology used to conduct signal detection in pharmaco-vigilance could be used for ‘signal detection’ to prevent medication errors in hospitals. To apply this methodology, all adverse events of one sector, e.g. the internal medicine ward, are compared with all adverse events of the other sectors. The pilot study was undertaken in 2015 on data collected between 2013–2014 and it was possible to identify a ‘signal’ for MEs. Now this methodology is promoted at HES using a database with more than 5,400 adverse events, excluding suspected adverse drug reactions, reported since January 2008. If the validity of this process can be proved, HES will start a prospective study.

Mauricio Perroud
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At the Hospital Estadual Sumaré, extra safety measures have been established to avoid medication errors, and an ME-prevention method based on the principles of signal detection is being investigated.
For the last 14 years, pharmacovigilance specialists across the Americas have been gathering annually to share the latest in drug safety. Here is how the 2017 event unfolded.

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Living with complexity
and big data

In causal dispositionalism, the characteristics of both medicines and patients are considered when estimating probable beneficial or adverse outcomes of treatments. In this article, Prof Ralph Edwards discusses how this approach can be applied to causality in pharmacovigilance.

**IN "THE PHILOSOPHY OF COMPLEXITY"**, author Chris Lucas writes that as a system “the parts are regarded as evolving in conjunction with each other in order to fit into a wider system environment, thus fitness must be measured in contextual terms as a dynamic fitness for the current niche, and not in relation to any imposed static function. The part structure will correlate to an external environment (giving a contextual fitness by structural coupling). This dependence upon environment contrasts with the isolated treatments of conventional science.”

Furthermore, he writes: “We have a considerable bias towards simplication and in many situations will reduce a complex multidimensional issue to a one-dimensional form more conducive to an either/or decision. Complexity changes the possibilities of recognising the situations where this is invalid and to providing an alternative form of treatment that can better deal with these problems – the philosophy of complexity.”

Therefore, in the different approaches to causal inference in pharmacovigilence is causal dispositionalism, and is applicable to complex data. This approach considers the dynamic, changeable nature (the dispositional) of both the medicinal product and the exposed patient – some properties, state, or condition that, under certain circumstances, gives the possibility of some further specific state or behavior. The relevant properties of the medicine would include its various pharmacological actions (pharmacodynamics, its distribution in the body (pharmacokinetics), and its interactions with other drugs. The relevant properties of the patient would include specific susceptibilities, such as genetics, age, sex, physiological state such as body weight or pregnancy, co-morbidities, drug–drug interactions, and social and environmental factors that have affected the patient.

Consider a medication M, with a set of dispositions, M[d1], M[d2], and so on, known to be able to cause benefits and harms, and a patient P with dispositions P[d1], P[d2], and so on. We may then begin to investigate the probabilities that any M[d] will produce beneficial or adverse outcomes in a patient with any P[d], asking the questions ‘how?’, ‘why?’ and ‘when?’; using wherever information we have about the medicine M and the patient P to determine the benefit to harm balance.

This type of analysis is not merely probabilistic, but takes into account the strengths – the power of M to affect P, as well as any outside factor that interacts with the causal link, e.g. drug-drug interactions. It also explicitly takes into account the power of P to respond to M. A disposition may be present but not become manifest until its power reaches a particular threshold, e.g. there is a certain amount of doses necessary for a medication, in combination with, for example, a certain degree of renal function impairment necessary to produce a result. Alternately, a medicine with disposition M may have minimal effects in patient P if the medication is taken in a lower dosage than could have been effective. Patients P may have partial or maximal effects in other cases, e.g. if the patient P has the disposition of Pi, but only if certain conditions are met. Disposition dB and dP tend to result in an additional influence, such as might occur when an external factor modifies what happens when a susceptible patient is dehydrated.

TIME COURSES of factors can also be included in this type of analysis, Matthew L. L. M. L. D. M has discussed the use of this approach in the diagnosis and management of a patient with back pain in a paper published last year in the British Journal of Clinical Practice. The Austin Bradford Hill observations on causation have been re-evaluated more broadly by Kristen Fedak et al. in the journal Emerging Themes in Epidemiology, and some of them can be interpreted in a dispositional way. We need to be able to relate them to real-life data. A. C. L. A. C. L. Lucraft wrote: “Breaking away from the constraints of old-style scientific axioms (which nevertheless remain valid within their limited domains) allows us to explore an organic world that until now has been difficult to understand as a whole. In such high-dimensional (multivalued) systems, reductionist thinking proves inadequate, isolated single-dimensional results do not predict real system behaviors. The co-evolutionary or epistatic nature of inter-related systems requires us to take a contextual approach, studying the dynamics of interactions rather than the static makeup of parts studied in more conventional science.”

Let’s be very broad-minded about what new value we can find in the multiplicity of big real-life data sets we can use to examine benefit and risk and thereby improve therapy.

Ralph Edwards
Senior Medical Advisor,
Uppsala Monitoring Centre

Uppsala Monitoring Centre teamed up with medicine regulatory authorities in 27 countries to launch a social media awareness campaign on the importance of reporting adverse drug reactions.

In November 2017, 27 countries across Europe, Latin America and Australasia ran a coordinated social media campaign to promote recognition and reporting of suspected adverse drug reactions (ADRs). The campaign formed part of the second ADR awareness week, and emerged from the Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action project, whose first EU-wide awareness campaign ran in November 2016. The initiative was led by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK and Uppsala Monitoring Centre.

The objective of the campaign was to raise awareness among health professionals and patients about the importance of reporting suspected ADRs to their national pharmacovigilance centre. Regulators rely on ADR reporting to make sure medicines on the market are acceptably safe. Unfortunately, all reporting systems suffer from under-reporting, and the campaign was important to help strengthen the system.

“Our mandate as regulatory agencies is to promote awareness and health literacy among patients, to remind them to use drugs in the most appropriate and responsible way,” said Mario Melazzini, director general of the Italian Medicines Agency (AIFA). “At the same time, we are providing patients with the right tools to play an active role in post-marketing surveillance of medicines. This is a universal mandate for all institutions in the health sector, and cooperation at the European level is crucial to disseminate and give greater resonance to key messages on these topics.”

CAMPAIGN MATERIALS included a light-hearted and amusing series of animations produced by UMC, featuring funny cartoon characters whose unfortunate misuse of medicines leads to comical calamities.

“Humour and memorable characters are powerful storytelling elements that help question current behaviours and develop new, healthier ones,” said Paula Alvarado, head of Global Communications at UMC.

“We believe in pushing the boundaries of health communications to engage a wider audience and promote change. Our efforts should not only raise awareness – that is not enough – but inspire people to take the step from awareness to action.”

The short animations were adapted for use in 19 European countries and New Zealand. Each country-specific version featured text in the local language, the logo of the medicine regulatory authority and a link to the national ADR reporting system. Seven additional countries supported the campaign by sharing non-tailored versions of the animations on their social media channels. Overall, the messages reached 2.3 million people on Twitter, Facebook, LinkedIn and YouTube, and resulted in 1,852 new ADR reports during the campaign week, an increase of 11% compared to the two months preceding and following the campaign.

“The eye-catching social media campaign helped us raise awareness of the importance of ADR reporting among young people, who are challenging to reach otherwise,” said Svens Henkuzens, director of the State Agency of Medicines of the Republic of Latvia (ZVA). “This is a contribution to drug safety not only during the campaign, but also in the long term.”

“Our efforts should not only raise awareness, but inspire people to take the step from awareness to action.”
In brief

Annie & Mac travel to Haiti

UMC’s comic book pilot Annie & Mac’s Adventures was run in two schools in Haiti – children can’t wait for the final version to be released in spring!

Visitors from Morocco

Dr Latifa Ait Moussa and Afaf El Rherbi from the WHO Collaborating Centre in Rabat, Morocco (seated, centre), visited UMC in November 2017. They spoke to UMC staff to learn about our work, and explained how the Moroccan centre operates to build pharmacovigilance capacity in francophone and Arabic countries.

In brief

Former UMC student Maarten van Eijk gets Meyler Prize

Maarten van Eijk, pharmacy student of Utrecht University who spent several months at UMC in 2017, was awarded the Meyler Prize for his Master’s thesis ‘Immunosuppressive antibodies and progressive multifocal leukoencephalopathy (PML): key reporting features and proposed search algorithm’. Congratulations Maarten!

New WHO PIDM members

Chad, Paraguay and Azerbaijan joined the WHO Programme for International Drug Monitoring as the 128th, 129th and 130th full members in January 2018. Papua New Guinea joined as the 131st full member in March 2018.

The 5th ISoP-UMC training took place in wintry Shenyang, China, in January. Over two days, 53 participants from Chinese regulatory, medical, and academic institutions learned about active surveillance, signal detection, and pharmacovigilance inspection.

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In brief

Join the conversation on social media!

In Memoriam

Dr Ana Maria Corrêa Nunes
(1947-2018)

IT IS WITH GREAT SADNESS that I write on the passing of our colleague and friend Dr Ana Maria Corrêa Nunes, on 24 December 2017. Ana obtained her medical degree in Lisbon in 1972 and specialised in internal medicine and cardiology. After a few years of clinical work, she moved to the pharmaceutical industry and later to INFARMED, the Portuguese national medicines authority. But Ana’s work went beyond the borders of Portugal.

I met Ana during her sabbatical in Uppsala in 1998 when she was working on the process of generating signals from international data. I had recently started a new job in the pharmacovigilance department of a company in Uppsala, and our meeting became the beginning of years of friendship, and sharing of knowledge and ideas. Ana later became a member of the UMC signal review panel.

Ana was the first secretary-general of the International Society of Pharmacovigilance (ISoP), and many of us know her from ISoP and then ISoP, and will treasure fond memories from those conferences. In 2005, Ana became a member of the Committee for Orphan Drugs at the European Medicines Agency, and a few years later she joined the ENC-PP Steering Group.

Ana was devoted to her work, determined to do what was right, and improve the life of patients. However, she always found time for friends and family. She had great integrity and was very caring, and with a good sense of humour. Ana loved the arts, opera, fado, orchids and everything that was beautiful. She also became an expert in decorating cakes with sugar art.

It was a privilege for me to have been a part of Ana’s life, which ended much too early. She passed away from a rare disease for which there is as yet no cure. Ana wanted us all to continue to improve pharmacovigilance and contribute to development of new treatments.

Christina Ström Möller
Pharmacovigilance Meetings 2018

2–4 May 2018
Medical Aspects of Adverse Drug Reactions
Fareham, UK
Drug Safety Research Unit
www.dsru.org
@DSRUDrugSafety

15–16 May 2018
Signal Detection and Regulatory Expectations
London, UK
Management Forum Ltd
www.management-forum.co.uk

16–17 May 2018
Periodic Safety Reports: PSURs and PBRERs
Fareham, UK
Drug Safety Research Unit
www.dsru.org
@DSRUDrugSafety

21 May–1 June 2018
20th International Pharmacovigilance Training Course
Uppsala, Sweden
Uppsala Monitoring Centre
www.who-umc.org
@UMCGlobalSafety

4–22 June 2018
Pharmacovigilance Fellowship
Accra, Ghana
African Collaborating Centre for Pharmacovigilance
www.acc-afro.org

5–6 June 2018
Pharmacovigilance Conference
London, UK
Drug Information Association
www.diaglobal.com
@DrugInfoAssn

12–14 June 2018
Le congrès SFPT 2018
Toulouse, France
Société Française de Pharmacologie et de Thérapeutique
www.pharmacol-fr.org

19–21 June 2018
Pharmacovigilance
London, UK
Management Forum Ltd
www.management-forum.co.uk

20–21 June 2018
Big Data in Pharmacovigilance
London, UK
Drug Safety Research Unit
www.dsru.org
@DSRUDrugSafety

4–5 July 2018
Medication Errors
London, UK
Drug Safety Research Unit
www.dsru.org
@DSRUDrugSafety

22–26 August 2018
34th International Conference on Pharmacoepidemiology & Therapeutic Risk Management
Prague, Czech Republic
International Society for Pharmacoepidemiology
www.pharmacoepi.org

5–6 September 2018
Back to Basics in Pharmacovigilance
Fareham, UK
Drug Safety Research Unit
www.dsru.org
@DSRUDrugSafety

24–26 September 2018
6th ISoP–UMC Joint Pharmacovigilance Training Course
Guayaquil, Ecuador
International Society of Pharmacovigilance & Uppsala Monitoring Centre
www.isopenline.org
@ISoPonline

11–14 November 2018
ISoP 2018 Annual Meeting
Geneva, Switzerland
International Society of Pharmacovigilance
www.isop2018geneva.org
@ISoPonline

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www.facebook.com/UppsalaMonitoringCentre
www.twitter.com/UMCGlobalSafety
www.youtube.com/c/UppsalaMonitoringCentre

Uppsala Monitoring Centre (UMC) is an independent non-profit foundation and centre for international service and scientific research. Our vision is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines. Our mission is to support and promote patient safety through effective global pharmacovigilance practise.