EuroDURG bulletin

No. 24 **January 2014**

NEWSLETTER OF THE EUROPEAN CHAPTER OF THE SPECIAL INTEREST GROUP OF DRUG UTILSATION RESEARCH (SIG-DUR) OF THE INTERNATIONAL SOCIETY OF PHARMACOEPIDEMIOLOGY (ISPE)

Editors. *This issue was prepared by the indicated members of the EuroDURG board and the DUR/HSR SIG chair. See also contributors on behalf of national groups. Send reactions to: benkoria@gmail.com*

The Chair's message

Dear European drug utilization researchers,

Happy New 2014!

Hundred years ago, most European countries were involved in one of greatest disasters in modern times, the First World War. Few drugs were available at that time to treat all those who suffered. However, it is important to recognize that some researchers were still active, and in 1914, a number of important discoveries were made:

- the Belgian surgeon Albert Hustin made the first successful non-direct blood transfusion, using anticoagulants.

- John Joly developed a method of extracting radium and applied it in radiotherapy.

- Edward Calvin Kendall isolated thyroxine

- Oxymorphone was developed in Germany

Still, few people had any knowledge about drug utilization and it would take several years until the European Drug Utilization research group was formed bringing together researchers from different parts of Europe interested in improving the use of medicines...

Sometimes it is good to look back and realize how much that has happened over the years and how many people we ought to thank for the development we have seen in the world and in our discipline.

Today there is no war in Europe and large numbers of new drugs have markedly decreased mortality and morbidity as well as improved the quality of life for millions of people. Still, there are lots of challenges which have been nicely presented in the WHO Priority Medicines report that was updated last summer. Consequently, there is an ever increasing need for Drug Utilization Research.

In 2014, we can look forward to an inspiring year with the conference in Groningen and a new handbook as the key highlights.

You find more information about them in this bulletin. During 2013, most of the energy in EuroDURG has been concentrated on the planning of these two events. Several telephone meetings and planning sessions have been held with the board but also involving other DU researchers in Europe and the rest of the world.

Since there was no general assembly in 2013, we have had the same board for EuroDURG in 2014 as in 2013:

Bjorn Wettermark (Sweden) – chair
Ria Benko (Hungary) – secretary
Brian Godman (UK) – treasurer
Elisabetta Poluzzi (Italy) – webmaster
Robert Vander Stichele (Belgium) – liason with ISPE

Continued at next page

Monique Elseviers (Belgium)
Vera Vlahović-Palčevski (Croatia)
Begler Begovic (Bosnia and Herzegovina)
Marion Bennie (Scotland)
Janet Krska (England)
Katja Taxis (The Netherlands)
Annabirna Almarsdottir (Denmark)

I particularly want to thank all of you for the active participation and engagement in all, sometimes rather chaotic, telephone meetings and all work that has been made in between.

During 2013, there was no specific Drug utilization conference in Europe but our society has been active in many other conferences including the 29th ISPE conference in Montreal, Canada, the 11th EACPT-conference in Geneva, Switzerland, the 16th ESPACOMP in Budapest, Hungary and the 8th CEESTAHC Symposium on Evidence-Based Health Care in Warsaw, Poland. Since drug utilisation is an eclectic discipline with linkage to many other scientific areas, participation in these events is important for learning as well as spreading the ideas and concepts of DUR. Reports of these meeting are found in the bulletin.

During 2013, many of us have also had the pleasure to travel outside Europe to meet colleagues in other continents. I had the opportunity for the first time to visit Latin America visiting a seminar called "Pharmacoepidemi -ology Research in Latin America" in Rio de Janeiro, Brazil, in April. This was followed by the X International Meeting of Pharmacovigilance in Barranquila ,Colombia in November. Both these events made strong impressions. A lot of interesting discussions were held with many inspiring colleagues and concrete collaboration has now been established between Europe and some Latin American countries building up systems for cross national comparisons of drug utilization. More of this will be presented during the year.
As a whole it has been an interesting year and I would like to thank all our members for paying interest in our activities. I also look forward to see you at the conference in Groningen in August!

Björn Wettermark
Chair of EuroDURG
European chapter of SIGDUR

Communication with DU researchers

As you may have experienced, the webpage of ISPE has been renewed last year. EuroDURG website is still available at: www.pharmacoepi.org/eurodurg/

We have a new contact person at ISPE (Philip Joseph) who is responsible to upload news to our webpage. Presently we continuously work on updating different contents. We welcome any ideas regarding the website. Please send your reactions to: **elisabetta.poluzzi@unibo.it**

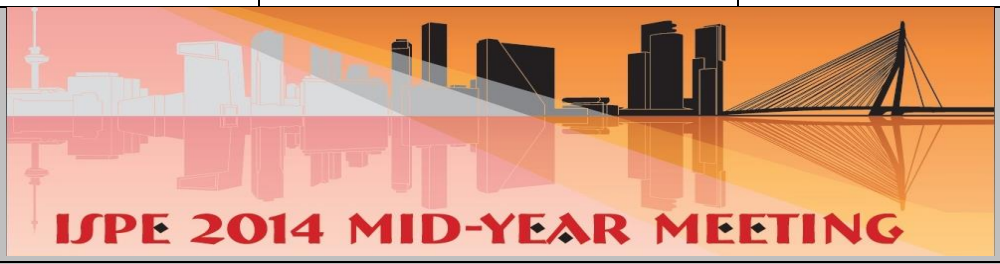
The EuroDURG ExCO has continued to directly inform individual DU researchers about important events. Moreover we asked national contact points and/or national chairs to distribute news within their own country. We involved DURs in the decision making as the scientific program of the Groningen conference has been driven by the result of the related questionnaire.
If you would like to join our group please visit the link you find in the box below. Please encourage students and those new in the field to do so!

Register as a DUR at:

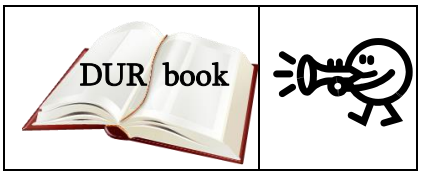
http://spreadsheets.google.com/viewform?formkey=dE9oeG94dHFwODFDUVhmUmlmakh1M2c6MA

It takes only 5 minutes!

Ria Benko



April 5-8, 2014; Rotterdam, The Netherlands



The DUR book: a challenging EuroDURG mission for 2014!

Great news! EuroDURG took the initiative to start the preparation of a book entitled:

"*Drug Utilization Research: Methods and Applications*"

Although the field of DUR was confronted with an enormous expansion during the last decade, we considered the available methodological information incomplete, fragmented and outdated. We started thinking about a complete handbook including methodological issues as well as applied DUR activities.
Rather than limiting the work to an overview of the specific DUR methodology, it is our intention to offer also a complete overview of the different applications of DUR, ranging from comparative research over DU in specific areas and populations to DUR applications in the broader field of pharmacoepidemiology and the assessment of the quality of prescribing.

The DUR book will be a useful educational tool for teachers and students and a basic reference guide for researchers and DUR users (health authorities, policy makers, etc), interested in the assessment of drug utilization, the rationale use of available medications and the improvement of the quality of prescribing.

The intense collaboration between the twelve members of the editorial board (including all EuroDURG ExCo members) during more than one year resulted in a final outline of the book content and an assignment of authors for each chapter. By now, dedicated authors in the different areas of DUR from all over the world are working out their contribution for the DUR book. An advisory board of DUR experts commented and approved the content of the book and will review the different chapters during the coming months. The writing process will be finalized in June and Wiley will take care about the publication. The DUR book will be launched by the end of 2014.

Further details will be communicated in our next Bulletin.

Monique Elseviers

Future of the ATC/DDD classification in DUR

With the advent of e-Health platforms in most developed countries in Europe and in the US, fundamental changes occur in the choice of terminologies that support medical registration.

Traditional use of the World Health Organisation Family of Classifications is under pressure. The classification of mortality and morbidity, the International Classification of Diseases (ICD), is causing confusion with unclear updates with unequal pick up for ICD-9, ICD10-CM, and upcoming ICD11.

The international Classification for Primary Care (ICPC) has been used widely for medical registration in primary care and for epidemiological research in sentinel practices, but without much support of governments and health administrations. The use of the Anatomical Therapeutic Chemical Classification and the Defined Daily Dose methodology has been successful in international projects such as the European Surveillance of Antibiotic Consumption (ESAC) and in yearbooks of individual countries describing the consumption of drugs in their countries. Currently, many Electronic Health Record systems and decision support systems rely heavily on these classifications to operate.

Recently, the UK National Health Service, the US Meaningful Use program, and the European Commission heavily promote the use of Systematized Nomenclature of Medicines – Clinical Terms (SNOMED-CT) as a one-in-all solution for medical registration.

For the WHO classification to stand a chance at survival, additional efforts will be needed to promote these classifications, to assure mapping with SNOMED, to assure multilingual management, to organise updates, and to embrace the semantic web technologies of the future.

A formal comparison of how drugs are classified in medication groups in ATC and in SNOMED-CT is urgently needed, to be able to evaluate the value of this classification and reference terminology for drug information and for epidemiological research.

Robert Vander Stichele

Conferences meetings

…Previous events

ICPE 2013

General summary

2013 saw yet another successful International Conference on Pharmacoepidemiology and Therapeutic Risk management (ICPE). The 29th ICPE meeting was held in the beautiful Canadian city of Montreal with delegates from around the world attending.

Keynote: Two solitudes: Are we talking to each other.

They keynote opening session comprised a debate on the neglected half of pharmacoepidemiology pharmaco -logy (JaquesLeLorier) or epidemiology (Bernard Begaud). Tom MacDonald (chair) embraced new technology to include the audience, not only as listeners, but with the use of a smartphone voting application, as participants within the discussion.

One of the highlights of the 29th ICPE was the focus on the patient and their role in pharmaco-epidemiology. Two plenary sessions stood out in the program in terms of bringing the patients' voice forward, especially in the risk benefit assessment.

Plenary: Risk Assessment to guide treatment - The case of natalizumab (Tysabri) and Progressive Multifocal Leukoencephalopathy (PML).

This session presented three different perspectives on one of the current challenges faced by pharmacoepidemiology. Gary Bloomgren spoke from the industry perspective about multiple sclerosis (MS), the history of treating MS with immunosuppresants and the risks, especially JC virus status, that have emerged associated with the use of natalizumab over the past 2 years, the industry perspective of a drug with the potential to improve quality of life for multiple sclerosis (MS) patients, yet which is limited by a serious adverse effect.

Stella Blackburn spoke of the challenge that natalizumab and PML continues to bring to the regulatory world. Regulators focus on ensuring that the patient benefits of any medication outweigh the risks of harm associated with its use, yet the natalizumab case continues to challenge this with great benefits to patients but equally great risk to a sub group of patients and that despite strategies to identify those at greatest risk and miminise harms the risk/benefit balance continues to challenge the regulatory world.

Ryan Kaplan, a MS patient spoke eloquently about the impact of multiple sclerosis and natalizumab on his life. He discussed his decision to start natalizumab following a relapse while on interferon 1beta. Ryan spoke of his interpretation of his risk of PML while on natalizumab and the impact the risk of PML had on his decision to start treatment. It was a strong reminder that as scientists, health professionals and regulators it is our role to present information regarding risk but that the ultimate decision regarding treatment rests with the patient.

Plenary: The patient's voice in benefit and risk

This session explored on international efforts to include the patient perspective in the risk benefit assessment. In this session the focus was on collection and use of patient reported outcomes (PROs) and how technology can be used to include the patient perspective in risk benefit assessment.

Ethan Basch presented his work on how the patient perspective of oncology-related adverse events differs from that from health professionals and in particular spoke about the difference in impact of adverse reactions perceived by health professionals with the actual impact reported by patients. Health professionals tended to underestimate the impact of almost all medication related problems when compared to the patients experiencing the problems.

Nabarun Dasgupta spoke of developments in using social media reports to identify adverse events (AE) as well as the development of smartphone applications to facilitate collection of AE reports at the FDA. John Ware presented methods for validating and evaluating PRO reports, while Neil Minkoff looked at how we can combine patient reported outcomes data with electronic medical records data to provide a more holistic view of the patient experience. The session concluded with a discussion by Nancy Santella and Til Sturmer.

Lisa Pont

SIGDUR NEWS

Drug utilization / Health Service research Special Interest group.

It was good to see a focus on drug utilization research throughout the Montreal conference.

Pre-conference education

The Drug Utilization Research/ Health Services Research Special Interest group (DUR/HSR SIG) held two pre-conference workshops, Introduction to Drug Utilization Research (Faculty: Lisa Pont, Hanne Strom, Morten Andersen and Julie Zito) and Advanced Drug Utilization Research (Faculty: Libby Roughead, Petra Denig, Colin Dormuth and Jerry Avorn). These sessions were well received with over 170 participants in the two courses. Thank you to all Faculty members for the time and enthusiasm.

DUR/HSR SIG meeting

Approximately 40 conferences delegates attended the DUR/HSR SIG meeting during the conference. Reports from our regional networks around the globe show a strong international presence in drug utilization research.

It is also fantastic to be able to welcome our Latin American drug utilization research colleagues to the SIG with Marcela Jiron taking the role of Latin American Network Liaison.

The 2013/14 DUR/HSR Steering committee comprises:

Executive Committee

Chair: Lisa Pont(Australia)

Past Chair: Morten Andersen (Sweden)

Chair Elect: Katja Taxis (Netherlands)

Educational Program: Douglas Steinke (UK) & Andy Gilbert (Australia)

Communications and web liaison: Gillian Caughey (Australia)

Regional network liaison

EURODURG (Björn Wettermark-Chair)

MURA (Lisa Pont–Chair)

NORTH AMERICA (Julie Zito& Ingrid Sketris)

AFRICA (IlseTruter-confirmed in advance)

LATIN AMERICA (Marcela Jiron)

Lisa Pont

Report on the 16th ESPACOMP meeting

ESPACOMP is the European Society for patients' adherence, compliance and persistence. The 17th ESPACOMP Annual Meeting took place in Budapest, 15 -16 November 2013, with 127 participants out of 18 different countries. Most participants came from Belgium, the Netherlands and Sweden. They sent in a total of 123 abstracts selected for oral or poster presentation.

Prior to the ESPACOMP scientific meeting, a one-day pre-conference educational day was organized with two parallel sessions in the morning, one focusing on statistical methods for longitudinal analysis of adherence data and the other dedicated to patient adherence problems in Central and East European Countries. In the afternoon, medication adherence interventions were presented, translating the state-of-the-art evidence into daily clinical practice.

The scientific meeting offered a mix of key lectures, selected abstract presentations, and a poster session of selected abstracts. Robert Vander Stichele opened the meeting with the traditional Jean Métry lecture handling measurement and determinats of the three elements

30th Anniversary ICPE: 24-27 OCTOBER 2014, TAIPEI, TAIWAN
Submit your abstract before February 15, 2014 11:59 pm

of patient adherence to medications: initiation, implementation, and dis-continuation. Further plenary sessions focused on (1) international initiatives towards adherence-related quality/performance metrics, (2) efficacy and effectiveness of medication adherence interventions, (3) use of claims databases or electronic medical records in adherence research and (4) adherence management through integra-ted e-health approaches.

Monique Elseviers

Report on the 11th EACPT Congress

The last congress of the European Association for Clinical Pharmacology and Therapeutics took place in Geneva in August, 2013.

The congress brought together a wide range of international delegates, including health professionals, clinical and life scientists, policy makers, professionals from biotechnology and pharmaceutical communities and others interested in the spectrum from basic to clinical pharmacology and pharmacotherapy, and from drug discovery to regulatory affairs.

Almost 600 delegates attended the congress, although it was hoped for 900. There were 101 invited speakers from 21 countries - 15 from the European region and a further 6 countries internationally, from the USA, Canada, New Zealand, China, Benin and India. Around 400 abstracts from 57 countries from all 5 continents were presented as oral and poster communications. During the three and a half fruitful days sessions were held in three parallel rooms covering topics in pharmacogenetics, patient perspectives, clinical toxicology, clinical trials, prenatal pharmacology, health technology assessment, use of molecular imaging biomarkers in drug development, prescribing and pharmacoeconomics, pharma-covigillance and drug safety, personalized medicines, therapeutic drug monitoring, biopharmaceuticals, PK/PD modeling, special pharmacotherapeutic areas like diabetes, cardiovascular, psychiatry, liver diseases, pain treatment, ethics in pharmacotherapy, rare diseases, drug-drug interactions, doping.

News

Key developments included a new journal affiliation with Clinical Therapeutics. The journal team attended the Congress and Editor-in-Chief Richard Shader gave a Masterclass on scientific publishing. A new Individual Associate membership category for EACPT was introduced, and future EACPT Congresses were announced for Madrid in 2015, Prague 2017 and Stockholm in 2019 as well as 11th EACPT Summer School in Nijmegen 5-8 July, 2014.

Awards

The 2013 Lifetime Achievement Award of the European Association of Clinical Pharmacology and Therapeutics was presented jointly to Professor Sir Michael Rawlins and to Professor Carlo Patrono, for their outstanding contributions to the national and international benefits of clinical pharmacology for medicine, health care and patient safety.

The EACPT Scientific Award went to Dr. David Devos. A Special EACPT Award was presented to EACPT co-founder, Professor Michael Orme and accepted on his behalf by fellow EACPT co-founder, Professor Folke Sjoqvist. There were 4 poster prize winners: Domenico Italiano (PP020), Annemarie Thijs (PP114), RoselinBouliei (PP219) and Caroline Samer (PP233).

Vera Vlahović-Palčevski

Below we list all fortcoming English language conferences and their abstract submission deadlines that may interest people engaged with DU research.

EuroDURG meeting 2014

We warmly invite you to join us for the next EuroDURG meeting to be held in Groningen from August 27 to August 29, 2014.

Groningen is a very lively and old European university city in the north of the Netherlands. For further information about this conference and abstract submission, see:

www.EuroDURG2014.com

Our aim is to bring researchers as well as health policy makers together for an exchange of ideas on how to improve rational use of drugs. We expect to reach around 200 participants. The meeting will bring a selection of educational sessions and lectures on the impact of interventions, drug use measures, prescribing quality indicators, and basic as well as advanced methodology in drug utilization research.

Key note presentations by international experts will address schemes to assess and improve medicine use and decision making from the perspective of policymakers, health care providers and patients.

Workshops and interactive sessions are planned on

- adherence to medicines
- drug utilisation research informing health policy
- drug use and pharmacovigilance
- cross-national and within population comparisons of drug utilization
- validity of data sources and data linkage
- patient perspectives on rational drug use.

We welcome your contribution for this meeting by the submission of abstracts for oral or poster presentation.

Abstracts for oral presentation are particularly sought for the following topics: adherence, DUR as a tool for health policy, drug use in hospitals, comparison of drug use across nations, drug use in the elderly and in children. Abstracts presented at other conferences during the last year can only be accepted for poster presentation. Best oral and best poster presentation of work not previously presented will be rewarded with a special prize.

Please note that the deadline for **abstract submission is 28 February 2014**.

The meeting will be organized according to the well-known EuroDURG tradition. We offer an excellent scientific conference in a friendly atmosphere, which includes an attractive social program and also the farewell symposium in honor of Prof Flora Haaijer-Ruskamp directly following the meeting on Friday afternoon, 29 August.

Groningen is easily accessible through Schiphol Amsterdam Airport (direct train to Groningen), City Airport Bremen (shuttle to Groningen) or Groningen Airport Eelde (selective number of European connections). Groningen is a lively city with a history of 950 years, which becomes evident from the historic warehouses, courts and buildings.

This EuroDURG meeting is the place to be for researchers and policy makers from academia, healthcare and other organizations supporting rational use of drugs. We hope that you will help us to spread this announcement and to encourage your colleagues to submit abstracts.
We look forward to welcoming you and your colleagues in Groningen!

Petra Denig and Katja Taxis from Groningen for the scientific committee of the EuroDURG2014 meeting.

ISPE 2014

MID YEAR MEETING

April 5-8, 2014, Rotterdam, the Netherlands

Abstract submission deadline has passed.

Congress includes Pre-Conference courses (Sunday, April 6, 2014)

The theme of the main mid-year meeting is Pediatric Pharmacoepidmiology, How do we grow this Child?
For more information: http://pharmacoepi.org/meetings/midyear14/

ISPE 2014

ANNUAL MEETING

30th International Conference on Pharmacoepidemiology & Therapeutic Risk Management.

October 24-27, 2014, Taipei International Convention Center, Taipei, Taiwan

Call for abstracts

Abstract submission is open for the 30th ICPE meeting.

Abstract submission deadline: 15th February, 2014.

Abstracts may be submitted for symposia/ workshop and oral or poster presentations. This year there is a special newcomers submission pro-cess where newcomers can have their abstract reviewed by an ISPE mentor prior to final submission.

For further information and abstract submission see http://pharmacoepi.org/abstracts/.

Each special interest group (SIG) has the opportunity to nominate one workshop/ symposium abstract for SIG endorsement. Only one SIG endorsed abstract per SIG may be submitted and all SIG endorsed abstracts must still undergo the usual peer review process.

If you are interested in submitting an abstract with SIG endorsement please email me as soon as possible lisa.pont@sydney.edu.au to facilitate the process.

ICPE Abstract reviewers needed for 30th ICPE.

Reviewers are needed for the 30th ICPE to be held in October in Taipei. This year interested members need to register to be a reviewer. Anyone can review as long as they are a current IPSE member, they register to review by Feb 7 and they are able to review 25-30 abstracts in Feb-March.
You do not need to be attending the Taipei conference to review abstracts.

Reviewing is a great way for ISPE members to have a say in the conference program and for us to ensure that drug utilization research continues to have a high profile at the conference. All current ISPE members should have received an invitation to be an ICPE reviewer.

To register as an ISPE reviewer for 2014 please go to http://www.call4abstracts.com/ispe_inv_rev/

Katja Taxis and Lisa Pont

International Society of Pharmacovigilance

The 14th Annual Meeting of ISOP will take place in Tianjin in China (one hour train from Beijing) between 19-22 October, 2014
The local organizer is the China Center for Pharmaceutical International Exchange, China Food and Drug Administration and chairperson of the Scientific Committee is Prof. Ian C.K. Wong from the University of Hong Kong.

Deadline for abstracts: not yet known

For more information: http://www.isoponline.org/

European Society of Clinical Pharmacy

Spring International Workshop: Safe Transition of Pharmacotherapy - The Clinical Pharmacy Approach.
Italy, 22-23 May 2014
Palermo, Italy

Deadline for abstracts: 5 March 2014
For more information: http://www.escpweb.org/cms/Palermo

43nd symposium, Patient Safety - Bridging the Gaps.
22-24 October 2014
Copenhagen, Denmark

Deadline for abstracts: 01 July 2014,
Workshop proposals deadline: 15 March 2014
For more information: http://www.escpweb.org/cms/Copenhagen

The International Union of Basic and Clinical Pharmacology

13—18 July 2014, Cape Town, South Africa

WCP2014 brings together healthcare professionals, academics, researchers, educators

and policy makers from diverse arenas, including medical, pharmaceutical and other healthcare disciplines, pharmaceutical industry, governments and non-governmental organisations from around the globe. Being a first of these meetings in South Africa and on the African continent, this also presents a gateway to, and showcase for African health sectors.

Deadline for abstracts: 31 January 2014
Deadline Late Breaker Abstracts: 31 May 2014

For more information: http://www.wcp2014.org/

ESPACOMP

European Society for Patient Adherence, COMpliance, and Persistence

The ESPACOMP meeting will take place between 20-22 November, 2014, in Lausanne, Switzerland.
Pre-conference educational day: Thursday, November 20

Annual meeting Friday, November 21 and Saturday, November 22 (morning) with key lectures on definition, causes, consequences of and solutions to non-adherence

Deadline for abstracts: not yet known
For more information go to:
http://www.espacomp.eu/about

Exploratory Workshop on geriatric pharmacotherapy

Enhancing the quality and safety of pharmacotherapy in old age

12-14 June, 2014 in Ghent, Belgium

During a two-day workshop funded by the European Science Foundation (ESF), 30 experts (including several EuroDURGers) from 10 European countries will focus on pharmaceutical care in old age, aiming to gather more insight in ADE problems and to discuss over- under and misuse of medication. The final objective will be to develop an adapt set of prescribing quality indicators useful for the regular electronic monitoring of the quality of prescribing in the elderly. Results will be disseminated during the following EuroDURG and ISPE meetings.

Katja Taxis

NorPEN

NorPEN is the Nordic Pharma-coepidemiology Network which was started in 2008 with a grant from the Nordic Council of Ministers since drug utilization databases on an individual basis were seen as a major strength and opportunity of the Nordic countries. Since then the funding from the council has run out, but the network still exists and will continue collaboration in the form of workshops and courses.
The main result of the NorPEN has been that it has brought Nordic drug utilization researchers closer together and currently there are a few publications out that can be traced directly to the existence of the network. In addition, studies have been started up across the countries. Some examples include children's use of psychotropics, drug use in pregnancy, and drug utilization and outcomes in Alzheimer´s patients.

The next meeting of the NorPEN will be held 18-19 November, 2014 in Oslo. EuroDURGers will be notified further when the program is released.

Anna Birna Almarsdottir

European projects

SENATOR project

SENATOR is an acronym which stands for the Development and clinical
trials of a new **S**oftware **EN**gi-ne for the **A**ssessment& optimization of drug and non-drug **T**herapy in **O**lder pe**R**sons.

Partners from Ireland, UK, France, Iceland, Italy, Germany, Spain, Belgium and Denmark have committed themselves for the next 5 years to run this EU FP7 project which started on October 1, 2012 and received almost 6 Million Euro from the European Commission.

The project aims to develop an efficient software engine (SENATOR) capable of

individually screening the clinical status and pharmacological and non-pharmacological therapy of older people with multi-morbidity in order to define optimal drug therapy, highlight ADR risk, indicate best value drug brand for selection and provide advice on appropriate non-pharmacological therapy. A randomized controlled trial will be implemented at six hospitals in Europe testing the software engine´s effect on ADRs as the primary outcome.

Drug utilization researchers play a keyrole in the SENATOR project. A work package is dedicated to the availability of drugs in the six countries where the software engine will be trialed. Drug compounds as well as brands, strengths, and packages available of the same compound vary across Europe. Not surprisingly, the WHO ATC code is the classification system used in this study and has a key role in linking the geriatric assessment to the drug in question.

The most important outcomes of interest to the DU researchers involved in the study are: how the trial patients' drugs change during the trial; how the STOPP START criteria influence drug utilization during hospitalization; whether these changes transfer into primary care; and how the criteria applied in the hospital setting influence drug costs in the outpatient setting.

Anna Birna Almarsdóttir

ARITMO project

The ARITMO project was formally concluded in June 2013 and the key findings are expected to be fully published in 2014. EuroDURG was involved in the collection of Drug Utilisation (DU) data on antipsychotics, antihistamines and antinfectives (in collaboration with ESAC) from 19 European Countries. In ARITMO, DU data were used to provide a population perspective to results on the arrhythmogenic potential of drugs belonging to the therapeutic classes of interest. Different methodological approaches to interpret DU data in conjunction with results on arrhythmogenic risk can be undertaken, with important public health implications. In this context, preliminary approaches are being considered with regulators such as the European Medicines Agency and results on antipsychotics have recently become available [Raschi et al. Plos One 2013 Nov 20;8(11):e81208]. Some general points under discussion are listed below:

- Large inter- and intra-class differences in the use of drugs among Countries were found.
- When a specific country emerges among the others in terms of drug use of a class involved in the ARITMO project (i.e., generally known for arrhythmogenic potential), the National Medicines Agency should check for potential areas of inappropriate use.
- When the use of a specific agent within a class generates concern, the reasons subtending large use should be investigated and, potentially, a switch towards safer alternatives should be considered and promoted only when really safer options are available.

- Drugs with average or low use should not be overlooked: both drugs recently marketed (and with increasing consumption) and drugs with peculiar use in a few Countries call for ad-hoc continuing surveillance.

- The three ARITMO drug classes are very heterogeneous for rules of dispensation (from hospital use for some agents of each class to OTC for some antihistamines). This aspect should be taken into account when considering possible regulatory decisions at national level. In this context, hospital use is probably less critical than OTC use from a clinical viewpoint because of stringent in-hospital patient monitoring, although pharmacokinetic issues (high doses and intravenous administration) and patients' clinical status (disease severity, comorbidities) should be considered.

Elisabetta Poluzzi

Protect project-CNC guideline

In 2011, Euro-DURG launched a scientific project to review DUR studies focussing on the comparison of drug consumption between countries. Preliminary results were presented at the

DUPHO Meeting in Antwerp, 2011, organised jointly by Euro-DURG, SIG-DUR and ISPE. The literature review is available at: http://www.pharmacoepi.org/pub/1c094bf0-2354-d714-513c-1bcc98255a3c

This project has now been revitalised in cooperation between the Ghent University, Belgium; Karolinska Institute, Sweden; the Universitat Autònoma de Barcelona and Euro-DURG.

The project is run in collaboration with PROTECT from the Innovative Medicine Initiative. It is now supported by a PhD researcher, responsible for finalizing the protocol and the search profile of the review, scoring the retrieved studies with a methodological template, and formulating conclusions with regard to methodological guidelines to conduct CNC studies.

Results are expected by mid 2014 and might form the basis for a formal guideline initiative within the European Network of Centres of Excellence in Pharmacoepidemiology and Pharmacovigilance (ENCEPP) network of the European Medicines Agency (EMA).

Robert Vander Stichele

Cross National Comparison (CNC) studies

There have been extensive activities during 2013 to appraise and publish on health authority activities across Europe following the availability of generic losartan, risperidone and venlafaxine. There have also been single country studies on the PPIs and statins comparing the findings to previous CNC studies, e.g. Belgium. These activities have resulted in an appreciable number of single country publications, inclusion of the findings in published review articles, submission of the CNC study results for publication as well as discussion of the CNC and single country findings at various International conferences, e.g. HTAi in Korea, EACPT in Geneva and CEESTAHC in Warsaw.

The findings can be summarised as follows:

- Multiple demand-side measures are needed to change physician prescribing behaviour when generics become available in a class/ related class and all the products in the class are seen as essentially similar in all/ nearly all patients at appropriate doses. This mirrors the findings from previous CNC studies with the renin-angiotensin inhibitors (ACEIs vs. ARBs), PPIs and statins

- Health authorities cannot rely on a 'spill over' of learnings from one class to another to effect change in physician prescribing habits even if the classes are closely related, e.g. multiple demand-side measures in Scotland limited the prescribing of patent ARBs vs. ACEIs, but there was no change in losartan utilisation following generics with no specific activities by the authorities in Scotland to encourage the preferential prescribing of losartan vs. patented ARBs. A similar situation was seen in one English Primary Care Organisation (Bury PCT) before multifaceted demand-side measures appreciably enhanced losartan utilisation
- However, demand-side measures are more difficult to introduce in disease areas where tailoring of pharmacological treatments to individual patients is recommended to improve outcomes. This includes diseases such as schizophrenia and bipolar disorders with the atypical antipsychotic drugs as well as depression with the newer agents such as venlafaxine. Consistently across countries, there was no change in the utilisation patterns of risperidone and venlafaxine post generics. This changed in Sweden with the introduction of prescribing restrictions for duloxetine. The prescribing restrictions resulted in no change in subsequent utilisation of duloxetine; however, a significant increase in the utilisation of venlafaxine

These various studies have shown that drug utilisation researchers can work effectively with health authority personnel helping them analyse the impact of their multifaceted interventions to better plan for the future. As a result, researchers do not necessarily have to purchase commercial databases to help with their analyses. In addition by working directly with health

authority personnel, drug utilisation researchers can be confident that they have fully captured all relevant supply- and demand-side measures and initiatives. Consequently, we would recommend this approach in the future.

Future CNC studies will look at biosimilars as well as new oral anti-coagulants and new drugs for Hepatitis C.

Please contact Brian Godman(Brian.Godman@ki.se; Brian.Godman@strath.ac.uk) for any further details of the published studies, some of which are documented below.

Selection of country studies in 2013:

1. Bucsics A, Godman B, Burkhardt T et al. Influence of lifting prescribing restrictions for losartan on subsequent sartan utilisation patterns in Austria; implications for other countries. Expert Review Pharmacoecon Outcomes Res 2012; 12: 809-19

2. HesseU, Godman B et al. Impact of delisting ARBs, apart from losartan, on ARB utilisation patterns in Denmark; implications for other countries. App Health Econ Health Policy 2013; 11:677–85

3. Martin A, Godman B et al. Measures to improve angiotensin receptor blocker prescribing efficiency in the UK: findings and implications. Jn Comparative Effect Res 2014; 3(1): 41–51

4. Godman B, Persson M, Miranda J, Barbui C et al. Can authorities take advantage of the availability of generic atypical antipsychotic drugs? Findings from Sweden and potential implications. Journal of Pharmaceutical Health Services Research 2013 4: 139–50

5. Godman B, Persson M, Miranda J et al. Changes in the utilisation of venlafaxine after the introduction of generics in Sweden. Appl Health Econ Health Policy 2013; 11:383–93

6. Godman B, Campbell S, Suh HS, Finlayson A, Bennie M, Gustafsson L. Ongoing measures to enhance prescribing efficiency across Europe: implications for other countries. J Health Tech Assess 2013;1:27-42

Brian Godman

ESAC –Net news

Beside the antimicrobial resistance interactive database (EARS-Net), the antimicrobial consumption interactive database (ESAC-Net) has been launched in last October on the European Centre for Disease Prevention and Control (ECDC) website.

It is available for everybody at: http://www.ecdc.europa.eu/en/healthtopics/antimicrobial_resistance/esac-net-database/Pages/database.aspx

Data is available back to 1997. Antimicrobial consumption rates, pattern, trends, etc. can be presented in various formats. For conclusions and interpretation of results presented please refer to the Annual reports, available on the same website.

Ria Benko

News from NATIONAL DURGs

Germany

In December 2013, the German national DURG "Society for Drug Utilization Research and Drug Epidemiology (Gesellschaft für Arzneimittelanwendungs-forschung und Arzneimittelepidemiologie GAA) has held its 20th Annual Meeting in Düsseldorf. Details of the meeting including the abstracts are given under http://www.egms.de/dynamic/en/meetings/gaa2013

For 2014, the 21st Annual Meeting of the GAA is planned to be held from November 20th – 21st in Bonn.

Please contact Katrin Janhsen (Katrin.Janhsen@uni-wh.de) or see our website for further information: http://www.gaa-arzneiforschung.de.

Katrin Janhsen
Chair of German -DURG

Italy

In 2013, several national and international initiatives concerning drug utilization and pharmacovigilance were placed in Italy. Representatives of DurgItaia participated in these initiatives.
From 23rd to 26th October 2013 in Turin the 36th national meeting of the Italian Society of Pharmacology "The role of the pharmacological research for the

growth and health in Italy" took place. Among the several scientific topics treated during the meeting, beside the classical aspects of preclinical and clinical pharmacology in different areas (neuropsychopharmacology, including pharmacology of neurodegenerative diseases, therapy of pain, treatment of drug addiction, immunopharmacology and therapy of immune diseases, cancer pharmacology, cardiometabolic pharmacology, etc.), great emphasis has been given to other emerging aspects such as personalized medicine, including gender pharmacology, the role of biomarkers, pharmacogenetics and pharmacogenomics, orphan drugs and gene therapy, pharmacoepidemiology, pharmacovigilance, herbal drugs, experimental and clinical toxicology. The complete meeting program as well as all the abstracts are available on: http://congresso.sifweb.org/.

On December 9, the 22nd conference on Drug Utilisation and Drug Safety was placed in Rome by the Italian Institute of Health. The seminar was presented by Giuseppe Traversa and by Roberto Raschetti. The seminar was divided into two general sessions, Drug use and appropriateness and the second on the Safety assessment of drugs, while the third was devoted to the efficacy and safety of new oral anticoagulants in atrial fibrillation. The programme and the abstracts are available on: http://www.epicentro.iss.it/farmaci/ConvegnoDic2013.asp.

A noteworthy national initiative started in 2013 by the National Centre for Epidemiology, Surveillance and Health Promotion of the Institute of Health, was the opening of a database on drug consumption called "VideoFar." It is an application which allows free consultation and analysis of drug consumption data, in the period 2000-2011. The system offers the possibility to analyze the volumes of various classes of drugs over time and regional context, allowing you to get a quick view of the dynamics of prescribing over more than a decade. For detail see http://www.epicentro.iss.it/farmaci/videofar/.

Domenico Motola and Alberto Vaccheri for DurgItalia.

Scotland

The FARR Institute of health informatics research (harnessing data for health science and e-health innovation) was formally launched in May 2013. Scotland is one of 4 centres (previously referred as eHIRC centres) and will have a designated pharmacoepide-miology work program, co-lead by University of Strathclyde and Dundee. The first Scottish conference was held in St Andrews in Aug 2013. The first set of post docturate researchers and PhD studentships have been recruited and have commenced project definition and scoping – focused on pharmacovigilance and clinical and cost-effectiveness of medicines, extending scope beyond health to include education and social care resource impact. A key focus will be use of record linkage studies involving our national prescribing dataset (now with individual level data from October 2009).
A second key development has been investment in the development of a NHS Scotland Infection Intelligence Platform which will bring together NHS and academia in a 3 year program of collaborative projects aimed at improving patient outcomes and reducing harm from infection through an innovative, integrated database, to answer important clinical questions in relation to antimicrobial stewardship and infection control.

Internationally Scotland has engaged in a number of cross national studies on drug use in 2013 and is posed to engage with the EuroDURG network and other colleagues to consider funding opportunities through Horizon 20:20.

Marion Bennie

Norway

The main scientific activity of the Society is the annual meeting where invited speakers present their ongoing research in the field of pharmacoepidemiology. In 2013 this was a half day meeting held 24 April in Tromsø. The number of participants was 33.

In this meeting research from projects at the University of Tromsø, the University of Oslo and the Norwegian Institute of Public Health were presented. Marit Herder, University of Tromsø (UiTø), talked about statins: "Can use of statins affect the development of atherosclerosis in arteria carotis? The Tromsø Study 1994-2008".

The title of Magritt Brustad's talk (UiTø) was: "Vitamin D- When little is good, is much even better?" Eiliv Lund (UiTø) talked about confounding in evaluation of mammography whereas Marte Handal's (Norwegian Institute of Public Health) presentation was about development of use of hypnotics in new users of Z-hypnotics. Pål Haugen talked about use of antibiotics in Norway, Tomas Log about use of Selective serotonin reuptake inhibitors in The Norwegian Women and Cancer study, NOWAC, and Beate H. Garcia about achievement of treatment targets for pharmacotherapy in patients with cardiovascular disease, all three from the University of Tromsø. Sture Rognstad from the University of Oslo closed the scientific meeting with a presentation of predictors of change in prescription habits of general practitioners.
Finally we had the general assembly meeting.
The Society has distributed a Newsletter to the members and circulated the EuroDurg Bulletins. The Society has given one consultative statement to the proposed new law about Health Registers. The Norwegian Society of Pharmacoepidemiology had 60 members in 2013. The membership fee is from 2013 NOK 200.
Further information about the Society can be found on the home page: www.farmakoepi.no
The annual meeting 2014 will be held on May 7at the Norwegian Institute of Public Health in connection with the ten-year anniversary of the Norwegian Prescription Database.

Randi Selmer
Chair of the Norwegian Society for Parmacoepidemiology

Denmark

The Danish Society for Pharmacoepidemiology pro-motes pharmacoepidemiology and drug utilization research, mainly through networking and annual meetings. The society has approximately 120 members representing academia, healthcare, authorities and the pharmaceutical industry. In 2013, I was appointed chairman, and two new board members, Anton Pottegård (Department of Clinical Pharmacy, University of Southern Denmark) and Espen Jimenez Solem (Department of Clinical Pharmacology, Bispebjerg Hospital), were elected. Christian Fynbo Christiansen (Department of Clinical Epidemiology, Aarhus University) and Helle Wallach Kildemoes (Department of Social Pharmacy, University of Copenhagen) continued as board members.
Our main activity during 2013 was our annual meeting. The theme was pharmacovigilance and a number of presentations were held about experience of DANPREP (Danish Pharmacovigilance Research Project). Furthermore, the annual meeting included two sessions, where young researchers in pharmacoepidemiology presented their impressive research.
During 2013 structural changes were made to the method by which Danish data is accessed. Access to data was earlier managed by the Danish Health authorities. This function has now been transferred to Staten's Serum Institute, which itself is a large research institution. The transfer led to a debate concerning equal access to data for all researchers in Denmark.
In 2014, the Annual Meeting of The Danish Society for Pharmacoepidemiology is planned to be the 10th of April in Odense. The theme will be introduction of new medicine and the pharmacoepidemiological challenges in assessing safety and efficacy when limited data is available.

Please see our website for further information:
http://www.farmakoepi.dk/

Anne-Marie Schjerning Olsen
Chairman of the Danish Society for Pharmacoepidemiology

Sweden

In Sweden, research in drug utilization is conducted by many different groups at the universities, the Medical Products Agency and the regional health boards. The Swedish Society for Pharmacoepidemiology pro-motes an arena for collaboration in pharmacoepidemiology and drug utilization research, mainly through networking and various educational activities. The society have had a number of smaller meetings with the highlight being the international symposium held in November in honor of Professor Ulf Bergman, who formally retired from Clinical Pharmacology but still will be active in DU. A number of foreign DU researchers visited Stockholm and presentations from all over the world on various DU topics were followed by a party at the royal castle.

During the year, there have also been a lot of activities around the newly developed National

Pharmaceutical Strategy, a long term plan for more efficient use of pharmaceuticals in the country. The strategy ranges from research and innovation to systems to improve monitoring of effects of drugs in clinical practice. There are also several activities suggested to improve patient safety and minimize the environmental impact of drugs. Many of the strategies are relevant for Drug utilization research.

Björn Wettermark
Board member
Swedish Society for Pharmacoepidemiology

United Kingdom & Ireland

A major re-organisation in primary care in England may result in the loss of pharmacist posts in medicines management and a change in focus for other healthcare professionals, so the 2014 PRIMM conference on "Medicines Optimisation in the new commissioning environment" is particularly relevant and timely. It will be held on 2nd May in London and we are lucky to have such reputable speakers as Dr Keith Ridge CBE, Chief Pharmacist Department of Health, England and Dr Neil Maskrey, Programme Director of the National Prescribing Centre at NICE.

Past PRIMM meetings have been very successful as networking events and around 50 research students and healthcare professionals attended the 2013 PRIMM meeting "Polypharmacy - it's not all about the numbers", which was held on January 13th in London. There were a number of keynote talks, for example Dr Martin Wilson who described Scottish Guidelines for reducing the drug burden in the elderly, and the afternoon was given over to cutting edge research (presentations are available on the PRIMM website). The 2012 Hugh McGavock Bursary winner Richard Keers reported that he had used the money to conduct a study which involved interviewing practising nurses about the causes of specific intravenous medication administration errors. The 2013 Bursary was won by Bernadette Flood for her abstract entitled "Multiple medication use in people aging with intellectual disability (PAWID) and behaviour disorders - Polypharmacy not superior Quality Indicator". The best poster presentation winner was Ms Sarah Appleton for her presentation entitled "Cardiovascular polypharmacy is not associated with unplanned hospitalisation?"

You can find out more about the PRIMM meeting on 2nd May on the PRIMM website: http://www.primm.eu.com/ or by contacting the administration team at Medway School of Pharmacy; email: C.Diaper@kent.ac.uk.

Registration prices are attractively low and the abstract submission deadline date is **14th March, 2014.**

Janet Krska

We invite other national groups to report on their activities!

Send your summary to:benkoria@gmail.com

Contact addresses of ExCo members

Björn Wettermark (**chair**)
Centre for Pharmacoepidemiology
Karolinska Institutet and
Department of Healthcare Development
Public Healthcare Services Committee
Stockholm County Council
Box 17533
SE-118 91 Stockholm
SWEDEN
Tel: +46 8-123 135 80
Tel: 070/558 56 41
E-mail: bjorn.wettermark@sll.se

Monique Elseviers
University of Antwerp
Campus drie Eiken
Universiteitsplein 1
B-2610 Wilrijk
BELGIUM
Tel: +32 473 98 56 14
Fax: +32 3664 84 59
Email:
monique.elseviers@ua.ac.be

Robert Vander Stichele
Heymans Institute of Pharmacology
Ghent University
De Pintelaan, 185, B-9000 Gent
BELGIUM
Tel: +32 92269808
E-mail:
robert.vanderstichele@rug.ac.be

Vera Vlahović-Palčevski
Unit for Clinical Pharmacology
University Hospital Rijeka
Kresimirova 42
51000 Rijeka
CROATIA
Tel: +385 51 658805
Fax: +385 51 337536
E-mail: vvlahovic@inet.hr

Anna Birna Almarsdóttir
Institute of Public Health, Research unit of Clinical Pharmacology
J.B. Winsløws Vej 19,
DK-5000 Odense C,
DENMARK
Tel: +45 6550 3089
E-mail: abalmars@health.sdu.dk

Katja Taxis
Department of Pharmacy Section of Pharmacotherapy and Pharmaceutical Care
University of Groningen
Ant. Deusinglaan 1
9713 AV Groningen
THE NETHERLANDS
Tel: +31- (0)50 - 363 8205
Fax: +31- (0)50 - 363 2772
Email:k.taxis@rug.nl

Elisabetta Poluzzi
Department of Pharmacology,
University of Bologna
Via Irnerio, 48
I 40126 Bologna
ITALY
Tel: +39 0512091809
Fax: +39 051248862
E-mail:elisabetta.poluzzi@unibo.it

Brian Godman (treasurer)
Division of Clinical Pharmacology
Karolinska Institutet
Stockholm
SWEDEN
Tel: +4687374081
OR 070/5585641
Fax: +46 8-737 40 12
E-mail: mail@briangodman.co.uk
OR Brian.Godman@ki.se; OR
godman@marionegri.it;

Begler Begovic
Department of Clinical Pharmacology Clinical Centre University of Sarajevo, Bolnicka 25, 71 000 Sarajevo
BOSNIA AND HERZEGOVINA
Telephone: + 387 33 563 086
Fax: + 387 33 667 309
E-mail: bbegovic@bih.net.ba

Marion Bennie
Strathclyde Institute of Pharmacy and Biomedical Sciences
University of Strathclyde
Room 501a Robertson Wing
Taylor Street
Glasgow, G4 0NR
SCOTLAND
Tel: +44 (0) 141 548 2113
Fax: +44 (0)141 552 2562
Email:
marion.bennie@strath.ac.uk

Janet Krska
Medway School of Pharmacy
The Universities of Greenwich and Kent at Medway
Chatham Maritime
Kent UK ME4 4TB
UNITED KINGDOM
Tel: 01634 202950
E-mail:j.krska@kent.ac.uk

Lisa Pont (SIGDUR chair)
Sydney Nursing school
University of Sydney
88 Mallet Street
Camperdown NSW 2006
Australia
Tel: +61 2 9351 0563 |
Email: lisa.pont@sydney.edu.au

Morten Andersen (past SIG DUR chair)
Centre for Pharmacoepidemiology,
Karolinska Institutet
Clinical Epidemiology Unit, T2
SE-171 76 Stockholm
SWEDEN
Tel: +46 8 517 761 78
Fax: +46 8 517 793 04
E-mail: morten.andersen@ki.se

Ria Benkő (secretary)
Dept. of Clinical Pharmacy
University of Szeged,
Szikra utca 8, Szeged H-6725
HUNGARY
Tel/Fax: +36 62 544 921
E-mail: benkoria@gmail.com

For updates please visit our website:www.pharmacoepi.org/eurodurg

Please distribute this Bulletin to your colleagues!