EuroDURG bulletin

No. 26 **February 2016**

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

Editors

The Bulletin was prepared by the EuroDURG board and the ISPE DUR/HSR SIG chair. See also contributors on behalf of national groups. Send reactions to: benkoria@gmail.com

The Chair's message

Dear Drug Utilization researchers,

Happy New 2016!

This will be the party year for all Drug Utilization researchers since there are not less than four reasons to celebrate:

- 40 years ago, in 1976, the first informal Drug Utilisation Research Group was formed and since WHO Regional Office for Europe served as the group's secretariat, it was often referred as the WHO-DURG.
- 20 years ago, in 1996, at a meeting at Lake Balaton the EuroDURG was formally established
- 10 years ago, in 2006, a special interest group (SIG) in Drug Utilization/Health Service Research was formed within ISPE with the aim to create a global forum for discussion and cooperation between drug utilization researchers in different continents
- This summer we expect our new textbook "Drug Utilization Research – methods and applications" to be launched through Wiley publisher.

If our society would be a human being, we would recognize it as midlife. However, that does not imply that there is any mid-life crisis due to dissatisfaction of unrealized goals. Over the years, drug utilization research has grown substantially and a Medline search using the term "drug utilization" gave more than 20,000 hits in 2015. In addition, several thousand drug utilization studies were found under other search terms related to the prescribing, dispensing and consumption of medicines.

During 2015, most of the energy in EuroDurg has been concentrated on completing the textbook including communications with reviewers and the publisher, but we have also been engaged in other projects. Since there was no general assembly in 2015, we have had the same board for EuroDurg as we elected on the Groningen meeting in 2014:

Bjorn Wettermark (Sweden) – chair

Ria Benko (Hungary) – secretary

Brian Godman (UK) – treasurer

Elisabetta Poluzzi (Italy) – webmaster

Robert Vander Stichele (Belgium) – liason with ISPE

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)

Cathrine Sermet (France)

Gabriel Sanfélix-Gimeno (Spain)

Paraskevi Voula Papaioannidou (Greece)

Gisbert Selke (Germany)

Jolanta Gulbinovic (Lithuania)

I sincerely want to thank all of you for the active participation and engagement in our telephone meetings and other activities we have done.

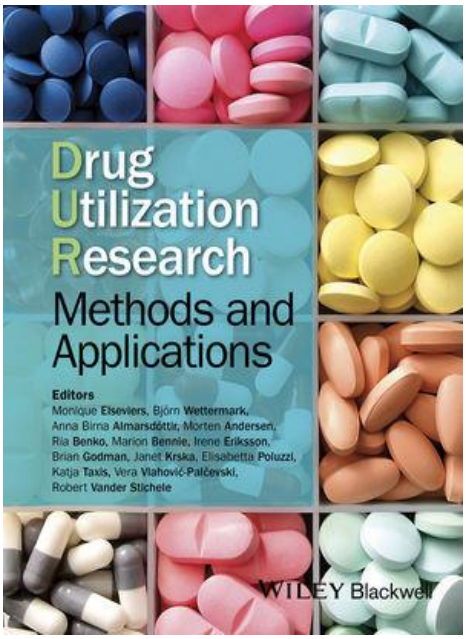
During 2015, we had no specific Drug utilization conference in Europe but our society has been active in many other conferences including the 31st ISPE conference in Boston, US, the 12th EACPT-conference in Madrid, Spain, the 19th ESPACOMP in Prague, Czech Republic and the 3rd Piperska Workshop on the Managed Introduction of New Medicines in Warsaw, Poland. Since EuroDurg 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.

Many of us have also travelled to other continents to promote Drug Utilization Research. On a meeting in July in Botswana, Medicines Research in Africa (MURIA) was founded. Brian Godman from our board played an active role in the foundation of this multidisciplinary network of people striving to promote sustainable, rational medicine use in Africa through collaborative research and capacity building in order to improve the quality of life of patients, as well as the quality of medicine utilisation in Africa. In November, I had the opportunity to visit Brazil for two different conferences. The first seminar entitled "Pharmacoepidemiology Research on Essential Medicines" took place in Rio de Janeiro. Important topics were discussed including access to medicines and various models to promote rational use of medicines. The second seminar was arranged by the Federal University of Minas Gerais and took place in the city Belo Horizonte. Experiences from different health systems and new guidelines for disinvestment of technologies were discussed.

Overall, 2015 was a fruitful year and I would like to thank all our members for paying interest in our activities. I look forward to celebrate the magic year of 2016!

Björn Wettermark
Chair of EuroDURG, European chapter of ISPE SIG DUR/HSR

LAUNCH OF THE DUR BOOK EXPECTED SOON!



In the bulletin of last year, we were proud to announce the publication of our DUR book: Drug Utilization Research: Methods and Applications. The realization of the book is an initiative of EuroDURG and the 13 editors are all closely related to the EuroDURG Board. The book does not only focus on the methodological issues of DUR but offer also a complete overview of the different applications of DUR, ranging from comparative

research over DUR in specific areas and populations to applications in the broader field of pharmacoepidemiology We hope that it will become a useful educational tool for teachers and students and a basic reference guide for all those involved in the analysis and interpretation of drug data.

It took us more than three years from the first discussions on the content till the submission of the last chapters of the book. After last summer, Wiley started their editorial work and mid December we received the proofs. We had one month to distribute the different chapters to our 100 authors for proofreading and to resubmit the corrected proofs. Right now, Wiley is able to provide the further planning, aiming to send the book to press by the beginning of March with the projected Singapore/Asia release in April and the UK release around 20 May. In the meantime, the editorial board is planning the launch of the book during this years' ISPE meeting in Dublin with some official events during the conference and a special 'DURbook launch' evening.

Also one of the first events where the DUR book will be promoted is a workshop entitled: "Drug Utilisation Research (DUR) – is it relevant to Social pharmacy researchers?") at the Social Pharmacy conference in Aberdeen in July 2016.

To follow the release of our DUR book and to obtain an overview of the content, please go to the Wiley website at http://eu.wiley.com/WileyCDA/WileyTitle/productCd-1118949781.html

Monique Elseviers

EURODURG related initiatives

Under the umbrella of EuroDURG and with the collaboration of members of the EuroDURG board, several working groups in drug utilization research were initiated during the last years.

1. Cross national comparison (CNC) of drug utilization: A European review

A first attempt to produce a review of European CNC studies was presented during the EuroDURG meeting in Antwerp in 2011. We continued our efforts under the lead of Yared Santa-Ana-Tellez and Aukje K. Mantel-Teeuwisse from the WHO Collaborating Centre for Pharmaceutical Policy & Regulation of the Utrecht University, The Netherlands. During the previous year, the group focused mainly on the framework to extract key information of the selected articles aiming to score their suitability for comparison with other CNC studies.

2. Good practice guidelines for conducting and reviewing cross-national drug utilization studies

Last year ISPE seeks proposals for one or more manuscripts that could be used for guidelines development or reference documents for

pharmacoepidemiology. The working group of the CNC initiative submitted a proposal and was very pleased to obtain an ISPE granting.
The work intend to develop a methodology to assess the validity of cross-national drug utilization studies and to develop Good Practice Guidelines for designing, conducting, analyzing, and reporting cross-national drug utilization studies. These guidelines will assist researchers in the development of cross-national comparison studies of drug utilization by highlighting the most common and potential limitations of this type of studies as well as to recommend procedures to overcome them.

3. Assessment of the quality of pharmacotherapy in the elderly

In 2014, experts from 8 European countries assembled in Ghent, Belgium, for an ESF European Science foundation) workshop. The international multidisciplinary team of experts (most with close relations to EuroDURG) focused on the quality and safety of pharmacotherapy in old age aiming to define the requirements for an electronic assessment tool based on the European lists of Potentially Inappropriate Prescriptions (PIPs). They engaged to continue their efforts in four working groups. Additionally, the Heymans Institute of Clinical Pharmacology launched an application for a 3-year PhD studentship on this topic. Ivana Ivanova, a Macedonian MD applied and started her exploratory studies using a repository of PIPs developed in collaboration with the working groups. EuroDURG members will be invited to participate offering their expertise in the evidence assessment of collected PIPs and offering secondary databases for validation studies.

Monique Elseviers

General summary

The 31st International Conference of Pharmaco-epidemiology & Therapeutic Risk Management (ICPE) was held in Boston, United States. The meeting took place in Hynes convention centre in the middle of the city, with the Pokémon World Championships concomitantly taking place in the same building. The participants enjoyed a number of good symposia, workshops, free presentations and posters. The first keynote session had the challenging title "Computer Power and Human Reason: From Calculation to Judgment" and focused on the computer development we have seen during the last decades and the opportunities and obstacles managing big data in science. The second plenary named "The Eye of the Beholder" explored benefit-risk of medicines from different perspectives. It started in a dramatic way with a patient linked up online from a hospital bed. The patient had recently experienced a Transient Ischemic Attack, after previously stopping anticoagulant use after a GI-bleeding and he discussed the pros and cons on using anticoagulants from his perspective. This was followed by reflections on benefit-risk of medicines by a physician, a regulator and a lawyer.

Another interesting plenary, "Pharmacoepidemiology and Evidence from Observational Data in Major Medical Journals: Sometimes Good Enough?" started with Jeffrey M Drazen, chief editor of New England Journal of Medicine, telling the history of tuberculosis giving his view on evidence on the shortcomings of observational studies compared to RCTs. This was followed by Liam Smeeth, London School of Hygiene and Tropical Medicine, who gave his advice on how to improve observational studies to get them published in top-ranked medical journals.

There were also some sessions of specific interest for Drug utilization researchers. One of them was the workshop on drug utilization studies on opioid use and misuse, on which the feasibility of conducting a cross national comparative study on opioid use was discussed. Finally, there were also some nice social activities including a bus ride with the Boston Duck Tours and a typically American social evening at Fenway Park, the home arena for Boston's baseball team Red Sox.

Björn Wettermark

SIGDUR

Drug utilization / Health Service research Special Interest group.

During the 31th ICPE conference in Boston we had a short meeting of the SIGDUR attended by about 30 members of our SIG. Outcome of the election of DUR Committee was as follows:

- Katja Taxis, Groningen, The Netherlands, new Chair
- Veronica- Wirtz, Boston, USA, Chair Elect
- Lisa Pont, Sydney, Australia, Past Chair
- Doug Steinke, Manchester, UK, Education
- Gillian Caughey, Australia, Communications

As a SIG we were successful in getting DUR aspects in the programme.

- Increasing number of DUR reviewers and abstract submission
- Two pre-conference educational session organized by Douglas Steinke
- Poster Walk (very well attended with approx. 35 people)
- 2.5 DUR dedicated abstract sessions
- Workshop for international collaboration on opioid use (well attended approx. 50 people with high interest in this group)

Bjorn Wettermark summarized last year's conference organized by EuroDURG in Groningen and gave a short update on the DUR book while Katja reported some information from the ICPE Board Meeting.

I would like to invite all SIG DUR members to come to the next SIG DUR meeting taking place during the next ISPE Conference in Dublin, Ireland. More information on the SIG DUR meeting will follow shortly before the Dublin meeting. If you have any questions about the SIG or want to get involved, please contact me on **k.taxis@rug.nl.**

Katja Taxis

Report from ESPACOMP meeting

Nearly 200 participants assembled in Prague from 12 to 14 November, 2015 for the 19th meeting of ESPACOMP (European Society for Patient Adherence, COMpliance and Persistence).

During the pre-conference day, attendees had the choice between two educational programs organized in two parallel sessions. Sabina de Geest lead an advanced level course on the implementing and sustaining of adherence interventions in real world settings. The second course lead by Dyfrig Hughes handled the economic evaluation methods and applications to medication adherence.

The welcome reception was held in the Old Carolinum, the original ancient college of Charles University and was preceded by a literature review of breakthrough/paradigm shift papers in adherence research of the past year.
Plenary keynote speakers focused on the economics of medication adherence and adherence in clinical trials, source-limited settings and

clinical practice. A round table discussion highlighted challenges, players, enablers and possible implications and resolutions of medications adherence policy making.

Twenty of the submitted abstracts were selected for oral presentations and presented in two parallel sessions. The remaining 50 abstracts were invited for poster presentations and included in one of the seven poster walks.
During the closing session, participants received an invitation for the 2016 ESPACOMP meeting that will be organized in Lisbon from 17 to 19 November, 2016.

Monique Elseviers

Report from EACPT conference

This congress is organized every two years and drew again a large academic audience of pharmacology teachers to Madrid. Around 1000 abstracts were presented (on electronic billboards, without printed abstract book).

Presentations can only be seen by members at the EACPT website. However, YouTube provides interviews with the speakers of some important sessions. One session was dedicated to drug information and decision support, organized by Ylva Böttinger, with speakers on semantic interoperability, alert fatigue, and the role of drug information centres. Visit: https://www.youtube.com/watch?v=6292NSnuOhI

Robert Vander Stichele

Report from NORPEN conference

The 2015 NorPEN meeting was held at The University of Southern Denmark, Odense on November 12-13, 2015.

NorPEN is a network of researchers with the purpose of facilitating research within the field of pharmaco-epidemiology in the Nordic countries. NorPEN was created in 2008 as a network of ten pharmacoepidemiology research groups from the five Nordic countries (Denmark, Finland, Iceland, Norway and Sweden) and was initially funded by Nordforsk. NordForsk is an organisation under the Nordic Council of Ministers that provides funding for and facilitates Nordic cooperation on research and research infrastructure.

It has now gone on to be a permanent network of researchers and in 2013 the steering group of NorPEN decided to open up the network to include other academic research groups in universities, public health institutions or public administration than those initially participating. See http://www.norpen.org/pages/norpen.html for further information.

The focus of the Odense meeting was on Pharmacovigilance – using spontaneous reports and large administrative databases. The first day was a symposium mainly consisting of invited lectures by Nordic experts on pharmacovigilance and pharmacoepidemiology. There were presentations of how signals are generated from spontaneous reporting and how databases in all the Nordic countries can be used in combination to strengthen detection of potential adverse drug effects. The generation of hypotheses from the linkage of drug utilization databases and diseases registries (e.g. cancer registries) were discussed and the hypothesis of free screening for associations (ADRs) were hotly debated.
The second day was a workshop where there were two activities. NorPEN has a couple of special ways of engaging researchers both young and old in the topics and methods within pharmacoepidemiology.
The first is the Pharmacoepi-sprint, which is a one hour session where examples of vexing problems encountered during ongoing or planned Nordic projects are presented by students and discussed in small groups. The second way is the Pharmacoepi-slam which is a session where each participant has 3 minutes to tell about their study. It is a contest where the winners are

those that are found a panel of ten judges to be able to deliver their study´s results in the clearest manner within the allotted time. This contest really engages the participants who are usually Ph.D. students or young researchers and could be something that could be tried by EuroDURG. It could be called ”DUR-Slam”?

Anna Birna Almarsdottir

Report from the ESCP conference

Medicines information: making better decisions', was the title of the 44th European Society of Clinical Pharmacy (ESCP) Symposium on Clinical Pharmacy, held on 28–30 October 2015 in Lisbon, Portugal. A report was published in Drugs & Therapy Perspectives 2016; 32:30-34.

The attendance was over 700 persons, with a strong focus on evidence-based medicine, information searching skills for clinical pharmacists, and decision support systems. Webcasts of the presentations: http://www.farmaactueel.nl/webcasts/extern/ESCP2015n/Inleiding.htm

There was a presentation of Robert Vander Stichele, a board member of EuroDURG on explicit criteria and implicit human judgment in multi-disciplinary medication chart review in older adults: a complex exercise in clinical decision making with physicians, pharmacists, and nurses.

Robert Vander Stichele

Report from ENCePP Plenary meeting

The European Network of Centres for Pharmaco-epidemiology and Pharmaco-vigilance (ENCePP®) (see: http://www.encepp.eu brings together expertise and resources in pharmaco-epidemiology and pharmaco-vigilance across Europe, support by the European Medicines Agency (EMA). ENCePP aims to facilitate the conduct of high quality, multi-centre, independent post-authorisation studies, in particular observational research. The group has developed methodological standards and governance principles, as well as providing opportunities for collaboration.

International Conference on Pharmacoepidemiology & Therapeutic Risk Management
August 25-28, 2016, DUBLIN

At the recent plenary meeting (24 November 2015) it was reported that a number of documents have been updated or are being revised and new ones developed. Key documents are: Code of conduct for pharmacoepidemiology and pharmacovigilance studies, currently being revised (see:http://www.encepp.eu/code_of_conduct/index.shtml)
Checklist for study protocols, which has recently been updated:(see:http://www.encepp.eu/standards_and_guidances/checkListProtocols.shtml).
Guidance on methodological standards in pharmacoepidemiology (see:http://www.encepp.eu/standards_and_guidances/methodologicalGuide.shtml).
ENCePP maintains a register of Post-authorisation (PA) studies being conducted across the EU, and also offers a 'quality' marker for studies, the ENCEPP seal. It was reported at the November meeting that 666 studies were registered, 183 of these are industry sponsored, but only 36 have the ENCePP seal. Also 344 of the 666 studies were requested by regulators and 213 of these were industry- funded. Alternative mechanisms are needed to encourage academics to become involved in post-authorisation studies and were discussed at this meeting. Such a move would potentially save tax-payer money, as industry currently funds clinical research organisations (CROs) to deliver the studies required by regulators, at high cost, thus adding to the overall cost of drugs. Academia could do these studies much more cheaply, hence saving public funds.
Another issue discussed was the need to maximise the use of registries, which are extensive across the EU, but variable. There is a lack of co-ordination between registries across countries, as well as a lack of harmonised protocols, methods, data sharing, transparency and sustainability. Many registries are for products not diseases and a lot also suffer from poor patient recruitment. A register of registries is being developed.
A full report of the meeting is available on the ENCePP website:(see:http://www.encepp.eu/publications/PlenaryMeetingReports.shtml)

Janet Krska

Below we list all forthcoming international or European, English language conferences and their abstract submission deadlines that may interest people engaged in DU research. For national conferences please see country specific news below.

ISPE 2016

MID YEAR MEETING

The ISPE Mid-Year Meeting will be organized in Royal Sonesta Harbor Court Baltimore, Baltimore, MD, April 10-12, 2016.
Abstract submission deadline has passed.
For more information visit: http://www.pharmacoepi.org/meetings/midyear16/

ISPE 2016

ANNUAL MEETING

The 32nd International Conference on Pharmaco-epidemiology and Therapeutic Risk Management will be held in the Convention Center Dublin, Dublin, Ireland between August 25-28, 2016.
The agenda will be available in the coming weeks.

Deadline for abstracts: February 17, 2016

For more information and submission of an abstract visit: https://www.pharmacoepi.org/meetings/32ICPE/

International Society of Pharmacovigilance

ISoP Mid-year training course "PV Management: Devising and organizing effective operations for ensuring safe and appropriate use of medicinal products." will take place at Makati-Manila, Philippines between 25-27 April, 2016.

This three day-course is conducted to leverage the Pharmacovigilance expertise of ISoP and is designed for interdisciplinary groups to learn and work together in order to enhance patient safety when medicines are used. This course is aimed to engage all interested pharmacovigilance professionals in a regulatory, industry, hospital, university or community setting.

For more information visit: http://isoponline.org/training/training-courses-mid-year-manila-2016/

The annua meeting entited ""Pharmacovigilance for safer tomorrow" will take place in Agra, India, 16-19 October 2016.

Deadline for abstracts: June 30, 2016

For more information visit: http://www.isop2016agra.org/

European Society of Clinical Pharmacy

The 2016 ESCP Spring Workshop: "Medication adherence: from theory to daily patient care" will take place in Basel, Switzerland, between June 10-11, 2016.

Deadline for abstracts submission: 15 March 2016.

For more information visit: http://www.escpweb.org/cms/node/388

The 45th ESCP Symposium: "Clinical pharmacy tackling inequalities and access to health care" will take place in Oslo, Norway, 5-7 October 2016. The symposium will be jointly organized with NSF, the Norwegian Association of Hospital Pharmacists.

The theme of the symposium reflects the increasingly widening gap between what is technologically possible to achieve with medicines, their increasing cost, and what is affordable to society and individual patients.

Deadline for workshop proposals: 16 March 2016.

Deadline for abstracts submission: 1 July 2016

For more information visit: http://www.escpweb.org/cms/node/387#node-387

European Society for Patient Adherence, COMpliance, and Persistence

The 20th edition of the ESPACOMP meeting will be organized in Lisbon, Portugal between November 17-19, 2016.

For more information please visit:http://www.espacomp.eu/meetings/view/43#toc_1

Abstract submission deadline: June, 2016

European Association for Clinical Pharmacology and Therapeutics

The 2016 EACPT Focus Meeting: "How to Assess Medicines from Research to Clinical Practice? Efficacy, Effectiveness, and Economic – 3E Assessment", will be held

between October 6-9, 2016, in partnership with the Croatian Society for Clinical Pharmacology and Therapeutics in Opatija, Croatia.
The main objectives of this meeting are to increase awareness, knowledge and use of critical assessment pillars for medicinal products in everyday clinical practice in order to improve healthcare outcomes in affordable manner.

For more information visit: http://www.eacpt.eu/2016-eacpt-focus-meeting-how-to-assess-medicines-from-research-to-clinical-practice-efficacy-effectiveness-and-economic-3e-assessment/

Health Technology Assessment International

The 2016 Annual Meeting of HTAi entited "Informing Health Care Decisions with Values and Evidence", will be hosted by the Graduate School of Public Policy, University of Tokyo in collaboration with HTA agencies of Japan in May, 2016 in Tokyo, Japan.

Pre-Conference Workshops: May 10-11, 2016.
Conference: May 12-14, 2016.

Abstract submission deadline has passed.

For more information visit: http://meeting.htai.org/events/tokyo2016/event-summary-4023afce0ec04ab387500e87f0a6a42d.aspx

European Social Survey

The 3rd International ESS Conference: "Understanding key challenges for European societies in the 21st century" will be organized between 13-15th July, 2016 at the University of Lausanne, Switzerland.
The two defined health sessions are: 1. Comparative health research: studying health and illness cross-nationally and over time 2. Health inequalities in Europe and their social determinants

Deadline for abstract submission has passed.

For more information visit: http://www.europeansocialsurvey.org

European projects

euromedicat

Medication Safety in Pregnancy

This four year EU-7 project has now successfully completed, involving 9 partner institutions and 14 participating EUROCAT registries. Studies of specific medication groups used a range of study designs (case-control, cohort) to investigate the risk of congenital anomalies relating to antiepileptics, antidiabetics, antidepressants (SSRIs), and antiasthmatics; drug utilisation studies of all four drug groups were conducted. Methodologically, the project developed and successfully implemented linkage of congenital anomaly registries to healthcare databases with prescription information, developed a systematic signal detection system, and developed common software and protocols. Further studies concerned the implications of internet use by women pre- and during pregnancy for information and purchase of potentially teratogenic drugs such as isotretinoin for acne, and to the adequacy of our information systems to monitor the efficacy of pregnancy prevention programmes used for teratogenic medication prescribing. Results of all

EUROmediCAT workpackages were presented during a European Conference "Safety of Medication Use in Pregnancy" in Poznan, Poland, 2-4 February 2015, with 620 participants from 24 countries.

Attention was given to the fact that the conference included representatives of patient organizations and people born with physical and visual impairments as a consequence of thalidomide use by their mothers during pregnancy. One of the invited speakers was Geoff Adams-Spink, Trustee of the Disability Rights in United Kingdom and Chairman of the European Dysmelia Reference Information Centre. The proceedings of the Conference can be found at http://www.euromedicat.eu/publicationsandpresentations/europeanconference,poznan2015. Abstracts of oral or poster presentations have been published in the PDS (DOI: 10.1002/pds.3865)

EUROmediCAT is now looking to the future. They have both a central database (200,000 congenital anomaly records documented with medication exposure up to 2013, being updated each year) and a distributed database with prescription data linked to congenital anomaly data. New registries have joined the partnership, and new projects are starting.

EUROmediCAT issued 25 Recommendations for European and national medicines regulatory agencies, public health authorities and professional clinical bodies 1) to improve future pharmacovigilance 2) to inform future drug safety measures relating to medication use in pregnancy and by women of childbearing age. The recommendations (see also: Dolk H et al. DOI: 10.1002/pds.3865) are designed to help make better use of current data, networks and infrastructures in Europe. If you would like to endorse these recommendations, please email h.dolk@ulster.ac.uk - we are creating a special place for further endorsements on the EUROmediCAT website.

Ria Benko based on the EUROmediCAT Newsletter written by Barbara Norton

News from NATIONAL DURGs

Austria

In October 2015, the third international PPRI Conference entitled 'Pharmaceutical Pricing and Reimbursement Policies: Challenges Beyond the Financial Crisis' organized by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies was held in Vienna. The presentations, the country abstract book, the poster abstract book and the Conference Supplement are accessible for download at: http://whocc.goeg.at/Conference2015/Programme

Researchers from three Austrian institutions published a paper in which they analysed, based on EHIS (European Health Information Survey) data, socioeconomic determinants in medicine use in eight Central and Eastern European countries. (see: http://www.equityhealthj.com/content/14/1/124

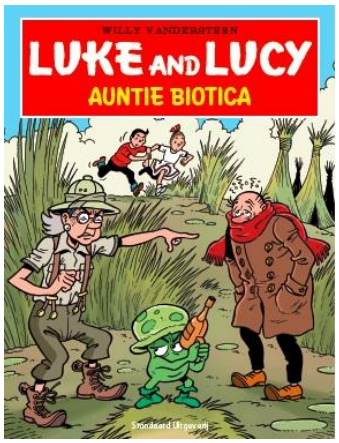
Variability of oncology medicine prices in European countries, Australia and New Zealand has been also evaluated and published (see:http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045%2815%2900449-0/abstract

Sabina Vogler

Belgium

The Belgian Antibiotic Policy Coordination Committee (BAPCOC) developed a comic on correct use of antibiotics as part of its most recent antibiotic awareness campaign. Auntie Biotica is a special edition of Luke and Lucy – the famous Belgian comics series (aka Bob et Bobette in French or Suske en Wiske in Dutch). Online versions of this comic in English, German, French and Dutch can be found at

www.correctuseantibiotics.be, the Belgian antibiotic awareness campaign website in these four languages.



This initiative is endorsed by the European Antibiotic Awareness Day, the Belgian scientific colleges for general practice and those for obstetrics and gynecology, and the Belgian National Institute for Health and Disability Insurance. The Dutch minister of public health, Edith Schippers, ordered 40 000 print copies to be distributed among general practitioners and pharmacies in the Netherlands. In Belgium 50 000 print copies are begin distributed. Public awareness on correct use of antibiotics facilitates primary care clinician's decisions not to prescribe antibiotics for flu, common cold and bronchitis.

Samuel Coenen

Germany

In November 2014, the German national DURG "Society for Drug Utilization Research and Drug Epidemiology (Gesellschaft für Arzneimittelanwendungs-forschung und Arzneimittelepidemiologie GAA) has held its 21st Annual Meeting in Bonn. Details of the meeting including the abstracts are given under: www.egms.de/dynamic/en/meetings/gaa2014/index.htm.

For 2015, the 22nd Annual Meeting of the GAA is planned to be held from December 3rd – 4th in Dresden.

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

The annual Report on drug utilization in Italy (Rapporto OsMED - Osservatorio dei Medicinali) is now available also in English:http://www.agenziafarmaco.gov.it/it/content/osmed-report. As regards the 2014 data: 1) no main changes in overall expenditure and consumption has been recorded in comparison with the previous year; 2) for the first time, antineoplastic and immunomodulators, driven by monoclonal antibodies, ranked in second position among categories with the highest impact on total expenditure (€3.934 million, just below cardiovascular medicines) and first in terms of public expenditure. 3) as usual, statins (among cardiovascular system medicines), proton pump inhibitor products (among the GI tract and metabolism medicines) and selective serotonin reuptake inhibitors (among the central nervous system medicines) were the drug classes recording the greatest impact on the public expenditure. 4) a specific section has been devoted to prescription quality indicators (PQIs), by linking prescription data to diagnoses (from electronic health records of Italian GPs); this approach allowed to assess appropriateness of the choice of therapy in the main chronic conditions (e.g. hypertension, diabetes, MRGE) and the relevant adherence.

The 37th Conference of Italian Society of Pharmacology (Naples, October 27th-30th) had two specific sessions and some symposia related to pharmaco-epidemiological research, by including a lot of contributions on Drug Utilisation. The main topics in this field were: DU in special populations (e.g. exposure to potential teratogenic drugs in pregnancy and drug-drug

interactions in the elderly) and DU appropriateness and healthcare costs (e.g. use and costs of new oral anticoagulants, experiences and scenarios of cost-saving with generics). The need to confirm/refuse evidence from premarketing studies by using real-world DU data strongly emerged, together with the importance of that data in supporting actions toward the sustainability of health care system. The program of the meeting is available at the following link (in Italian language:http://congresso.sifweb.org/index.php

Two important events were organised by the Italian National Institute of Health in Rome: a meeting entitled "Biosimilars: use, safety, sustainability" (June 25th) and the 24th edition of the National Seminar of Pharmacoepidemiology. The former gathered main stakeholders (regulators, drug companies, citizens, prescribers) and scientists to present evidence, gaps in knowledge and "perceptions" on this topic. The Italian Medicines Agency (AIFA) presented his position paper (available in Italian at the link http://www.agenziafarmaco.gov.it/sites/default/files/AIFA_POSITION_PAPER_FARMACI_BIOSIMILARI.pdf) concerning the international and national regulatory scenario. The program and the presentations of the conference are available (in Italian) at the following link http://www.epicentro.iss.it/farmaci/Biosimilari2015.asp
The latter addressed presentations of DU research especially to: switch in use of biologics and biosimilars, appropriateness of use of antihypertensives, integration of different information systems to build indices of severity of disease in general practice, impact on people of antibiotics used in veterinary medicine. Results of observational studies concerning different therapeutic classes were also presented (e.g. respiratory medications, insulins, new anti-hepatitis C drugs). The program, the abstract book and the speakers' presentations are available (in Italian) at the following link http://www.epicentro.iss.it/farmaci/convegnoFarmaci2015.asp

Elisabetta Poluzzi and Carlo Piccinni

Kosovo

It is the first time that we inform the newsletter readership about the DUR Related activities in Kosovo. During 2015 we have presented the final report and successful ending of project named "Capacity Building to Implement State of the Art Surveillance Systems for Antibiotic Consumption and Resistance in Kosovo", financed by European Commission Liaison Office of Kosovo (Reference: EuropeAid/132 003/L/ACT/XK, contract number 2012/297-251). The project was implemented by the National Institute of Public Health of Kosovo, in partnership with University of Antwerp, Belgium. The main objectives of this project were to monitor volumes and patterns of antibiotic use in order to identify targets for quality improvement and to establish a comprehensive surveillance system of antibiotic resistant bacteria in hospital- and community acquired infections through improvement of the research capacity of central and regional laboratories. Data on antimicrobial use were collected in seven hospitals in Kosovo using the point prevalence methodology (PPS)developed by the ESAC team. Using the PPS methodology we have collected the data in 2015 and we will continue during next coming year in order to be part of project supported by the European Surveillance Antimicrobial Consumption (ESAC) project.
The Kosovo utilization team also participated at numerous event like the "Multi-Country AMR Workshop" in Copenhagen (organized by the WHO Regional Office for Europe and supported by the -ECDC),the "Train-the-trainer" workshop for surveillance of healthcare-associated infections (HAI) and

antimicrobial use in long-term care facilities and the third ECDC meeting of the European ARHAI networks in Stockholm, We were also trained on the ATC/DDD Methodology. The antibiotic utilization group will get the task and duties in the coming years.

National led activities were also focused on the antiinfectives: we have organized a workshop on Antimicrobial Stewardship with the support of the Ministry of Health,

In 16th November 2015 the Ministry of Health of Kosova organized the European Antibiotic Awareness Day.

Furthermore the Kosovo utilization team published the research article on antibiotic and analgesic utilization of an orl surgery Department (Krasniqi et al. DOI: 10.2147/TCRM.S87595)

Shaip Krasniqi

Netherlands

Annual conference of PRISMA on pharmacy practice research was held in May 2015 in Amersfoort. This was attended by more than 200 Dutch and Vlamish practice researchers and much of the research also covered DUR topics. Information can be found on: http://www.knmp.nl/professie/wetenschap/onderzoeksnetwerken/prisma-1

The next PRISMA symposium will take place on 24th May 2016 with a plenary session on access to new expensive medication. Practice researchers are also invited to send in abstracts to present their work. More information is available on: http://www.knmp.nl/agenda/prisma-symposium

Katja Taxis

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 2015 the annual meeting was held at the Institute of Health and Society, University of Oslo. The main topic was "Drug use in children and adolescents". Dr. PhD Marte Handal talked about the increase in use of psychotropic medications among children and adolescents in Norway whereas researcher Øystein Karlstad talked about use of ADHD medications among children and adolescents in the Nordic countries. The title of College Lecturer Siv Skarstein's talk was "Youth with high consumption of pain killers without prescription". Senior researcher Vidar Hjellvik talked about "Russ celebration with antibiotics" and professor Hege Salvesen Blix about use of antibiotics in children. *Associate professor Marit Waaseth talked about intake of* vitamin A, D and E among Norwegian women and professor Olav *Spigset about use of* medications for urine incontinence based on data from the Norwegian Prescription Database and the HUNT study. At last Dr PhD *Svein R. Kjosavik* gave an overview from a research stay in Australia.

Finally we had the general assembly meeting. The society is represented in the NorPEN (Nordic Pharmacoepidemiological Network).

The Norwegian Society of Pharmacoepidemiology had 60 members in 2015. The yearly membership fee is NOK 200.

Further information about the Society can be found on at: http://www.farmakoepi.no/cmsms/

The annual meeting 2016 will be held on May 3 in Trondheim NTNU. The main topic is "Linkage of health registries in pharmaco-epidemiological research - opportunities and challenges"

Randi Selmer
Chair of the Norwegian Society for Parmacoepidemiology

Russia

Development and validation of novel methodology for calculation of antimicrobial consumption in children is one of the top priority projects for our scientific group. As WHO proposed ATC/DDD methodology is not precise due to age-dependent dose variations in children we aim to create a more accurate instrument to measure antimicrobial consumption in pediatric inpatients and outpatients as well as in mixed age patient population in multi-field hospitals.

In order to achieve that we have created a new methodology for assessment of systemic antimicrobial consumption in children based on child Defined Daily Doses (cDDD) for children aged 0 to 12 years as these age groups commonly require dose adjustment. cDDD is an average maintenance dose of an antimicrobial per day per unit of body weight in a child with normal renal and liver function as recommended by national guidelines. Initial calculations were based on average body weight in each age group obtained from centile tables with 50% centile corridor with further adaptation by comparison of theoretical cDDDs with real practice derived prescribed daily doses and correction of the former in case of ≥25% divergence to create final cDDDs. Results of clinical approbation proved that cDDD based methodology was more precise then generally accepted DDD methodology for calculation of antimicrobial consumption in hospitalized children [Rachina S.A. et al. 23rd ECCMID 2013, poster P891].

We are currently working on validation of the proposed methodology in order to improve its accuracy in subpopulations of pediatric patients of different age groups as well as for utilization of different groups of systemic antimicrobials and on adaptation of this approach to assessment of antimicrobial consumption in multi-field hospitals with different shares of pediatric inpatients. We are looking to cooperate with interested parties in the process of further improvement of this methodology and its implementation for drug consumption assessment in pediatric patients in different settings. For more information, please contact project coordinator Yuliya Belkova (yuliya.belkova@antibiotic.ru).

Svetlana Rachina and Yulia Belkova

Scotland

2015 has been a busy year for pharmaco-epidemiology activity in Scotland. Our central event was the UK Farr Institute meeting in St Andrews in August attended by a broad UK and international audience of multidisciplinary teams with a focus on the use of record linked datasets for maximal public benefit. Pharmaco-epidemiology had its own parallel session with presentations from across Europe and Canada including key themes on cardiovascular, infection and use of federated networks to conduct pharmacoepidemiology studies. The Farr Scotland Consortium also secured in 2015 an EMA preferred partner status for conducting rapid pharmacovigilance studies, one of five European centres. We extended our European networks onto the international platform with development of collaborations with Brazil, China and Canada. Progress continues with studies to use data intelligence to drive quality improvement and develop clinical decision support tools (predictive analytics/modelling application s on our national datasets) for our clinical services both in hospital (focus on infection and evolving for cancer) and community care (including respiratory, infection, high risk medicines). Looking forward we are starting the planning with EuroDURG colleagues for the EuroDURG 2017 conference to be held in Glasgow. 2016 will also see our next UK Farr conference in collaboration with the International Population Data

Linkage Network Conference in Swansea Aug 16.

Marion Bennie

Sweden

During 2015, the national medicines strategy was updated with a new action plan. The strategy was originally developed in 2011 by the Swedish Government together with a broad coalition of stakeholders in the pharmaceutical sector with the aim to promote safe, innovative and equitable use of medicines in the country. The updated strategy has three long-term objectives, based on some current challenges:

- Efficient and safe use of medicines
- Improved availability and equitable use of medicines
- Economically and environmentally sustainable use of medicines

There are 18 priority activities including many topics of interest in drug utilization.
Some examples include better monitoring of dosages, structured introduction and follow up of new medicines, activities to combat antimicrobial resistance, better reporting of adverse drug reactions and drug utilization studies in paediatric populations.

During the year, the Swedish Prescribed Drug register with individual-level data on all dispensed prescription medicines in the country celebrated ten years. This was celebrated with a symposium, also given in honour of Andrejs Leimanis who retired from his position at the National Board of Health and welfare where he had been responsible for the register since its foundation.

Björn Wettermark

United Kingdom & Ireland

Doctors, pharmacists, nurses and social scientists were among the 65 delegates at the 2015 conference held in London in January. They were treated to an enlightening series of talks on medicines management from the perspectives of an academic GP (Prof Tony Avery), an academic pharmacist (Dr David Alldred), an academic nurse (Prof Sue Latter) and a patient advocate (Margaret Murphy).
Tony Avery described some of his work on prescribing errors in primary care, including the PRACtICe study, which found a prevalence of prescribing or monitoring errors of 4.9%, and the PINCER trial, which demonstrated the effectiveness of a pharmacist-led IT-based intervention in reducing these in general practice. David Alldred described his work on medication review and medication errors in care homes, (including the CHUMS study), which found that 70% of care home residents had at least one medication error. Sue Latter described some of her work on nurse and pharmacist prescribing, which suggested that perhaps not all those qualified to prescribe in these professions are not using their abilities to the full. Margaret Murphy described an initiative in Ireland "Let's talk medication safety" (please visit:http://www.isqsh.ie/index.php/lets-talk-safety) which has developed booklets for patients and the public, provides a 'medication tracker' and lots of other ways in which patients can help themselves to ensure they optimise their medicines use.

There were a total of 33 posters displayed, 12 of which were also presented in more detail during two poster walks, plus five oral presentations of submitted work.
The Hugh McGavock prize of £200 was won by Dr Lucy Moore for her work on "How patients optimise medicines in daily life". Best poster prize of £50 was awarded to Sarah Thomas for her study on "Investigating medication prescribing accuracy for critical error types: the IMPACT tool".

The 2016 PRIMM conference will be held on January 29th at the Health Foundation, London.

Janet Krska

We invite other national groups to report on their activities in the next years' Bulletin!

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