EuroDURG bulletin

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NEWSLETTER OF THE EUROPEAN CHAPTER OF THE SPECIAL INTEREST GROUP OF DRUG UTILISATION RESEARCH (SIG-DUR) OF THE INTERNATIONAL SOCIETY OF PHARMACOEPIDEMIOLOGY (ISPE) *Editors* The Bulletin was mainly prepared by the EuroDURG board members. See contributors below each paragraph. Edited by Ria Benko Send reactions to: benkoria@gmail.com



Dear Drug Utilization Researchers!

Wishing you all well for 2019 !

It is my pleasure to send this message to you all as we commence the New Year and undertake to promote our area of science in contributing to the safe and effective use of medicines across Europe and more internationally.

2018 has been a productive year as you will see from reading the national news from across Europe and the reports on conferences in this bulletin. Personally, the year started with reflecting on the Glasgow Conference and writing the final report with colleagues – a nice opportunity to recognize the depth and breadth of DUR activity across the community and award and celebrate through our prize winners.

Consequently, and not surprisingly the EuroDURG Board has been discussing and started to plan for our next EuroDURG conference. I am delighted to announce that this will take place in Hungary (4th-7th March 2020), hosted by Ria Benko and the local team. We are busy working with Ria to confirm the venue over the next month to announce this more formally to all. In addition, we are at the early stages with the Board of constructing the Scientific Programme – this will be shaped in part by your feedback after Glasgow BUT please send me any thoughts on key topics, issues evolving that you consider would be good for this event.

The EuroDURG Board took the opportunity to reflect on our key achievements and look forward to what should be the priorities to progress as a team over the next 1-2 years. We took our thoughts to the Prague ISPE where we had a great attendance at the EuroDURG meeting and have used this feedback to shape an initial five priorities (see details below and in further Bulletin parts):

 firstly, using the *DUR book*, produced by the EuroDURG community, as the focus for development of educational materials / programmes starting with a new summer school in 2019 in Stockholm (see advert)

- secondly, development of a DUR database maturity index system, initially across Europe, to better understand the level of readiness of our resources to evolve and plan for a potential programme of cross national studies through EuroDURG.
- thirdly, progressing the *Glasgow Declaration* which seeks to lobby for improved access for researchers to DUR data nationally and globally
- fourthly, progressing an initial *exploratory project* with an international data analytics company which would explore how our DUR expertise and their data analytics and dataset coverage may be synergized to address an important public health topic
- fifthly, and finally to develop a
 PhD/Postdoctorate research
 forum in collaboration with
 ISPE SIG DUR to promote connection / networking
 for our evolving talent.

I hope this gives you all a good insight into the work of the Board, who I wish to thank through this communication for all their support in my first as chair. Also and vear importantly, a big thank you to full EuroDURG our membership all your for endeavors to progress DUR internationally. I wish you all well for 2019 and hope to have the opportunity to meet up through the range of different events in the upcoming 2019 calendar.

Marion Bennie Chair of EuroDURG European chapter of ISPE SIG DUR

EuroDURG ExCO 2017-2020



Marion Bennie (Scotland) – chair

Björn Wettermark (Sweden) – past chair

Katja Taxis (the Netherlands) – chair elect

Elisabetta Poluzzi (Italy) – webmaster

Brian Godman (UK) – treasurer

Ria Benko (Hungary) secretary

RobertVanderStichele(Belgium) – liason with ISPE

Monique Elseviers (Belgium)

Vera Vlahović-Palčevski (Croatia)

Begler Begovic (Bosnia and Herzegovina)

Katja Taxis (The Netherlands)

Anna Birna Almarsdottir (Denmark) Cathrine Sermet (France) Gabriel Sanfélix-Gimeno (Spain) Paraskevi Voula Papaioannidou (Greece) Gisbert Selke (Germany) Jolanta Gulbinovic (Lithuania) Hedvig Nordeng (Norway) Verica Ivanovska (Macedonia) Sabina Vogler (Austria) Seán MacBride-Stewart (UK)



EuroDURG meeting at ISPE 2018 Prague

successful EuroDURG А meeting has been organized annual during the ISPE conference. The 1.5 hours slot visited been has by 45 participants from all over the world.

First our chair, Marion Bennie reported on previous EuroDURG activities. First, she evoked the last successful EuroDURG meeting that was held in Glasgow and attracted more than 250 participants from over 39 countries.

Then she mentioned present activities of EuroDURG including the Cross National Comparison good practice guideline for designing, reporting conducting, and reviewing CNC studies. This project will be finalised soon

and the related documents will be published on ISPE website (see more details in this Bulletin under EU projects).

The other important initiative EuroDURG that of was initiated during the Glasgow conference preparation (hence the name: Glasgow declaration) is the need for more easy data access for academia and policy making. Evolvement in this project can be read below. Thirdly, Marion announced the ideas of how EuroDURG can contribute to the next conference of EACPT (see EuroDURG Summer School advertisement below).

After the short reports Marion proposed future activities for EuroDURG: continue to disseminate the knowledge that has been accumulated during the DUR book preparation: educational courses/webinars. etc. primarily targeting young researchers/newcomers/PhD students. Secondly to start cooperation topics research EuroDURG the within network.

We have discussed the proposals further during our regular teleconferences and appointed small groups of board members who will take a leadership role in the agreed areas.

EDUCATIONAL

a) To run a DUR education summer school and to commence a programme to develop e-learning materials. The leadership team will be Monique Elseviers, Hedvig Nordeng and Anna Birna Allmarsdottir.

b) Prepare for a EuroDURG
congress, Hungary 2020.
The leadership team will be
Ria Benko supported by the
EuroDURG Executive team.

RESEARCH

- a) Conduct a rapid appraisal of DUR database maturity for EuroDURG member countries. The leadership team will be Sean MacBride-Stewart, Björn Wettermark, Katja Taxis and Monique Elseviers.
- b) Progress the Glasgow Declaration seeking improved access to DUR data globally. The leadership team will be Monique and the international team who ran the Prague workshop.
- c) Progress discussion with IQVIA to explore public health topics of common interest and undertake a collaborative use case

exemplar study. The leadership team will be Marion Bennie, Katja Taxis and Sabine Vogler.

Ria Benko

EURODURG SUMMER SCHOOL IN DRUG UTILIZATION RESEARCH



Preceding the EACPT meeting next summer in Stockholm, EuroDURG will organize a 3days summer school in DUR in close collaboration with ISPE, Karolinska Institute and Stockholm County Council.

The course will start on Wednesday 26/06/2019 (lunchtime) and will end on Saturday 29/06/2019 (lunchtime).

The main topics that will be handled are:

- Study designs in DUR
- Classification systems & measurement units for DU
- Primary data collection and secondary data sources for DUR
- Development of quality indicators for DU
- Descriptive and analytical statistical methods in DUR
- Applied DUR in the areas of adherence, elderly, antibiotics and quality indicators

With this program, the organizers intent is to attract PhD students, postdoc researchers in the field of DUR and civil servants handling DU data.

Should you be interested, please note the date. Registration details will follow soon.

Monique Elsevier

ISPE Mid-Year meeting

Increasing access to Drug Utilization Data



It was EuroDURG who initiated an action to increase access to DU data during the EuroDURG conference in Glasgow in November 2017. A first version of the Declaration was proposed to the participants of the EuroDURG conference with the invitation to subscribe the declaration on web-based platform. а

During the following months a DU data working group with global representation was created aiming to improve the Declaration. During the ISPE conference of 2018 in Prague, the SIG DUR organized a wellattended workshop where the challenges of accessing DU data in different parts of the world were discussed, barriers and enablers were identified and strategies to address them were proposed. It became more clear that in many regions of the world, efforts still have to concentrate on creating noncommercial databases of DU,

for public and private sectors of health care. In other countries, actions have to concentrate on the accessibility of existing DU data, in a timely manner and free of charge for policy purposes and research. The DU working data group is discussing now how to develop a strategy for dissemination of the Declaration and to organize the subscription by individuals as well as organizations.

Monique Elseviers



New WHO Collaborating Centre focused on the patient perspective at the University of Copenhagen

'The WHO Collaborating Centre for Research and Training in the Patient Perspective on Medicines Use' is the name of the unit established by the Social and Clinical Pharmacy research group at the Department of Pharmacy at the University of Copenhagen in cooperation with the UN World Health Organization (WHO).

The appointment is recognition of the fact that the research group for decades has set an example with regard to integrating patient perspectives in research on medicines use,

As collaborating centre, the research group has committed to three work activities within research and teaching. Among other things, they must make their research results and qualitative methods more widely available to researchers and health authorities in other countries, teach the WHO's international network to study the patient perspective on medicines, and how patient views and behaviour can be used to plan treatments and in policy making.

The research group cooperated with WHO before the establishment of the centre on disseminating ways of fighting antibiotic resistance in 13 countries. and the strong, highly structured international network provided by WHO is very valuable to the research group.

The designation by WHO was finalised in the spring of 2018, and on 12 November the department held an opening symposium to celebrate.

Anna Birna Almarsdóttir



SIG DUR launched regular newsletters The Monthly Dose



Launched in September 2018, The Monthly Dose is the regular newsletter of the Special Interest Group in Drug Utilization and Health Service Research (SIG DUR) of the International Society of Pharmacoepidemiology (ISPE). The Monthly Dose has over 100 subscribers and features original contributions by its readers from hot topics in drug utilization research to events and short announcements.

Highlights over the past issues of The Monthly Dose have been contributions from our members based in Nigeria, Sudan, India, and Sri Lanka. With a strong growing membership from African and Asian countries, the SIG DUR has benefited enormously from a more inclusive and global member representation. Please sign up here to receive *The Monthly Dose*: <u>Sign up</u>

Here is the link to access our January 2019 issue: <u>The Monthly</u> <u>Dose, January 2019</u>

The Monthly Dose always welcomes contributions by its readers. Are you interested in publishing about your drug utilization work in The Monthly Dose? Please send your contribution to <u>ispesig.dur@gmail.com</u>

We look forward to hearing from you.

Veronika Wirtz and Ismaeel Yunusa, Editorial Team of The Monthly Dose

Report on the ENCePP activities

The ENCePP activities for the last year have been adjusted to the EMA Business Continuity Planning (BCP) which prepares for the consequences of the United Kingdom's exit from the European Union. This decision has had a temporary impact on ENCePP related activities, as the ENCePP plenary meeting scheduled for November 2018, which was cancelled. However, ENCePP activities undertaken bv partners and not requiring EMA organisational and meeting support continued as before.

Report on Working Group activities (WG)

Working Group Research Standards and Guidances.

The latest revision of the ENCePP Methods Guide was published on 13 July 2018. A couple of new chapters have been included.

Due to developments in some areas or need for restructuring and clarification, the ENCePP Guide has been more significantly revised in the following chapters:

- 4.3. Patient registries
- 4.5. Social media and electronic devices
- 4.6. Research networks
- 5.1. Definition and validation of drug exposure, outcomes and covariates
- 5.3. Methods to address bias
- 5.9 Methods for
 - pharmacovigilance impact research (new chapter)

Working Group Independence and Transparency

The Steering Group supported the publication of the ENCePP Code of Conduct Rev.4. The publication will include feedback from various stakeholder perspectives. Α survey will be distributed to industry, patient organisations, organisations, HCP public health institutions, HTA and ENCePP partners.

Working Group Data sources and multi-source studies

This working group is focusing on an Inventory of EU data sources and methodological approaches for multi-source studies. It has identified a need for clarification on the chapter of the ENCePP Methods Guide on the different strategies in Europe for the conduct of multi-database studies. The group will publish a relevant commentary.

Report on Special Interest Groups

Special Interest group on Drug Safety in Pregnancy

The document "Overview of data sources for drug safety in pregnancy research" is periodically reviewed and available on the ENCePP website.

The EMA has funded a study to identify, across all member states, all data sources that are or can potentially be used for evaluating associations between in utero exposure and adverse pregnancy outcomes that do not become apparent until long after exposure or marketing.

Special Interest Group on Measuring the Impact of Pharmacovigilance Activities

The mandate of this SIG is to provide recommendations (e.g.

in form of guidance documents) to the PRAC Interest Group on impact on the key methodologies for measuring health outcomes of pharmacovigilance activities. The Group has worked on the two new chapters included in the ENCePP Methods guide.

Report on other ENCePP activities:

A symposium at this year's ICPE meeting has been presented. The objective was to outline the achievements of ENCePP after 10 years (see also publication in PDS: doi: 10.1002/pds.4381.) and discuss future ENCePP dynamic development. An interesting presentation was given by Jiri Vlcek on the status of pharmacoepidemiology in Eastern European countries. The presentation highlighted the low level of training and expertise, lack of requirements from national authorities to involve PhEpi experts and lack of access to data. The ENCePP Steering Group (SG) was invited to reflect on how ENCePP might help to improve this situation.

It was suggested that there is a big scope for cooperation at academic level. Support is particularly needed in the area of outcomes research, and the SG considers it most useful to start contacting the individuals from eight countries identified by Jiri Vleck who already have relevant experience, in order to identify priorities and possible actions most useful to engage Eastern European countries. This telephonconference happened in the autumn with the participation of 3 Eastern EU countries (Hungary, Croatia, Romania). ENCePP will do further actions.

A teleconference between the ENCePP Steering Group and Sten Olsson, President of ISoP, took place on 12 September 2018. The meeting was organised to discuss suggestions from ISoP. The teleconference was ended wirh a series of agreed actions.

Luisa Ibanez



Successful Nordic Pharmacoepidemiology Network (NORPEN) meeting in Oslo, Norway.

Several EuroDURG members attended the 11th NORPEN meeting in Oslo 7-9th November 2018. During two days 96 researchers in Pharmacoepidemiology across the Nordic countries met to exchange ideas and present the latest of their research on Drug utilization and Drug Safety. The topic of the conference was "From the Womb to the Grave Life-Course Pharmacoepidemiology".

In total, 6 key note lectures, 1 round table debate, 9 presentations of Nordic collaborative studies/hot topics and 19 "Pharmacoepi slam" presentations were given. An important topic was also how to share sensitive data across the Nordic countries.

A preconference courses on "genetic epidemiology" was attended by 23 participants.

The next conference will be in Denmark in 2019. More information can be found: http://www.norpen.org/ pages/meetings.html

Hedvig Nordeng

News from other continents with involvement of EuroDURG



LATIN AMERICA

Brazilian chapter

The International Brazilian Chapter of ISPE was born from several important initiatives. Firstly, scientific meetings that took place in Rio de Janeiro: the "Pharmaco-2013 seminar epidemiology Research in Latin America", the 2015 seminar "Pharmaco-epidemiology Research on Essential Medicines" and the 2017 seminar "Drug Utilization in Country and Research Contexts". Health System These seminars were held in Rio de Janeiro, Brazil, and were coordinated by Prof. Dr. Claudia Osorio-de Castro. The 2017 seminar was co-chaired by Drs Tatiana Borges Luz and Juliana Álvares. Also of critical importance were two collaborations in projects ISPE funded bv and coordinated by Dr. Maribel Salas.

Considering the involvement of Brazilian researchers who Utilization conduct Drug (DUR), Research and participate in both the EuroDURG and ISPE groups, the founding of the Brazilian Chapter was motivated by the possibility of collaborations in national surveys with experts from other continents. It was agreed that there should be a proactive group in Brazil that could stimulate and facilitate training in methods for Pharmacoepidemiology & Pharmacovigilance, collaborative research, share information and facilitate access to data throughout Brazil.

The projects Pharmacoepidemiology Capacity Building Electronic Survey for the Latin American and African Regions and Good Practices of Drug Utilization Studies in Countries from the LatAm and African Regions, coordinated by Prof. Maribel Salas, who has always worked strongly for the Brazilian chapter to be created, have provided the engagement of Brazilian researchers with researchers from various regions of the world. Subsequently, with the encouragement of Prof. Dr. Monique Elsevier, we proposed the Publicly Available Data Sources Project for Drug Utilization Research in Latin American (LatAm) countries. This Project aims to identify catalogue publicly and available data sources for DUR from LatAm countries and to characterize these data sources. We have been able to involve in this project researchers from eight Latin American countries.

Currently, the Brazilian International Chapter, officially approved in April 2017, is made up of 23 members from several countries. Several active members in EuroDURG participate in the Brazilian chapter, such as Prof. Drs. Monique Elsevier and Björn Wettermark. Since work began, there have been five educational Webinars to expand and improve the quality of DUR in Brazil.

Two Symposia of the Brazilian Chapter are planned in different regions of Brazil. Two major conferences offered to host the Brazilian International Chapter meetings: the Brazilian Congress of Hospital Pharmacy (May 2019) and Congress of the Regional Pharmacist Council of São Paulo (October 2019).

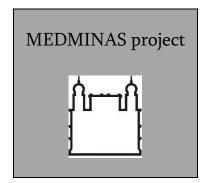
The Brazilian Congress of Hospital Pharmacy, Fortaleza, CE, Brazil is expected to be attended by 1,000 participants including foreign guests. The first meeting of the Brazilian International Chapter of ISPE will take place on Saturday, May 25. For this first event a round table will be held, with participation of Drs. Monique Elsevier, Maribel Salas, Claudia Osorio-de-Castro, Luciane C Lopes and other Brazilian researchers.

The second congress that offered to host a meeting of the Brazilian International Chapter of ISPE is the 20th Meeting of the Regional Pharmacy Council, São Paulo, Brazil, 10-12 October, which attracts approximately 3,000 participants from all areas of Pharmacy. The president of this congress proposed two activities that will focus on DUR, that our Chapter will be coordinating. The final

program is under discussion with members of the Chapter.

DUR in Brazil must happen in a way. The collaborative databases do not provide linkage possibilities. Data and information health. on although described as 'available' when formally requested, are not always so. There are still challenges as to equity in access to reliable information by research groups in Brazil. There are several PE Pharmacovigilance & publications, as can be seen on indexing bases such as PubMed, groups but the do not collaborate with each other and do not share information to improve the quality of research or even to form new groups. This chapter is expected to be able to change this scenario.

Luciane Cruz Lopes (Chair) Claudia Osorio-de-Castro (Co-Chair), Maribel Salas (Co-Chair)



A new collaborative project has been launched in Brazil. Providing and articulating data on context, rationale, benefits and threats to health programs is essential to healthcare system managers for system's development and refinement. Under this perspective, the research project "Pharmaceutical Services Based on Primary Care in Minas Gerais: evaluation of services and medicines provision and of use of medicines. MedMinas Project", a mixed methods study in 26 municipalities of Minas Gerais State was started last year. The project is funded by Minas Gerais State Agency for Research and Development (Fapemig), the **MedMinas** project is coordinated by Dr Tatiana Luz, researcher from and Fiocruz. involves researchers from six universities/research institutes in Brazil. Aiming to describe drugs prescribed and dispensed within Primary health care, to assess medicine availability, use patterns, spending and perceptions of social capital, health status and comorbidities. and whether pharmaceutical services programs are fulfilling their goals, it also presents the innovative goal of proposing professional guidelines to training for pharmaceutical services' personnel. Throughout 2018, five Seminars were held in Belo Horizonte, Minas Gerais, to discuss the project with academics and non-academics (healthcare managers and health professionals). From these discussions, the research developed team seven instruments to collect data from managers, health professionals and patients, as well as educational materials to be distributed to patients. Data collection will begin soon. The

MedMinas project is expected to offer new understanding about what works in the Brazilian pharmaceutical services, and what does not, assessing how true the healthcare system in Brazil is staying to its mission and vision.

Tatiana Chama Borges Luz



MURIA (Medicines Utilisation Research in Africa) Group grew out of initiatives with ISPE, EuroDURG, and the World Congress for Basic and Clinical Pharmacology in South Africa in 2014.

MURIA 4 was held at the University of Namibia in 17 -20 June 2018, with topics again both infectious including diseases and NCDs. In addition to the educational workshops run by ISPE personnel, Dr Sean MacBride-Stewart (Scotland), Prof Ilse Truter (South Africa), Prof Hennelie Meyer (South Africa), Dr Margaret Oluka (Kenya) and Dr Sylva Opanga (Kenya) conducted Advanced workshops including: Developing Quality Indicators ambulatory for care. Undertaking Qualitative DU Research. Undertaking adherence/persistence studies and Undertaking pharmacovigilance studies. The symposium subsequently included presentations from a number of African countries around their ongoing DU activities principally around antimicrobials. This was followed by multiple oral and poster presentations of ongoing research (25 oral presentations in all as well as 46 posters). The last session of the symposium included a business meeting to progress the development of a draft constitution for MURIA, closer ties with ISPE/ ISPE Africa as well as agree the venue for MURIA 5. This is important as DU research in Africa is challenging, with typically many healthcare systems still paper based and with extensive self-purchasing of medicines. The enthusiasm for DU research in Africa has already resulted in over 70 publications in peer-reviewed involving journals **MURIA** members from 2 or more countries since 2015. In addition, a number of MURIA members have been part of national action plans in their country addressing concerns with current antimicrobial use and the rising prevalence of NCDs.

Planning for MURIA 5 to be held at the North-West University, Potchefstroom, South Africa, from 8 to 11 July 2019, is now well underway led by the Scientific and Local Organising Committees (led by Prof Johanita Burger). А proposal has also been sent to the ISPE Executive Committee, endorsed again by the Global Development Committee, to support 3 Professors to come to South Africa in July 2019 to conduct educational workshops sponsor as well as 4 postgraduate students to present their work. Funding has also been obtained for Dr Pia Caduff-Janosa to present on the efforts of the Uppsala Monitoring Centre to increase pharmacovigilance in the African region and future plans. More details will be available on the MURIA website as they evolve. In the meantime, any DU researcher interested in working with colleagues in Africa is urged to mark these dates on their calendars and attend to develop closer links with colleagues in Africa, as well as complete a membership form for MURIA: http://muria.mandela.ac.za/Me mbership) and join the ISPE Africa chapter.

Brian Godman



Please, find information about current international or European conferences, held in English of interest for DU studies or research. For national conferences please see country specific news below.



The 2019 Mid-Year Meeting of ISPE will be organised at the Radisson Blue Hotel, Rome, Italy, April 6-9, 2019.

Abstract submission deadline has passed

For more information visit: <u>https://www.pharmacoepi.org/</u><u>meetings/mid-year-2019/</u>

The35thInternationalConferenceonPharmaco-epidemiology&TherapeuticRisk Managementwill be heldatthePennsylvaniaConnectionCenter,Philadelphia, PH, USA August24-28, 2019.

The agenda will be available in the coming months.

Deadlineforabstractsubmission(poster/oralpresentationorsymposium,workshop:February 13, 2019.

For more information and submission of an abstract: <u>https://www.pharmacoepi.org/</u> <u>meetings/35icpe/</u>



The 19th Annual Meeting of the International Society of Pharmacovigilance (ISoP 2019), "New opportunities for new generations", will take place in Bogota, Columbia, 6th-9th November 2019.

The abstract submission deadline is not yet available

The draft program includes topics such as medication errors, risk communication, risk management plans and signal detection, pharmacovigilance education throughout the system, herbal medicines, women's medicines, social network impact in pharmacovigilance, patients and pharmacovigilance.

Venue: Grand Hyatt Bogota, Bogota, Columbia.

For more information visit: http://www.isop2019bogota. org/

International Conference on Pharmacoepidemiology & Therapeutic Risk Management



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Deadline for abstract submission: 13th February, 2019

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European Association for Clinical Pharmacology and Therapeutics

The 14th EACPT Congress will be held from 29th June to 2nd July, 2019, in Stockholm, Sweden, in partnership with the Swedish Society for Pharmacology, Clinical Pharmacology and Therapeutics.

Many themes will be of interest for drug utilisation researchers.

For more information visit the website of the organisation: https://www.eacpt.eu/eacpt-meetings-scheduled-for-stockholm-2019/

Preceding the EACPT congress, a 3 day EuroDURG Summer School will take place in Stockholm. See further information earlier in this Bulletin.



The ESCP spring workshop 2019 "State of the art in anticoagulation therapy: challenges and opportunities for pharmacists" will be held on 17 and 18 May 2019 in Antwerp, Belgium. This conference will explore the roles and responsibilities of pharmacists working in various settings, including community pharmacies and hospitals, in providing the best pharmaceutical care and clinical pharmacy services to patients on anticoagulation.

Abstract submission deadline: 10 February 2019

The 48th European Symposium on Clinical Pharmacy, "Support of e-health/clinical decision support systems and big data to optimal clinical pharmacy" will be held in Ljubljana, Slovenia, 23rd -25th October, 2019

For more information visit: <u>http://www.escpweb.org/</u>



The HTAi 2019 Annual Meeting: "Strengthening the Evidence-to-Action Connection", will be held June 15 – 19, 2019 at the Maritim Hotel Cologne, Cologne, Germany.

One year ahead of the end of a number of prominent HTA strategies and projects, the course will (and has to) be set for future development of HTA worldwide in 2020 and beyond. Thus, the preliminary results will fuel the debate about the future of HTA.

Abstract submission deadline has passed.

For more information visit: <u>http://htai2019.org/</u>



EuroDURG summer school on drug utilisation research

DATE: 26th – 29th June, 2019 Venue: Stockholm City Centre



The 23th 'meeting of the European Society of Patient Adherence, Compliance and persistence (ESPACOMP) will be organized in Porto, Portugal between November 21-23, 2019.

Further information will follow soon. For more information please visit: http://www.espacomp.eu/meeti ngs/view/54#toc_2



The next meeting of the Nordic Pharmaco-epidemiology Network meeting will be held in Aarhus, 13-15 November 2019.

For more information visit: http://www.norpen.org/pages/m eetings.html

Gabriel Sanfélix-Gimeno, Ria Benko



Good practice guidelines for conducting and reviewing cross-national comparison (CNC) drug utilization studies

In 2015, the EuroDURG working group on CNC studies received an ISPE grant to develop a methodology to assess the validity of cross-national drug utilization studies and to develop a good practice guideline for designing, conducting, reporting and reviewing CNC studies. After several rounds of internal discussion and external review, we submitted in 2018 the following materials for final approval:

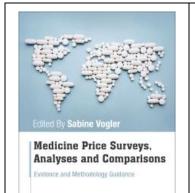
• An article describing how the different CNC tools and the

guideline were developed, amended and presented in the final format

- A scoping review of Cross National Comparison (CNC) studies providing a comprehensive overview of methodological approaches to perform CNC studies
- A checklist to evaluate CNC studies focusing on the systematic evaluation of all sources of bias that could jeopardize the validity of the comparison.
- A good practice guideline for CNC studies highlighting the specific comparative aspects of DU studies offering DU researchers and reviewers a practical tool for designing, conducting, reporting and reviewing CNC studies.

After approval by the ISPE Planning Committee, the documents will be made publicly available on the ISPE/EuroDURG website.

Monique Elseviers



Medicine Price Surveys, Analyses and Comparisons. Evidence, Methodology and Guidance is a recently published comprehensive book on medicine prices: addressing researchers, teachers and students, policy-makers, and public health experts, it reviews evidence on medicine prices for different therapeutic groups in various regions of the world. The book also offers guidance on how to conduct medicine price studies. Several chapters related to external price referencing inform about implementation, benefits and limitations of this pricing policy and discuss options for improvement.

Read more: https://www.elsevier.com/books/medicine-price-surveys-analyses-and-comparisons/vogler/978-0-12-813166-4

News from European NATIONAL DURGs

Austria

From 23 to 27 July 2018, 38 participants of public and nonfor profit institutions working in the field of pricing and reimbursement of medicines of 23 different countries attended the third Summer School on Pharmaceutical Pricing and Reimbursement Policies in Vienna. The WHO Collaborating Centre Pharmaceutical for Pricing and Reimbursement Policies at the Austrian Public Health Institute (Gesundheit Österreich GmbH / GÖG) and the World Health Organization (WHO), Regional Office for Europe organised the five-day Further training course. information:

https://ppri.goeg.at/summerscho ol2018.

The Pharmaceutical Pricing and Reimbursement Information (PPRI) network comprises competent authorities for pharmaceutical pricing and reimbursement in 47, mainly European, countries. The aim of the network is to collect and share information about pricing and reimbursement policies for medicines and to exchange experience about good practices. Recently, the WHO Regional Office for Europe and the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies have been working on identifying

approaches of collaboration with the Commonwealth of Independent States (CIS) through more targeted cooperation in a **PPRI CIS** network. Following up on a kickoff network meeting with competent authorities of this region, held in Chisinau (Moldova) in 2017, the PPRI CIS network had a second meeting in Baku (Azerbaijan) in May 2018. More information: https://ppri.goeg.at/Regional PP **RI** networks

The Austrian Presidency of the Council of the European Union (July – December 2018) had medicines as one focus in the area of health. In support of the Austrian Council Presidency 2018, the European Observatory on Health Systems and Policies prepared two Policy Briefs on the topic of access to medicines: http://www.euro.who.int/ data /assets/pdf file/0009/379701/PB 29 AUSTRIA web 13082018.p df

http://www.euro.who.int/ data /assets/pdf_file/0009/379710/Pol icyBrief_AUSTRIA_PB30_web 13082018.pdf

Save the date: 4th PPRI Conference, Vienna, 23 and 24 October 2019

The 4th international PPRI Conference titled "Medicines access challenge - The value of and reimbursement pricing policies" will be organised by the WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies in Vienna on 23 and 24 October 2019. The conference will look

into current developments in pricing and reimbursement policies and future challenges. To ensure equitable access to affordable and cost-effective medicines. the following perspectives will be discussed:

- Strand 1: Local challenges, global learnings? – Learning from best-practice examples in the field of pricing and reimbursement of medicines
- Strand 2: "Fake prices" Are price surveys still useful? The value of list prices in light of external price referencing and managed entry agreements
- Strand 3: Fix the future? -Innovative policy options

A call for abstracts will be launched in February 2019. For further information: http://ppri.goeg.at/ppriconferenc e2019

Sabine Vogler

Norway

In November 2018, the Norwegian Society for Pharmaco-epidemiology participated in the organization of the NorPEN-meeting (Nordic Pharmacoepidemiological Network, www.norpen.org). The

meeting was held at the University of Oslo. The theme of the meeting was "From the Womb to the Grave Life-Course Pharmacoepidemiology".

International and Nordic researchers, as well as PhD-

students shared and discussed their research experiences during three long days. A special thanks to the internal keynote speaker Dr Kristin Palmsten; Dr Palmsten presented her latest research on longitudinal trajectories to model exposure in pharmacoperinatal epidemiology research. Of special interest the was discussion about how to share sensitive data across the Nordic countries.

In May 2018 the Norwegian Society Pharmacofor epidemiology held its annual meeting in Bergen. The annual meeting had multiple presentations related to drug utilization research, specifically about use of psychotropic medications in women with urinary incontinence, use of hormonal contraceptives among second-generation firstand immigrant women in Norway, or medications prescribed by dentists in Norway between 2004 and 2015. Other themes of the annual meeting spanned from risk factors for stroke and choice of oral anticoagulant in atrial fibrillation, to how data from the Norwegian Prescription Database can be of value in providing novel knowledge on Parkinson disease. Details about the full program of the meeting can be found here: https://farmakoepinorge.files.wo rdpress.com/2018/03/fagligprogram-vc3a5rmc3b8te-2018.pdf.

In 2019, the annual meeting of the Norwegian Society for

Pharmacoepidemiology will be held in Oslo on April 25th.

Angela Lupattelli

Germany

In November 2018, the German national DURG "Society for Drug Utilization Research and Drug Epidemiology" (Gesellschaft für Arzneimittelanwendungsforschung und Arzneimittelepidemiologie, GAA) held its 25th annual meeting in Bonn.

The meeting had four main themes: medication safety (AMTS) and discharge management, drug utilization research with secondary data in times of the innovation fund, ethical and cultural aspects of medication therapy and the Choosing Wisely initiative, a campaign led by the German society for internal medicine: a critical analysis with a special focus on medication therapy. Several speakers were invited to provide insight into the topics. Further presentations were given by various researchers who presented their ongoing research in these fields in Germany. Research projects of participants were presented during oral and presentation poster sessions. Details of the meeting including the abstracts are to be found at http://www.egms.de/de/meeting <u>s/gaa2018/</u>.

For 2019, the 26th GAA Annual Meeting is planned to be held

from November 21st–22nd in Bonn.

Please contact Katrin Farker (<u>katrin.farker@med.uni-jena.de</u>) or see our website for further information: <u>http://www.gaa-arzneiforschung.de</u>.

Katrin Farker Chair of German DURG

Italy

The 2017 Italian DU report has been published by the Italian Medicine Agency (AIFA) and it is available at the following address

http://www.aifa.gov.it/content/rapp orti-osmed-luso-dei-farmaci-italia . It describes amount and expenditure of reimbursed medicines, with some aggregated data on private expenditure and self-medication. Also a synopsis for each single region has been made available.

National DU data for the most used drug classes are also included in the annual report of the Italian College of General Practitioners and Primary Care (http://report.healthsearch.it/),

which combines information on diagnoses with drug prescription. The Regional Healthcare Agency of Tuscany (ARS Toscana) published its third report on drug utilization

(https://www.ars.toscana.it/imag es/Documento_Farmaci_2018_D EF.pdf), that contains 11 burning questions and the relevant answers throughout the analysis of DU data (e.g., switches among biosimilars and relevant consequences in terms of expenditure and clinical effects; durability as proxy of efficacy of antidiabetic drugs; pattern of antidepressant use in different settings of care).

The National Institute of Health (ISS) organized the บรบอโ conference on drug utilization and pharmacovigilance, with specific focuses on deprescribing initiatives on PPIs, inappropriate drug use in the elderly, adherence to drug therapy in sclerosis multiple (http://www.epicentro.iss.it/farmaci /valutazione-uso-sicurezza-farmaciesperienze-italia-2018).

The "Mario Negri" Institute prepares a quarterly newsletter on the initiatives in pharmacoepidemiology (publications and events) in Italy with the collaboration of the Italian members of the ENCePP network.

On March 18-19, 2019 the Spring Conference of the Italian Association of Epidemiology will take place in Bologna. The section on pharmacoepidemiology will include a focus on drug utilization.

On April 6-9, 2019, ISPE midyear conference will take place in Rome https://www.pharmacoepi.org/m eetings/mid-year-2019/agenda/ .

Elisabetta Poluzzi

Scotland

In our news from Scotland this year we report on a number of initiatives which have kept our growing pharmacoepidemiology and health care research team at the University of Strathclyde busy. But firstly, I would like to thank again the team and our wider Scottish DUR research and health service community for helping us to host the Glasgow conference, for which I have had great feedback on when travelling to present and engage in DUR activities across Europe and more internationally in 2018 engagement your and hospitality to our visitors has certainly put Scotland on the map - and I hope this also provided you with a platform for collaboration through 2018.

In 2018 we saw the completion of the Farr Institute 5 year program of work with a celebration of our achievements in May 2018 in Dundee. This funding provided the platform to progress work to better curate, provision and use our national primary care prescribing dataset -PIS- including a nice piece of work using natural language processing to codify drug instructions on our 100 million prescription items per annum and make this available through our national data save haven platform to researchers who have sought the necessary approvals. (McTaggart Nangle S, С, Caldwell J, Alvarez-Madrazo S, Colhoun H, Bennie M. Use of

text-mining methods to improve efficiency in the calculation of drug exposure to support pharmacoepidemiology studies. International Journal of Epidemiology 2017 Nov 23. DOI: 10.1093/ije/dyx264 2).

The new UK Health Data Research (HDR) institute, was established, May 2018, building upon the work of Farr. The Scottish Centre is a collaborative across the five medical schools and the pharmacy school at Strathclyde and includes a workstream focused on Precision Therapeutics, building on our Farr pharmacoepidemiology programme and extending to include pharmacogenomics.

The Scottish DUR community has also played a key part in shaping a Scottish Government report: Building Capability to Assess Real-World Benefits, Risk and Value of Medicines: Towards a Scottish Medicines Intelligence Unit

https://www.gov.scot/Topics/H ealth/NHS-

Workforce/Pharmacists/datasco pingtaskforcereport, published September 2018. This report sets out our current capabilities, the gaps and recommends key next steps - worth a read.

Finally, we continue to work with our international partners in Brazil (focusing on cancer), Kenya and South Africa building their antimicrobial stewardship capacity and also looking to expand our Scandic collaborations, centred on patient level analyses. We look forward to a busy and exciting 2019– growing the team, hosting visitors and supporting our local and international communities with high quality evidence using real world prescribing data to shape clinical practice.

Marion Bennie



The 30th Annual Scientific Meeting of PRIMM (Prescribing Research in Medicines Management), was a celebratory event. They also celebrated the life and work of Prof Hugh McGavock one of the founders of this organisation, known then as the Drug Utilisation Research Group (DURG). Several committee members and some attendees recall the early meetings, when there were no other conferences or meetings at which the patterns of and research into drug use was being discussed. Prof Colin Bradley with shared the meeting attenders the innovative and dedicated work to which Hugh McGavock devoted many years (Mr. McGavock died in 2018). There were many outstanding lectures. Prof Stephen Byrne, College University Cork,

described the trials and tribulations of trying to carry out an international study involving computerisation of the STOPP/START criteria: SENATOR. A total lack of harmonisation of the drugs files and codes used across the six countries involved in the study meant a great deal of time was needed to develop a common drug list, before the STOPP criteria could be embedded into online an decision support system to enable alerts to be generated. Despite the problems, two large studies have been completed: observational an study involving 600 patients which validated the STOPP and criteria а randomised controlled trial of the use of STOPP in clinical decision support systems. More on ongoing EU projects involving STOPP-START the criteria https://www.senator-project.eu https://operamand 2020.eu/index.php?id=1488

Jackie Whittle, Leeds Teaching Hospitals NHS Trust, described computerisation how can. however, support the patient journey, through linking a patient's electronic health record with medicine charts and laboratory data. The Leeds electronic health record enables integrated care to be supported across boundaries, extending not only into general practices, but also hospices and out of hours care. There is a desire to include community pharmacies at a later stage once IT infrastructure and governance are in place. Trust have developed their electronic health record systems internally and ensured the involvement of clinical staff at all stages. The

statistics for electronic prescribing were impressive: it covers 146 clinical areas, enables electronic discharge advice notes and around 10,000 prescriptions are processed every day. Echoing the previous speaker, Jackie's take home message was that digitalising the NHS is about people - knowing how they work, finding out how they may need to change the way they work and if they are ready to change.

Victoria Hussey, from the Behavioural Insights Team, talked about changing practice and behaviour by 'nudging' people to make better decisions and presented some examples of how a very inexpensive and simple change to a way of working can have a significant impact on behaviour. Her team's philosophy is to develop interventions which are based on formula the EAST: Easy, Attractive, Social and Timely. An example with important implications was a letter, sent to the general practices in London with the highest level of antimicrobial prescribing, signed by the Chief Medical Officer and listing three easy ways they could take action to change their prescribing. This made use of both social norms theory and the messenger effect (use of a respected opinion leader) as well as using simple messages to make change easy; the intervention showed a reduction in antibiotic prescribing reduced in the practices that got the letter versus the control group (no intervention).

Finally, Teresa Chinn MBE described ways in which social media could be harnessed to empower people to take control of their own healthcare and be actively involved in it. She described four ways of using social media in healthcare: to share practice, as a part of practice, to inform practice and practice. celebrate For to example, it could be used by professionals health to communicate with the people they are caring for, enable them to connect with each other so they can ask questions and benefit from expertise, but also create opportunities for coproduction maybe leading to new ways of working. Health professionals do need to learn how to use social media to

The meeting was attended by a good number of PhD students. A 20 total of posters were displayed, plus four oral presentations given. The winner of the Hugh McGavock bursary was Dr Elaine Walsh, University College, Cork, for the PHARMS Patient Held Active Record of Medication Status.

support healthcare.

The winner of the poster prize was Fatema Algenae, a PhD student from the University of Manchester. her poster for "Prevalence and nature of medication errors and medication related harm immediately following discharge from hospital to community settings: a systematic review".

The posters and presentations demonstrated the diversity and quality of research going on in the area of medicines use in the UK and Ireland. Abstracts will be published in Pharmacoepidemiology and Drug Safety later this year.

Sean MacBride-Stewart

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