



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patient focus at ICPE 2014

International Conference on Pharmacoepidemiology & Therapeutic Risk Management

Presented by Priya Bahri
Lead Pharmacovigilance Guidelines & Communication Research

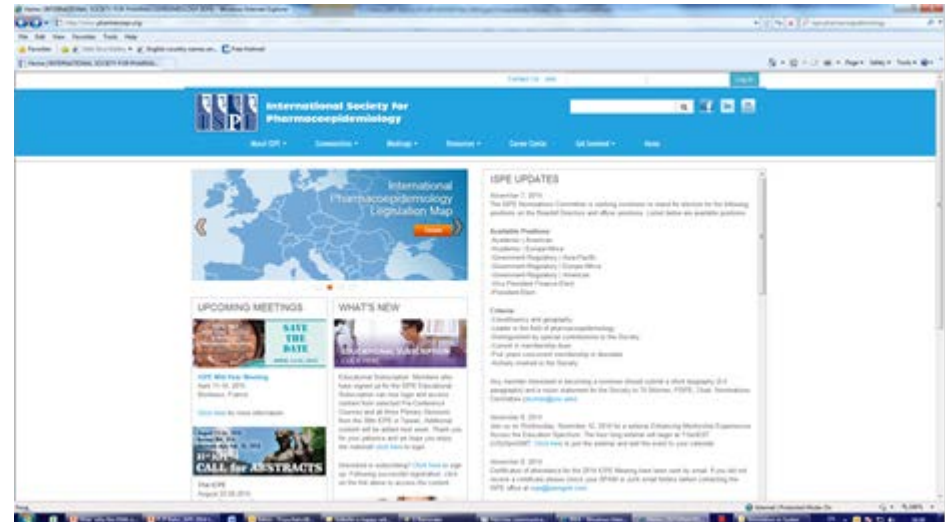
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International Society for Pharmacoepidemiology (ISPE)

- Non-profit international professional membership organization
- Pharmacoepidemiology = science that applies epidemiologic approaches to studying the use, effectiveness, value and safety of pharmaceuticals.





ICPE 2014 Plenary

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AGENDA Sunday, October 26

11:45am-12:45pm
Spotlight Poster Sessions (101)

- Best of the Day
- Adherence
- Benefit Risk Assessment, Communication and Evaluation (BRACE)
- Comparative Effectiveness Research
- Pregnancy

1:00-2:30pm PLENARY SESSION (Plenary Hall, 3rd Floor)

Using Patient-Centered Information in Pharmacoepidemiology: A Global Perspective

Faculty:

- Priya Bahri, Pharmacovigilance, EMA
- Nancy Dreyer, FISPE, Quintiles
- Francois Houyez, Director of Treatment Information & Access, Eurordis; Co-Chair of ISPOR Patient Centered Advocacy Group
- Lynn Weekes, CEO NPS Medicinewise

Moderators:

- Kate Lapane, FISPE, University of Massachusetts Medical School

Patient-centered information (PCI) has gained increasing recognition in recent years, particularly in the realm of comparative effectiveness and safety research. While clinicians have routinely utilized social, behavioral, functional, and symptom-related PCI from their patients to make informed clinical decisions, there is an increasing emphasis from

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“How and why the European Medicines Agency uses patient input during the evaluation of medicines”

ICPE 26 October 2014

Nathalie Bere, presented by Priya Bahri
European Medicines Agency (EMA)



The value of interaction



- Increases **transparency** and builds **confidence** in the regulatory system
- Involvement at operational level leads to **tangible impact** on outcomes;
 - Patients' views on benefit-risk deliberations **contribute to final recommendations** from the committees
 - Review of product information and safety communications - comments are taken into account and **lead to amendments**
- Helps **bridge the gap** between clinical trial data and real world data; thus improving the outcome of regulatory decisions



Input from patients, completes the picture.....





ICPE 2014 Symposium of Special Interest Group BRACE

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Comparing Incremental Net Benefit (INB) of Apixaban, Dabigatran, Rivaroxaban, and Warfarin in Patients with Atrial Fibrillation (AF) [671]
Mehdi Najafzadeh, Sebastian S Schneeweiss, Niteesh K Choudhry, Amanda R Patrick, Jennifer M Polinski, Jerry L Avorn, Joshua J Gagne. (United States)

2:15pm

Comparison of ATRIA and CHA2DS2-VASc Risk Stratification Schemes for the Prediction of Stroke in the Individual Patient with Atrial Fibrillation and the Impact on Treatment Decisions [672]
Hendrika A van den Ham, Olaf H Klungel, Daniel E Singer, Hubert GM Leufkens, Tjeerd P van Staa. (Netherlands)

2:30pm

Testosterone Laboratory Testing and Testosterone Supplementation Use among Adult Males in Denmark [673]
Thomas Bøjer Rasmussen, Helene Nørrelund, Sinna Pilgaard Ulrichsen, J Bradley Layton, M Alan Brookhart, Henrik Toft Sørensen, Christian Fynbo Christiansen. (Denmark)

Methodological Challenges and Potential Cross-Continental Collaboration [678] (201BC)
• Edward Chia-Cheng Lai, Ian Douglas, Kiyoshi Kubota, Byung Joo Park, Nicole Pratt, Ian Wong, Yea-Huei Kao Yang, Soko Setoguchi. (Taiwan)

Special Issues in Pharmacovigilance in Emerging Countries [679] (Elegance Lounge, 4th Floor)
• Syed Rizwanuddin Ahmad, David Lee, Gloria Shalviri, Marie Lindquist. (United States)

The Patient's Voice in the Heart of BRACE (Benefit-Risk Assessment, Communication and Evaluation) [680] (201AF)
• Meredith Smith, Priya Bahri, Gerald Dal Pan, Swapu Banerjee, Peter Mol, Debashish Dey. (United States)

Using Pharmaceutical Data for Evaluating Medicines Policy and Informing Quality Use of Medicines [681] (102)
• Libby Roughhead, Flora Haaijer-Ruskamp, Veronika Wirtz, Parthasarathi Gurumurthy, Lisa G Pont. (Australia)

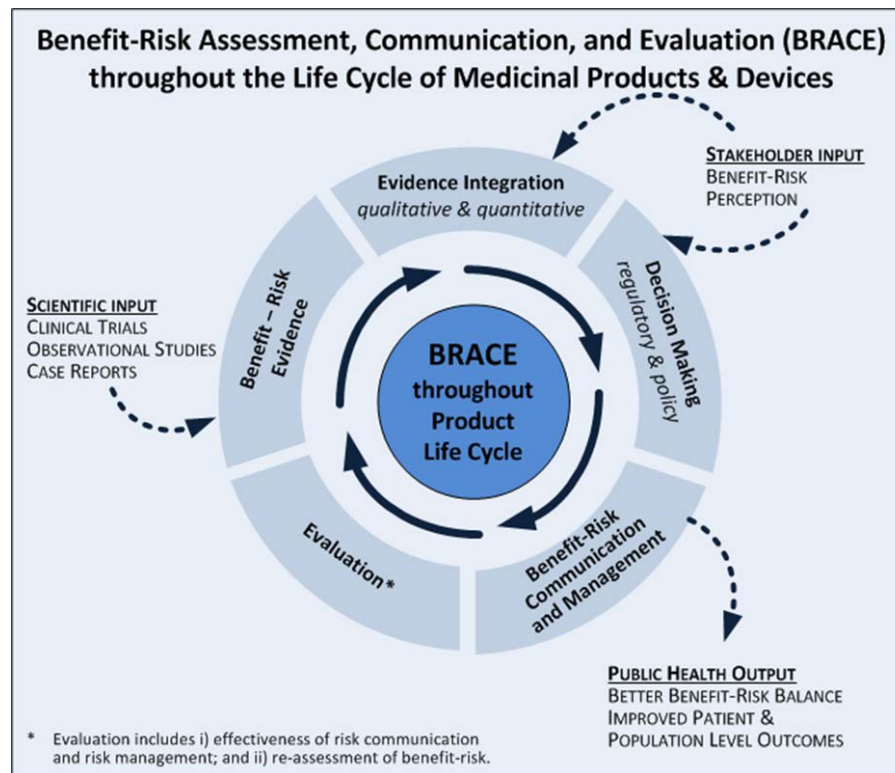
4:45-5:30pm

THE FINAL WORD (4th Floor VIP)

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BRACE cycle





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ISPE Symposium 20 October 2014

The Patient's Voice in the Heart of BRACE - Benefit-Risk Assessment, Communication and Evaluation

How patients contribute to assessments at the EMA and messages for pharmacoepidemiology

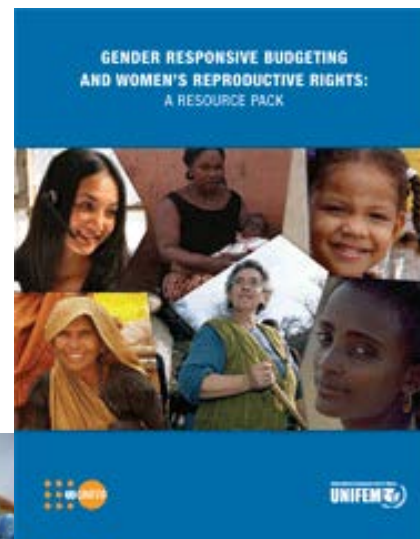
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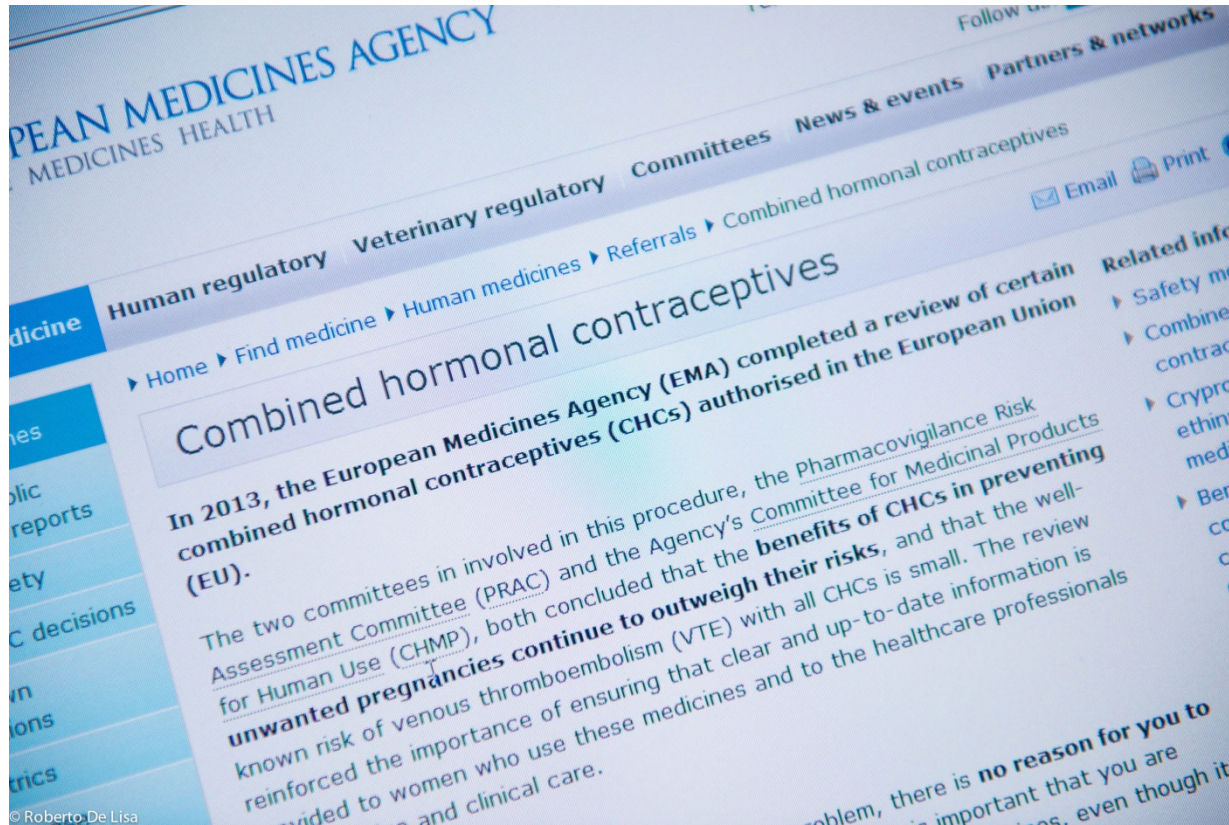
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Combined hormonal contraceptives and VTE







Combined hormonal contraceptives (CHCs) Referral 2013 - Patient/consumer involvement

- Ad-hoc expert group meeting, including patient/consumer organisation representation*
- Pharmacovigilance Risk Assessment Committee (PRAC) written consultation with patient/consumer experts*
- PRAC has patient/consumer members
- Review by patient representatives of educational materials

*Involved organisation: European Institute of Women's Health



Ad Hoc Expert Working Group and PRAC written consultation of patient/consumer experts

- Present absolute and relative risk in understandable language, for different age groups and with information on baseline risk and risk changes over time
- Preferred options for presenting the information on differential risks (PO: table, HPs: relative and absolute risks in a graph)
- For CHCs containing progestogens other than levonorgestrel, include risk for LNG
- Preferred options re comparison with VTE risk during pregnancy (PO: no, HPs: helpful)
- Stress that actual risk is not large, especially not in young women and that all CHCs are very safe with many non-contraceptive and non-contraceptive benefits
- Giving denominator (10, 000) first to see immediately that risk is small (PO)

Internet search on patient perceptions – Example of German patient blog “Risiko-Pille”





Literature search on patient perceptions – Example of Danish study by Hansen DL in female adolescents





EMA-procured study: Patterns and Determinants of Use of Oral Contraceptives in the European Union

The screenshot shows the ENEPP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) website. The main content area displays the details of a study titled 'Patterns and Determinants of Use of Oral Contraceptives in the European Union'. The study is listed as 'Official title' and 'Study type' as 'Observational study'. The study description states: 'The study aims to serve as a basis for future safety evaluations of oral contraceptive use in Europe by assessing current use and treatment characteristics in daily practice in five European databases from the Netherlands, UK and Italy, replacing a source population of 20 million individuals. Specific study objectives are to assess among women using oral contraceptives in 2009 and 2010 in different countries in Europe: prevalence and incidence estimates, demographics, health indicators and mortality and OC treatment characteristics.' The study was last updated on 05/02/2010. The study is coordinated by Exorise, Inc. Pharmacology, Department Research group, Exorise University Medical Center, with a website at www.exorise.com. The primary investigator is Professor Muckelbauer.

ENEPP European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

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E Register of Studies
EU PAS Register

Administrative Details | Scope of the Study | Methodological Reports | Documents

Status: Finalized
Last updated on: 05/02/2010

1. Study Identification

Official title: Patterns and Determinants of Use of Oral Contraceptives in the European Union.
Study title acronym: Use of OC in the EU
Study type: Observational study
Brief description of the study: The study aims to serve as a basis for future safety evaluations of oral contraceptive use in Europe by assessing current use and treatment characteristics in daily practice in five European databases from the Netherlands, UK and Italy, replacing a source population of 20 million individuals. Specific study objectives are to assess among women using oral contraceptives in 2009 and 2010 in different countries in Europe: prevalence and incidence estimates, demographics, health indicators and mortality and OC treatment characteristics.

Was this study requested by a regulator?
Yes: EMA

2. Research centres and investigator details

Coordinating study entity

Centre to which the investigator belongs: Exorise, Inc. Pharmacology
Department/Research group: Pharmacology/Pharmaceutical Research University
Organisation/Affiliation: Exorise University Medical Center
Website/Homepage: www.exorise.com

Details of (Primary) lead investigator

Title: Professor
Last name: Muckelbauer



How can we inform about differential risk for informed choice and create VTE awareness for risk management without creating a scare?

Specific points:

- Natural frequencies
- Hazard function
- Risk factors (or absence)
- Comparator





Messages and questions for pharmacoepidemiology: Important areas for multi-disciplinary BRACE research

How can we obtain good data for:

- Representative patient values, preferences and risk acceptability in relation to benefit
- Utilisation of medicines including differential prescribing and adherence in relation to BR perceptions
- Patient-reported outcomes for benefit and risk
- Risk expression in natural frequencies with denominators taking into account average length of use and hazard functions
- Effectiveness of communication based on combined methods, e.g. survey or media monitoring and medicines utilisation studies



Thank you for your attention

Further information

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Division