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Patient focus at ICPE 2014

International Conference on Pharmacoepidemiology & Therapeutic Risk Management

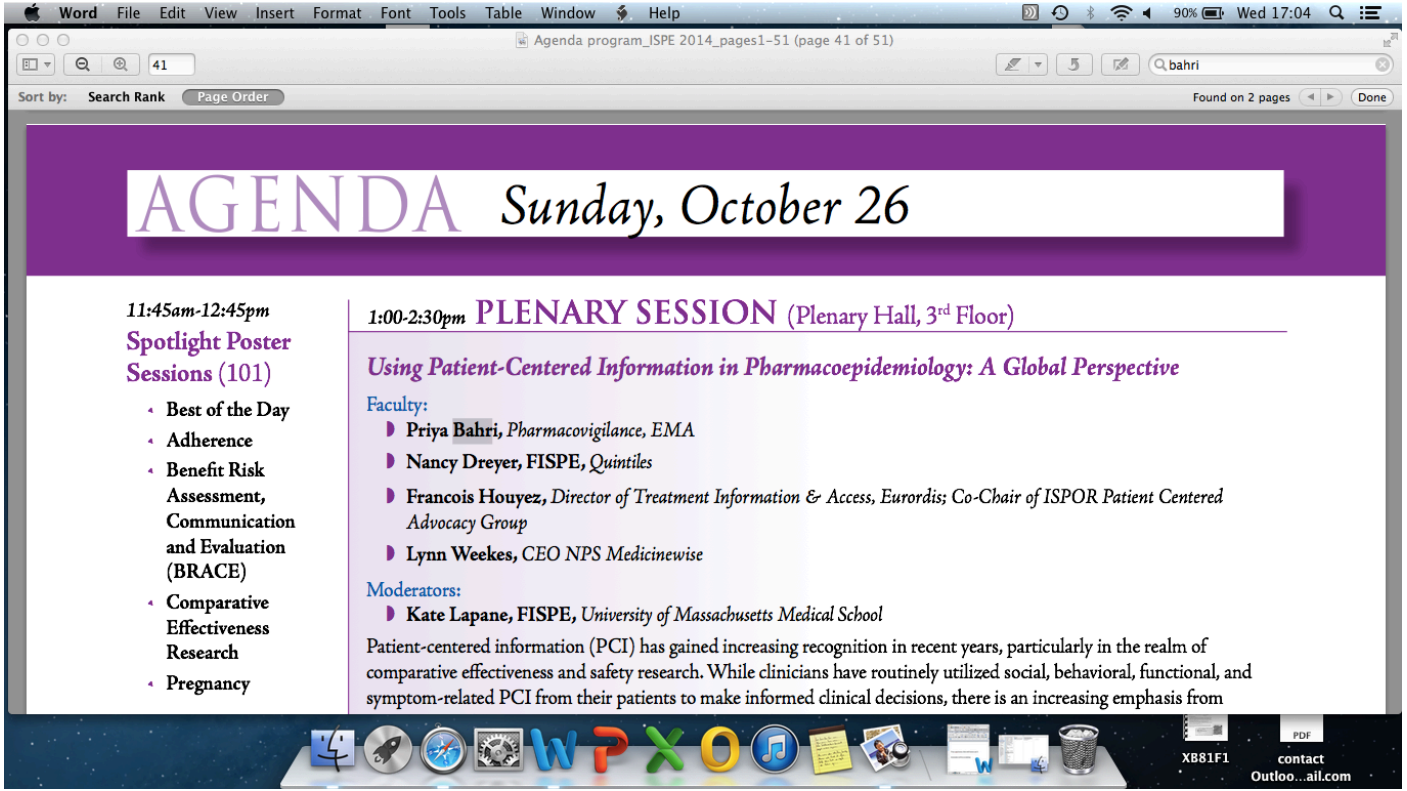
Presented by Priya Bahri
Lead Pharmacovigilance Guidelines & Communication Research

An agency of the European Union

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

ICPE 26 October 2014

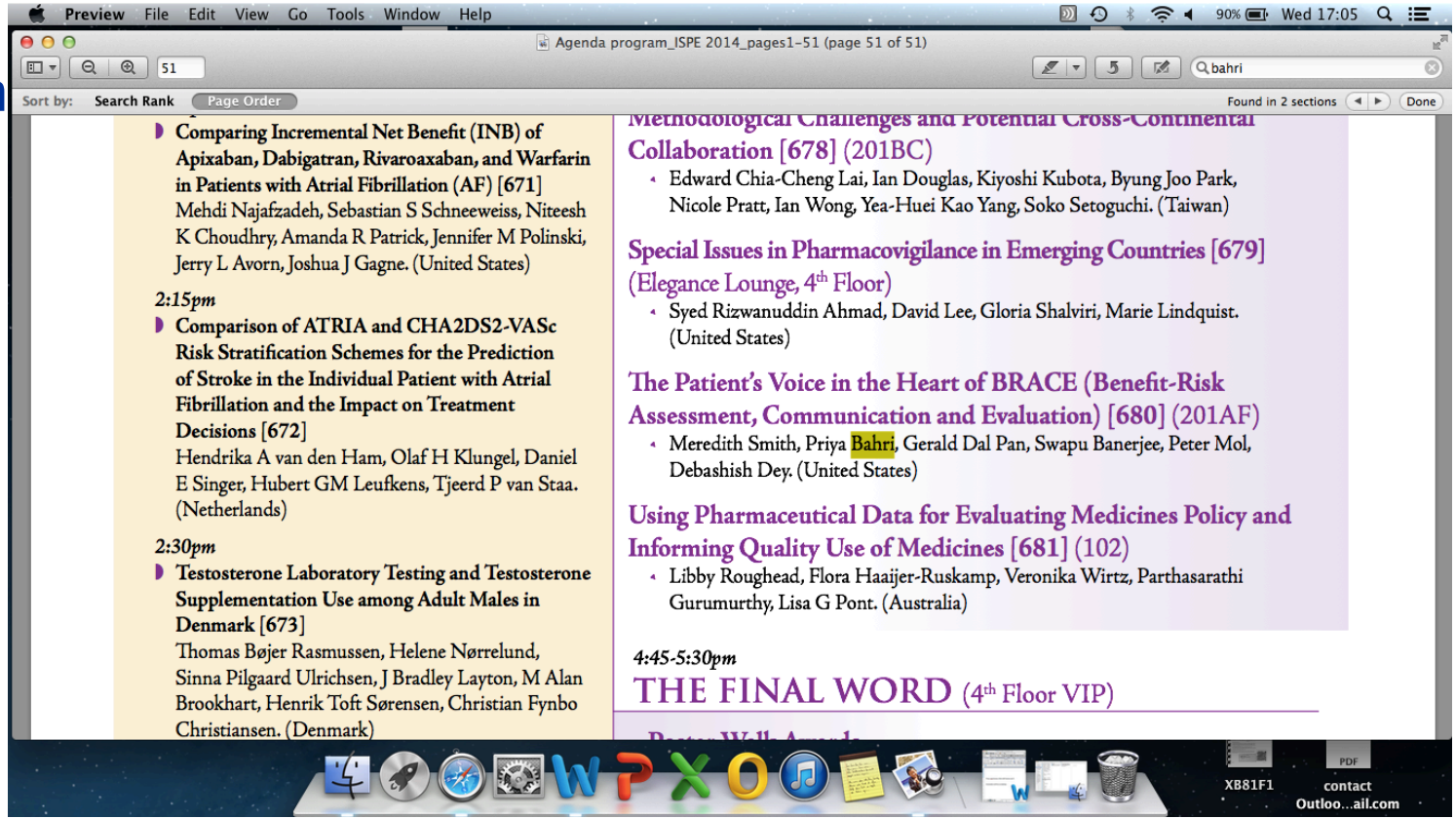
Nathalie Bere, presented by Priya Bahri
European Medicines Agency (EMA)

The value of interaction

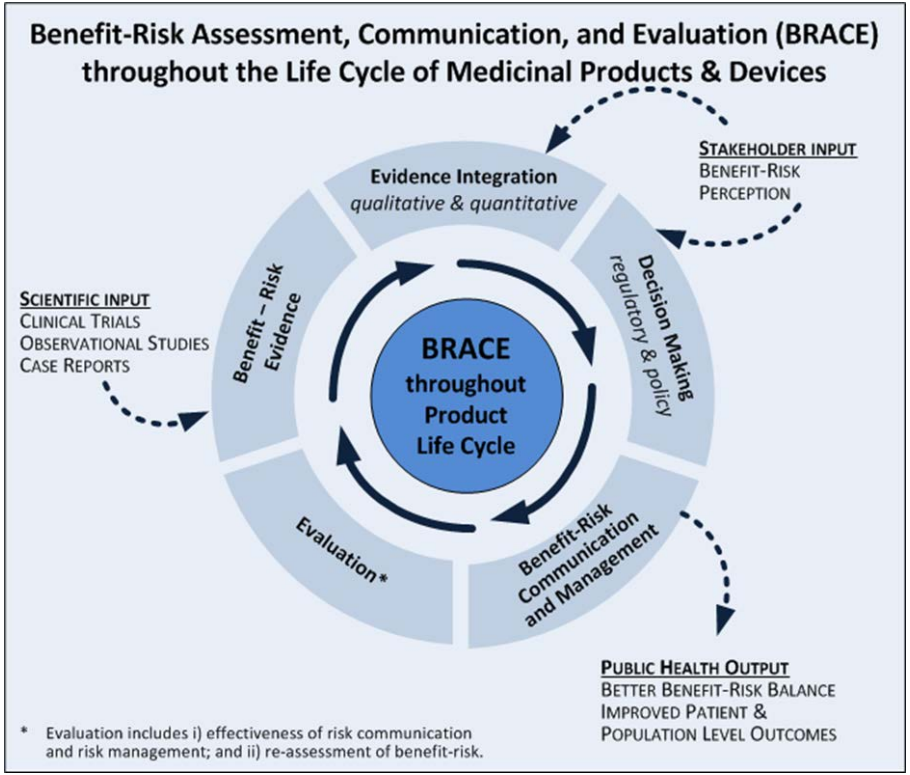
- Increases **transparency** and builds **confidence** in the regulatory system
- Involvement at operational level leads to **tangible impact** on outcomes;
  - Patients' views on benefit-risk deliberations **contribute to final recommendations** from the committees
  - Review of product information 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



BRACE cycle


Benefit-Risk Assessment, Communication, and Evaluation (BRACE) throughout the Life Cycle of Medicinal Products & Devices
Evidence Integration
qualitative & quantitative
Decision Making
regulatory & policy
Benefit-Risk Communication and Management
Evaluation*
Benefit – Risk Evidence
BRACE throughout Product Life Cycle
STAKEHOLDER INPUT
BENEFIT-RISK PERCEPTION
SCIENTIFIC INPUT
CLINICAL TRIALS
OBSERVATIONAL STUDIES
CASE REPORTS
PUBLIC HEALTH OUTPUT
BETTER BENEFIT-RISK BALANCE
IMPROVED PATIENT & POPULATION LEVEL OUTCOMES
* Evaluation includes i) effectiveness of risk communication and risk management; and ii) re-assessment of benefit-risk.

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ISPE Symposium 20 October 2014

The Patient's Voice in the Heart of BRACE -

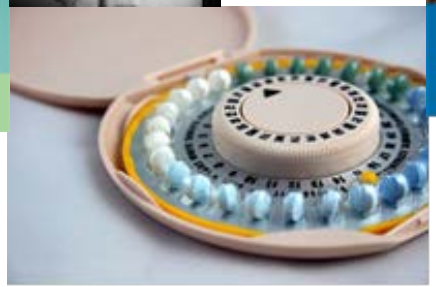
Benefit-Risk Assessment, Communication and Evaluation

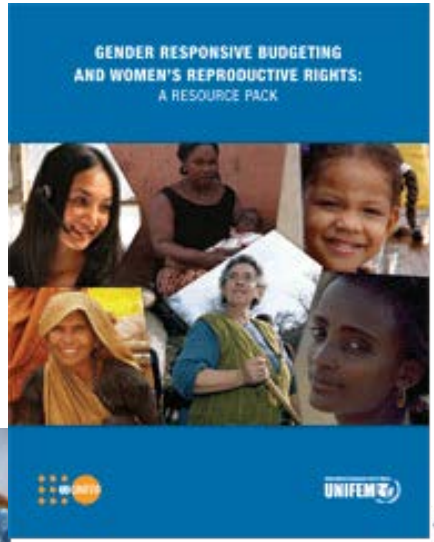
How patients contribute to assessments at the EMA and messages for pharmacoepidemiology

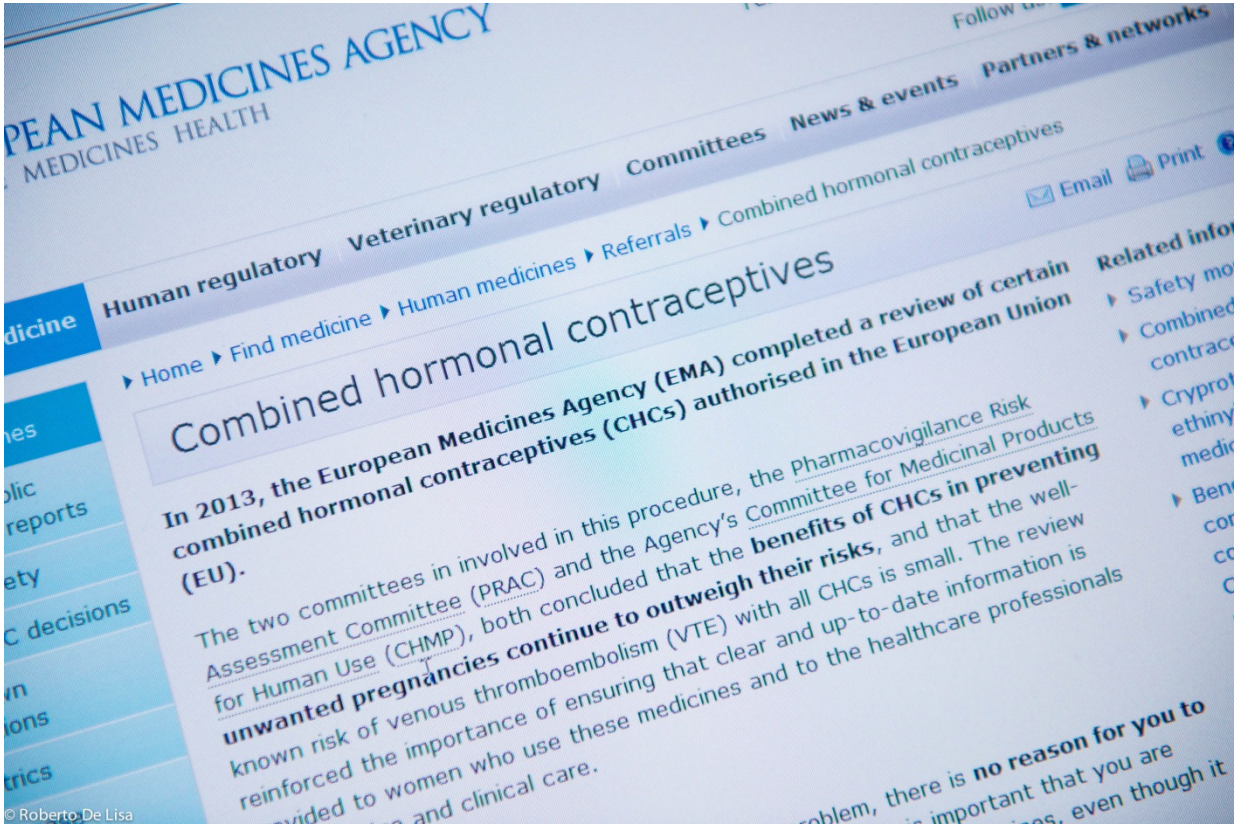
Presented by Priya Bahri
Lead Pharmacovigilance Guidelines & Communication Research

An agency of the European Union

Combined hormonal contraceptives and VTE



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Combined hormonal contraceptives
In 2013, the European Medicines Agency (EMA) completed a review of certain combined hormonal contraceptives (CHCs) authorised in the European Union (EU).
The two committees in involved in this procedure, the Pharmacovigilance Risk Assessment Committee (PRAC) and the Agency's Committee for Medicinal Products for Human Use (CHMP), both concluded that the benefits of CHCs in preventing unwanted pregnancies continue to outweigh their risks, and that the well-known risk of venous thromboembolism (VTE) with all CHCs is small. The review reinforced the importance of ensuring that clear and up-to-date information is provided to women who use these medicines and to the healthcare professionals and clinical care.
Related info
Safety mo
Combined contrac
Cyprot ethiny medic
Ben co c
problem, there is no reason for you to important that you are even though it
© Roberto De Lisa

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

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

<u>Specific points</u>:

- 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

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Division

Further information

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