EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Research Topics

ENCePP Plenary Survey (April 2011)

Q: Can you suggest any research topics that you would like to see included in public funding programmes?

More than 40 research topics have been suggested by the ENCePP partners, ranging from purely **methodological topics** to **specific adverse reactions** of interest, **special populations** or **safety of particular drugs or classes of drugs**.

1. Methodological Topics (1 of 4)

- Advanced methodological aspects of observational studies
- Methodological innovations in non-interventional safety studies
- Class effects: effectiveness and safety
- Methods for comparative effectiveness
- Cross-national effectiveness research based on common protocols
- Testing health indicators
- Health organisation models

1. Methodological Topics (2 of 4)

- Conduct of independent proactive pharmacovigilance surveys
- Risk/benefit profile
- Intensive monitoring of innovative drugs
- Signal detection and substantiation with new techniques
- Novel methods for assessing long term drug safety effects in children
- ADRs survey on paediatric drugs

1. Methodological Topics (3 of 4)

- ENCePP and the potential for meta-analysis
- The integration of data from meta-analysis of other data sources and projects
- Systematic reviews of observational studies to complement the available evidence from RCTs with particular reference to long term events for chronic diseases and rare events
- Topics for which it is difficult to obtain funding elsewhere, but that are crucial in further developing PhV and PhEpi e.g. comparing different measures of disproportionality / developing new measures, establishing to what extent pregnancy loss can be evaluated in healthcare databases or other data sources, etc.

1. Methodological Topics (4 of 4)

- How to properly describe/assess the current level of drug safety in a given country
- How to evaluate the performance of a drug authority re drug safety/ADRs
- Simplifying ways of getting answers; reducing bureaucracy etc.
- Inappropriate prescription
- Measuring renal function relevant for drug dosage
- Applying notions on drug toxicity to the personalisation of medical interventions
- Relation between external validity of clinical trials and adverse reactions of marketed drugs

2. Specific Adverse Reactions

- Suicide
- Depression
- Rheumatic diseases
- Disability
- Drug-induced bleeding disorders
- Drug-induced nephrotoxicity
- Drug abuse (marketed drugs)
- European network of drug-related liver transplantations (EDRLT)

3. Special Populations (1 of 2)

- Observational studies on special populations (elderly, children, pregnant women)
- Gender related topics
- Elderly patients, in particular polymedicated patients
- Elderly patients and chronic diseases
- Drug-induced severe diarrhoea in geriatric patients
- Inappropriate medication in the elderly
- Supportive care in oncology

3. Special Populations (2 of 2)

- Effectiveness of influenza vaccine in prevention of severe influenza episodes in children
- Non-for-profit research in PhV with particular reference to paediatrics
- Drug pregnancy (impact of minimisation plans)
- Effects of pregnancy related drug use
- Medication in children and pregnancy
- Safety of drugs for neonates

4. Safety of Particular Drugs or Class of Drugs

(1 of 3)

- Risk of infections and cancer in biologically treated psoriatic patients
- Adverse effects of psychotropic medication
- The safety of commercialised natural products/herbal remedies especially with regard to hepatotoxicity
- Comparative assessment of the b/r profile of old and new anticoagulants in knee and hip replacement surgery
- Prescription drugs abuse
- Medicines and bone fractures

4. Safety of Particular Drugs or Class of Drugs

(2 of 3)

- Lower gastrointestinal bleeding and drug use
- Effect of measures to reduce the impact of ADRs with anticoagulant drugs
- Long term safety of long acting bronchodilators in the treatment of asthma
- Generics
- PhEpi studies focussing on improving methodology to assess safety of biologicals

4. Safety of Particular Drugs or Class of Drugs

(3 of 3)

- Safety of biosimilars, biological agents
- Safety of analgesics (NSAIDs type)
- Vaccine safety
- Safety of thrombopoietin stimulating factors; impact of their off label use in myelodysplastic syndromes
- Geographical variability in the appropriateness of drug use after myocardial infarction: effect on outcome

For discussion:

1. How do we make best use of this information?
2. Next steps?

Possible next steps: for discussion

- Publish on ENCePP website
  - those with sufficient substantiation
- Forward methodological topics to IMI-JU
  - Further scrutiny by ENCePP [+ those with sufficient substantiation]
- Forward specific drug-safety topics to PhVWP and CHMP to inform annual selection of EMA research priorities in the context of the framework programmes
  - those with sufficient substantiation
- Other?