Department of Pharmacy
& Pharmacology

A/H1N1 pandemic vaccines and pregnancy outcomes

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Study / consultancy funded by the European Medicines Agency

The application process

- 1st hurdle: bureaucracy easily overcome
  - It fits in a fat A4 envelope
- 2nd hurdle: EU procurement
  - Invitation to tender issued with a draft agreement
  - Need to ensure all issues are addressed before submitting the tender
- Contract – no amendments

Study outline: 3 ‘aims’

1. To identify anyone who has done anything to study A/H1N1 vaccine safety in pregnancy in Europe
2. To carry out a meta analysis of A/H1N1 vaccine safety in pregnancy where possible
3. To set up a long-term network for studying medicine safety in pregnancy

All this in the context of

- An existing ENCePP network
- An existing VAESCO network
- A planned EUROMediCAT study

Resources in Europe

- Teratology information services
- EUROCAT
- Clinical trials data
- Medical databases

However, given the study aims and exposure / outcome frequency, Europe is not big enough

Outline of actions

1. Write to all stakeholders (ISPE, WHO, medicines regulatory agencies, public health agencies, CDC, ENCePP members) and all study coordinators already identified
2. Search conference proceedings, Medline, EMBASE
3. Search clinical trials.gov & EudraCT
4. Invite all PIs identified to contribute to the meta analysis as appropriate and the longer term network

Data to be gathered

- Study design & setting
- In- and exclusion criteria
- Recruitment start- & end date
- Availability & completeness regarding exposure, pregnancy outcomes, confounders & effect modifiers, data sources used, ethics approval

Creating a network for meta-analysis and future research

- Liaison with Prof S Evans, LSHTM regarding meta analysis
- Meeting with all PIs willing to collaborate
  - Discuss inventory results
  - Discuss hurdles for meta analysis (methodological as well as ethics & other)
  - Agree timelines where collaboration possible
  - Initiate dialogue regarding long-term network
- Monthly conference calls to move forward on agreed actions

Studies identified thus far

- EUROCAT
- Teratology information services in Europe & North America
- 4 clinical trials (mostly 2nd trimester exposures)
- VAESCO study participants
- Cohort studies in France, Spain, Canada
- Medical birth registries in Scandinavia
- CDC, Slone Epidemiology Unit

Timelines

- Identify all studies by end 2010
- Gather all info on study details by Q1 2011
- Initial meeting with PIs Q2 2011
- Proposal for network sent out to stakeholders by Q3 2011
- Final proposal for network submitted to EMA Q4 2011 / Q1 2012
- Data lock March 2012
- Final analysis May 2012

Questions?

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