Synergies between ENCePP and Health Technology Assessment

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Joint Action

A total of 34 government appointed organisations from 23 EU Member States, Croatia and Norway and a large number of relevant non-for-profit organisations that produce or contribute to HTA

Main objective

to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level

EUnetHTA 2010-12: Work Packages

1. Coordination
2. Dissemination
3. Evaluation
4. Core HTA including adaptation
5. Relative Effectiveness Assessment (REA) of Pharmaceuticals
6. Information management system
7. **New Technologies. Facilitating Evidence Generation and Collaboration on (Pre-coverage) Assessments**
8. Strategy development (Business model for sustainability including capacity building to do HTA)

Current situation

- Some new technologies (medicines, other HT)
  - Identified evidence gaps and need (common for several HTA bodies) for additional evidence
  - Data requirements: not clearly specified, not coordinated, not harmonised
  - Multiple studies with heterogeneous designs performed to answer similar requests
  - Inconsistent results
- Lack of critical mass of robust data to reduce uncertainty
- Waste of time and money

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Expected benefit from WP7

- Update information on new technologies and identify evidence gaps
- Update information on additional data requirements in the countries where the technology was assessed
- Possibility for collaboration to harmonise data requirements
- Studies (multinational or not) with comparable designs and outcomes
- Better quality information provided to decision makers at the time of the re-assessment

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Action Plan - Objectives

- Define criteria for selection of technologies that need additional evidence generation
- Share information (database) on new technologies
  - Evidence gaps
  - recommendation for additional data collection (research question, type of study),
  - HTA guidance and coverage and reimbursement status
- Registry of planned or ongoing clinical studies
  - PICO structure
  - Minimum dataset development

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Deliverables

- **Criteria**
  - to select, among new technologies, the ones for which additional data collection will be useful and efficient
- **Database**
  - User friendly IT functionalities
  - Visual structure with rapid information access

Perspectives

- Standardisation of further research recommendations in HTA reports
- Facilitating collaboration between sponsors/funders on agreed core protocols for a technology of interest
- Effective collaboration to set up policy relevant studies
  - Individual studies based on common core protocols
  - Multinational studies

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EVIDENT Database

- content: **information on**
  - health technologies (assessment status, evidence gaps, research questions, required additional studies, coverage decision status)
  - planned studies (a minimum information necessary for establishing collaboration: PICO, protocols, results of studies, etc;)
- scope:
  - all types of technologies (drugs, devices, procedures)
  - studies requested by European HTA bodies following a HTA,
  - studies still in the development phase
- goal: **support European collaboration and help avoiding duplication of studies, promote global analysis of results (critical mass of consistent data)**

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EVIDENT vs. ENCePP

(register of studies)

Scope

- all types of technologies (drugs, devices, procedures)
- studies requested by European HTA bodies following a HTA,
- studies still in the development phase
- Restricted access

- Only drugs
- Any pharmacoepidemiology and pharmacovigilance studies
- Any phase of the study
- Public access

Partial overlap of studies intended to be registered

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EVIDENT vs. ENCePP

content

- **information on**
  - health technologies (assessment status, evidence gaps, research questions, required additional studies, coverage decision status)
  - planned studies (a minimum information necessary for establishing collaboration: PICO, protocols, results of studies, etc;)

- **information on**
  - planned and ongoing studies
    - **identification of the drug, the sponsor, the investigator,etc…**
    - **description of the study design, the study progress and the results**

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Collaboration EVIDENT/ENCePP

- **First steps:**
  - Participation of ENCePP Public consultation on Evident
  - ENCePP representative attending the next WP7 Face to Face meeting next september
- **Further development:**
  - Encapsulated search on ENCePP through EVIDENT
  - Alert in EVIDENT on new studies being entered in ENCePP
  - Access to EVIDENT for ENCePP members to be discussed

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