Patient Registries & HTA

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The need... The challenge....

• **HTA analysis** of medicinal products and medical devices is more and more in need of *‘real-world’ data* in order to address aspects of **clinical effectiveness** and **economic evaluation**.

• A valuable **candidate source** for such data is **patient registries**.

• The use of registry data for HTA purposes has been limited and faced with **data quality**, as well as **procedural barriers**.

• The Cross-border Patient Registries Initiative (PARENT) Joint Action has initiated a dialogue and collaboration with the European HTA community in order to improve the present situation.
PARENT Summary

Aim: Provide MS with guidelines and recommendations on improving registry interoperability and use of data for secondary purposes (indicators, research, etc.) in a cross-border setting

05/2012 - 05/2015 (36 months)
Budget: 3.4 Mio € (60% EC)
11 Associated partners
12+ Collaborating partners

PARENT Associated Projects Group:
EAR EFORTE, EPIRARE (&RD-CONNECT), EUReMS, EUCERD JA, EUBIROD, EUROCISS, EPAAC, EurAHS, eHGI, epSOS, EUnetHTA, SHN, EHR4CR (&EMIF)
Additional partners and stakeholders:
NICE UK, CPME, ESIP, EFPIA, EBE, EUREGHA, HIQA Ireland and many others

PARENT envisions a Community of Patient Registry holders sharing common interests. This to be achieved via issuing guidelines and producing supporting tools targeted at improving the quality of registry data, as well as registry maintenance and operations.
Patient registries are...

• “an organized system that uses observational study methods to collect uniform data (clinical or other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose(s)”
PARENT Framework: the tools

Guidelines, Recommendations, Methodologies

Best practices

Information models, ontologies, vocabularies

Services, SW tools repository

Registry of Registries

Knowledge Management Platform

PARENT Framework
PARENT-RoR.eu

Pilot Registry of Registries (www.parent-ror.eu) released in November 2013
Mapping patient registries across the EU
PARENT Methodological guidelines

Contribution of ≈ 40 authors

Steps in the process:
- **12/2013** – Workshop Review and discussion of draft structure
- **05/2014** structure presented at eHGI representative meeting
- **06/2014** First draft of the Guidelines - workshop on open issues
- **Ongoing**: Final editing
- **12/2014**: Final version

May 2015: Guidelines to be presented for endorsement by eHealth Network
Two key use cases will be supported.

Use case 1:

• Help existing and new registries to be more interoperable (*Guidelines, best practices, CDS, SW*)

• Assess Interoperability of these registries/data sources (*Assessment Tool*)

Use case 2:

• Ability to identify registries/data sources (*PARENT Registry of Registries*)

• Provide search, retrieval and maintenance of (RoR) metadata from these registries

• Support exchange of data across registries (Query broker)
Who benefits?

- EC
- JRC
- MS
- HTA authorities (MS and EC)

- Research organizations
- Pharma & Device Industry
- Insurers

- EC
- JRC
- MS
- HTA authorities (MS and EC)

- Reducing barriers for data re-use
- Access to data

- Guidelines
- Comparison IT tools

- Access to data
- Quality of data

- HTA authorities (MS and EC)
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HTA & patient registries: the collaboration

• PARENT WP6 WORKSHOP: The policy and implementation context for cross-border patient registries, Brussels 27.03.2014

• PARENT, ESC, EUnetHTA JA2 meeting Brussels, 15.04.2014

• Review of the ESC CRF/registry model for Atrial Fibrillation - fitness for HTA of Novel Oral Anticoagulants (NOAC)

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Emerging themes from HTA - feedback points

So far collaboration has pointed out:

• **Registries** could add to regular HTA methods:
  – Real life safety and clinical effectiveness
  – Rare events
  – Long term data
  – help in describing the population of interest
  – help in collecting data for later assessments

• An absolute necessity for registry data used in HTA is that registries **publish studies** based on the use of their data - > Guidelines, RoR
HTA & patient registries

• HTA related questions
  – Do relevant registries exist already? -> Need for data resource identification tool
  – Do we need to alter/edit/change registries to facilitate HTA re-assessments?
  – Should we always contact registries to inform them of new technologies?

• HTA could use registries
  – Early detection of new methods: collaboration in deciding which data to collect
  – Access to real life data when evaluating or monitoring the method over time (re-assessments)
• **Time-critical element in data acquisition** – particularly for rapid assessments. Use of HTA methods vs. the lifetime of technology (e.g. - early phases of the technology, registry data not yet available.)

• **Meaningful data** – **patient outcomes.** In a HTA perspective, it is important that we choose the most relevant outcomes, especially patient centered outcomes. → Methodology guidelines are needed about the outcome data (PARENT WP5 – RoR impact)
Joint Synergies (long term)

In order to address the above issues:

• Need to **investigate and enhance the linkage between registries and planned HTA work.**

• Establish a **process of notification** of registries with regard to **emerging/new technologies**. Such a process could be a means of closing the HTA/registry loop (e.g. by ensuring that the necessary codes are in use by the registries).

• ....etc.
Joint Synergies (short term)

Based on the potential ability of PARENT on promoting and supporting of registry-based HTA, PARENT and EUnetHTA JA (& EMA), joint synergies may include:

- PARENT’s Guidelines for Patient Registries to incorporate relevant issues from:
  - The HTA Core Model
  - Methodological Guidelines for Rapid REA of Pharmaceuticals
  - Glossary of HTA Adaptation Terms
- Contribution to PARENT guidelines (HTA section co-authorship, review)
- PARENT’s **generic registry data** set to be integrated to the extend possible with the **HTA Core Model**

The advantage of PARENT is that it can link the HTA needs with the registry holders and thus improve data quality and limit procedural barriers.
USE OF REAL WORLD DATA

W8: PATIENT REGISTRIES AS HTA TOOLS IN ECONOMIC OUTCOMES RESEARCH: REQUIREMENTS, BARRIERS, AND THE WAY FORWARD

Workshop participants will be provided with an overview of the analysis and results achieved through the collaborative work (PARENT JA & EUnetHTA JA2) accomplished thus far. In addition, participants will have the opportunity to get hands-on experience with the tools developed by PARENT JA.
Thank you for your attention

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