INFORMATION PAPER

for eHealth Network[1]

Guidelines on patient registries and supporting tools

Introduction

Article 14(2)b of the Directive on patients' rights in cross-border healthcare states that among the objectives of the eHealth Network will be to ***draw up guidelines on effective methods for enabling the use of medical information for public health and research***.

Due to their sheer number and large volume of collected medical information, patient registries[2] present significant potential for research and public health improvements in EU. Patient registries are of increased importance due to public health needs (e.g. monitoring of patients' treatments, safety assessment) and the trends of translational medicine (e.g. registry-based clinical trials, personalized medicine).

The quality and structure of data currently held in patient registries is however inconsistent and – due to lack of use of common methodology – in most cases cannot be directly used for secondary purposes[3]. Processes and legal agreements for data sharing across registries and Member States are seldom established. Time-consuming search and identification constitutes another important barrier. Although there are some best practices in particular areas such as Rare Disease, the need for a generalised methodology across diseases and medical cases is of paramount importance.

As a consequence this large and growing amount of medical data in the EU remains unavailable for broad research and public health purposes. To improve long term use of this data it is necessary to agree on EU-wide guidelines and tools for making patient registries interoperable across the EU, addressing the needs of data sharing for secondary use. Patient registry holders and a number of EU stakeholders have already expressed a need for EU level sharing of registry-related knowledge and best practices, as well as for tools and services improving quality of data and data availability for secondary use.

What is PARENT doing?

PARENT is a joint effort by Member States and the European Commission as a direct response to the objective set in Article 14(2)b of the Directive. PARENT aims to improve secondary use of data from patient registries in a cross-border setting for both public health and research needs. Based on analyses performed, these objectives can only be achieved by:

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[1] Drafted by the Patient Registries iNiTiative Joint Action (PARENT), www.patientregistries.eu

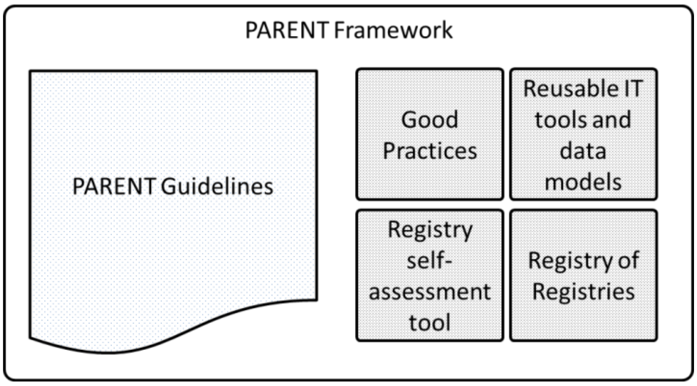
[2] A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. Three general categories with multiple subcategories and combinations account for the majority of registries that are developed for evaluating patient outcomes. These categories include observational studies in which the patient has had an exposure to (1) a product or (2) service, has a particular (3) disease or condition, or various combinations thereof.' (Gliklich RE, Dreyer NA, eds: Registries for Evaluating Patient Outcomes: A User's Guide. 2nd ed., 2010).

[3] Including areas such as Quality of Care, Pharmacovigilance, Safety, Health Technology Assessment, Public Health Policy and others

1. (1) improving use of primary data sources for feeding data into patient registries[4];
2. (2) improving data quality and interoperability of new and existing patient registries;
3. (3) mapping of patient registries in the EU with the purpose of supporting search and identification of available data sources; and exchanging information about national best practices and lessons learnt on patient registries;
4. (4) supporting data sharing between and across registries; and data reporting to authorities and relevant bodies;
5. (5) providing support services for registry holders at EU level.

Therefore PARENT is developing methodological guidelines and recommendations for efficient and rational governance of interoperable patient registries (the *Guidelines*) and additional implementation tools and services to be available in Autumn 2014.

Fig. 1: PARENT Guidelines and supporting tools



PARENT partners: 22 MS
PARENT Associated Projects Group: EAR EFORT, 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

The Guidelines on patient registries (to be released in autumn 2014) cover the entire registry lifecycle, including a guide and good practices on registry design, set-up, governance and management, as well as secondary use of data. The structure of the guidelines is provided in Appendix 1 and is based on extensive ongoing consultation process with key EU stakeholders (PARENT Stakeholder Forum, relevant EU Joint Actions and eHealth projects). They represent a key resource to be used by registry holders and stakeholders (i.e. European Reference Network, Joint Research Centre). There is a clear need for common adoption and further implementation of Guidelines on EU level in order to create value of data from patient registries.

A pilot **Registry of Registries (www.parent-ror.eu)** has been released in November 2013, in order to facilitate the mapping of patient registries across EU. It currently holds descriptions of approximately 140 national or regional registries across the EU and is increasingly being used by stakeholders (such as the European Society for Cardiology) to map registries relevant to them.

A **self-assessment functionality** will be added by autumn 2014, to support clear added value to registry holders and support its sustainability by providing assessment and tailored improvement guidance (based on *Guidelines*) to registry holders, as well as an indication of registry ability to share data – to be used by regulators, medical knowledge researchers, funders, etc. EU and Member

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[4] Where PARENT recognizes the results and ongoing work of several projects focusing on improving interoperability of Electronic Health Records (EHR) as primary sources of data (i.e. SemanticHealthNet, EHR4CR, TRANSFoRM, EMIF, SALUS);

States' authorities will be able to use the Registry of Registries and assessment tool to monitor improvement of registries' interoperability capacity for providing **data for secondary use** and to assess the level of the implementation of the guidelines on patient registries, and the resulting positive outcomes.

As collaborative effort is a prerequisite for **common data models in registries**, PARENT is establishing an online collaborative environment where registry experts contribute towards development of generic and field specific registry datasets. A number of existing proposals for a common/minimum data set are being analysed and made available in a semantically interoperable format based on the approach used in SemanticHealthNet.

The eHealth Network and Patient Registries

As the leading body in EU eHealth policy, the eHealth Network will be requested to adopt the guidelines on patient registries and promote the use of the Registry of Registries. PARENT therefore also proposes that the supporting interoperability assets (Registry of Registries, Assessment tool etc.) are taken into account for the Connecting Europe Facility. In November 2014 the eHealth Network will be presented with the main outcomes of PARENT and will be asked to discuss and adopt the necessary documentation. PARENT is expected to run until 1st May 2015, and will be able to take on request by the eHealth Network for further dissemination. Below is the draft roadmap leading towards validation by the eHealth Network (eHN):

- Information paper presentation at eHN meeting (May 2014)
- PARENT Seminar on Sustainability; Draft Guidelines Workshop (June 2014; MS representatives invited to provide feedback)
- Launch of PARENT Guidelines and Framework (Oct 2014)
- Discussion paper presentation at eHN meeting (Nov 2014)
- Guidelines Adoption paper presentation at eHN meeting (May 2015)

For information

APPENDIX 1: DRAFT index of "*Methodological guidelines for efficient and rational governance of interoperable patient registries*":

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  - **2.3 Diversity in Use of Patient Registries**
  - **2.4 Overview of European Registries**
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    - **4.2.4 Case Study: Developing Registry Design**
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