eHealth Network

Recommendations on patients' registries in particular on the use of knowledge gathered through the PARENT Joint Action[1]

[1] Joint Action PARENT: http://patientregistries.eu/general-objectives

The eHealth Network is a voluntary network, set up under article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth. The Joint Action supporting the eHealth Network (JAseHN) provides scientific and technical support to the Network.

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Introduction

Patient registries have served as a additional source of data needed to assess clinical performance as well as for health technology assessment (HTA) and policy implications at local, regional, national and in some cases international level. As a result, hundreds of registries have been set up for patients with shared characteristics (e.g. rare or chronic disease, implanted device or therapy, risk to developing a chronic a secondary use as a key source for scientific research.

Over the last 15 years, information technology has provided the opportunity for greatly redesigning the way informed decisions are made via the collection, sharing, comparison, and analysis of large patient data sets particularly at the population level.

Not so well developed however, is the way in which information and knowledge is harnessed from the wealth of available health data – be it within a given type of registry, but especially across national boundaries or between different types of registries altogether.

To increase the usefulness of data collected in the registries, it is necessary to ensure that registries are interoperable and of high quality – especially with regards to reliability and completeness of data – and also that they have a capacity for monitoring relevant patient outcomes.

Interoperability, in particular, is a critical factor for all aspects of a registry's life-cycle and has to be considered at every stage, from establishment through development to operation, use, and governance. In context of which, specific consideration must be paid to the core data set and to semantic interoperability (specifically in relation to the coding system, the coding standards and the data model used).

A registry that is not designed in accordance with the interoperability requirements will not only miss capturing important information but also eventually end up creating expensive and time-consuming solutions for linking its information with other data sources (such as health records, other disease/patient registries, environmental and socio-economic databases, etc.). The problem is further exacerbated when considering the wider and increasingly more important dimension of EU level operations – particularly in view of the benefits accruing from a connected European environment.

Another crucial aspect for the ultimate usefulness of a registry is data quality, which per se includes the quality of all the intermediate data-feeding processes.

Concerning the practical task of setting up a new patient registry or modernising an existing one, appropriate guidance is required to facilitate the choice of methodologies, processes, technologies, and governance issues associated with the registry, including the important question of the long-term value and sustainability of the registry itself.

In this regard, the Guidelines under the Cross-Border Healthcare Directive 2011/24/EU on: (i) the ePrescriptions dataset for electronic exchange, and (ii) minimum/non-exhaustive patient summary dataset for electronic exchange, constitute an important step towards cross-border interoperability for the exchange of patient data. PARENT has utilizers the

endorsed patient summary dataset as the basis for exploring the feasibility of a minimum registry dataset.

In addition the following documents have an important bearing:

- eHealth[2] Multi-Annual Work Plan 2015-2018 identifies the need to align relevant parties playing a leading role in the development of eHealth standards and specifications, and to promote the use of the standards for furthering the progress towards practical semantic interoperability.
- EUnetHTA[3] Guidelines on Methods for health economic evaluations state that clinical evidence should be based on the most appropriate sources, which in most cases is considered to be randomized clinical trial (RCT) studies. If no RCT studies have been carried out or cannot answer the research question on the intervention under consideration, other sources may be acceptable depending on the type of technology under consideration.

The aim of the PARENT Joint Action is to provide Member States with guidelines and recommendations on improving registry quality and interoperability readiness which in turn can encourage and improve the use of data for secondary purposes in a cross-border setting[4]. By improving registries' interoperability and secondary use of health data the total costs of data acquisition can be substantially reduced. In particular, the streamlining of governance and management processes according to the PARENT guidelines on implementation and use, will facilitate registry holders with the knowledge necessary to address questions related to data protection and other central administrative matters.

Moreover, the assessment tool which is part of the PARENT pilot Registry of Registries (RoR) can provide a useful indication of all levels of registry interoperability.

In consideration of the foregoing arguments, the eHealth Network recommends

Member States and the European Commission:

- to promote the inclusion of further registries in the Registry of Registries (providing a collated overview on the data held in the different registries) and to support the dissemination and uptake of PARENT Guidelines, whilst ensuring mechanisms for their improvement[5];
- to encourage collaboration between the registries and other stakeholders to address relevant research questions dependent on cross-border use and pooling of health data (to share good practices and avoid duplicated data capture as far as possible).

[2] http://ec.europa.eu/health/ehealth/events/index_en.htm#anchor1
[3] EUnetHTA website: http://www.eunethta.eu/
[4] The most prominent Parent JA deliverables include:
- Pilot web-based registry of registries (RoR)- http://www.parent-ror.eu
- Methodological guidance and recommendations for efficient and rational governance of patient registries. – covering the entire registry life cycle including a guide and good practices on registry design , set-up, governance and management, as well as secondary use of data.
- IT component – IT-based knowledge-management platform

[5] To this end PARENT is investigating the concept of National Contact Points.

The European Commission:

- to explore mechanisms for updating of the Guidelines and monitoring their implementation;
- to strengthen the collaboration and integrate the PARENT deliverables with the work in which the JRC (Joint Research Centre) is currently engaged in the area of cancer registries and rare disease registries;
- to provide an input to the activities developed by the European Reference Network;
- to bring together the experiences of the Registries set up already at EU level;
- to pilot the PARENT deliverables on some test cases (for example: within the areas of medical devices or pharmaceuticals) and with this experience to adapt the PARENT guidelines, the information technology components, and the data-quality indicators;
- to explore further the usefulness of identifying a specific body to work on health-data interoperability and quality and to provide an appropriate platform for data exchange.[6]

Registry holders and Member States

- to improve registry quality and interoperability between registries and their data sources by following and implementing the PARENT Guidelines;
- to demonstrate the importance of registry data;
- to increase patients' awareness of the importance of high-quality registry data and encourage their involvement in the generation and use of data;
- to share the national legislations, plans and strategies concerning the areas of registries, eHealth/Electronic Health Records, Rare Diseases, HTA and potentially European Reference Network.

[6] Collaborating on elements such as data quality and interoperability in eHealth (e.g. for data used in health records and registries both disease-specific and product-specific; patient summaries; and for the purpose of HTA).