Recommendation on patients' registries in particular on use of knowledge gathered through Parent Joint Action

Patient registries have served for decades as a key source of data needed to assess clinical performance as well as Health Technology Assessment and policy implications on 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 disease, etc.).

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 amounts of patient data particularly at the population level.

Not so well developed however, is the way by which information and knowledge is harnessed from the wealth of available health data – be it within a given type of registry, especially across national boundaries or between different types of registries altogether. In this respect, the task of setting up a new patient registry requires appropriate decision aids or guidelines, 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.

In particular, interoperability is a critical factor in all aspects of a registry's life-cycle that has to be considered at all stages, from establishment through development to operation, use, and governance. A registry that is not designed accordingly will eventually end up creating an expensive and hugely time-consuming task of linking its information with other data sources (such as health records, other disease/patient registries, environmental and socio-economic databases, etc.) – even at single region/country level. The problem is further exacerbated when considering the wider and increasingly more important dimension of the EU – particularly in view of the benefits accruing from a connected European environment.

The other crucial pillar for the ultimate usefulness of a registry is data quality, which necessarily includes the quality of all the intermediate data-feeding processes.

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.

Moreover, the eHealth Network 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.

The most critical features of the registries, which could improve or discourage semantic interoperability, are: coding system, standards and data model used.

To increase the usefulness of the data collected in the registries, it is necessary to ensure that registries are interoperable and of high quality, in terms of their comprehensiveness, collection of important data, and monitoring of relevant patient outcomes.

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[1]. By improving registry interoperability and secondary use of health data the total costs of data acquisition can be substantially reduced. Moreover, the streamlining of governance and management processes supported by the PARENT guidelines implementation and use, will provide registry holders with the knowledge necessary to address e.g. questions of data protection and other central administrative matters.

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 both mutually and with their data sources (e.g. EHR) and information users (e.g. researchers)

In consideration of the above arguments, the eHealth Network recommends the Member states and the other stakeholders to:

- strengthen the collaboration and integrate the PARENT JA deliverables with the work in which the JRC (Joint Research Centre) is currently engaged in the area of cancer registries and rare disease registries;
- improve registry quality and interoperability between registries and their data sources by following and implementing the Guidelines prepared in PARENT JA;
- set up a permanent mechanism for regular updating of the Guidelines and monitoring the implementation;
- promote the inclusion of further registries in a Registry of Registries (to provide a collated overview on the data held in the different registries);
- encourage collaboration between the registries and other stakeholders to address policy-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);
- to increase patients' awareness of the importance of high-quality registry data and encourage their involvement in the generation and use of data;
- 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 IT components, and the data-quality indicators;

[1] The most prominent Parent JA deliverables include:

- Pilot web-based registry of registries (ROR)
- 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

- explore further the usefulness of entitling a specific body to work on health-data interoperability and quality and to provide an appropriate platform for data exchange. [2]
- collaborate with the eHealth joint action WP on Electronic health records and secondary use of data.

[2] 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).