

Medical Technology Registries Six Key Principles

Executive Summary

In this paper MedTech Europe suggests **6 Key Principles** that should apply when **European public health authorities request to collect** registry/real-world data through means of registries **to inform healthcare decisions** (e.g. reimbursement, coverage with evidence development, population/sub-population access). We believe that by following these principles, applicable European regulations and national laws, the quality, acceptability, efficiency of collecting and analysing this data can improve research and decision making.

The 6 Key Principles are:

- 1) Define the SCOPE
- 2) Set up the right GOVERNANCE
- 3) Establish fair and transparent FINANCING amongst all the parties
- 4) Ensure collection of QUALITY DATA and DATA PROTECTION
- 5) Make data AVAILABLE AND REPORT the DATA
- 6) Guarantee the right EDUCATION and QUALIFICATION

MedTech Europe supports principles of evidence-based healthcare, health economics and social science. The future growth and well-being in Europe critically depends on the adoption of effective, qualified and sustainable methods to increase the quality and efficiency of decision making in healthcare and to have the right measures in place to assess the value of the investments made.

The medical technology industry makes significant investments to ensure safety, performance, traceability and quality of care delivered by their products. Furthermore, expensive and resource-intensive research is carried out to show the added value of the therapies. Adding to these investments, the industry is often being asked to engage major resources (human and financial) to support the increased demand for the establishment of registries to collect registry/real-world data.

Before such longer term commitment is taken, the value of the investment and the feasibility of setting up registries need to be carefully assessed and the benefit defined for the different stakeholders involved in such a partnership (patients, healthcare professionals, notified bodies, competent authorities, payers¹ and industry).

As medical technology manufacturers we agree that **registry data collection to inform healthcare decisions might bring value** and we are willing to support the collection of registry data, where relevant and provided that the following aspects are taken into account:

1. **the gathered information effectively guides the policy decision** and makes a unique contribution to the informed decision on healthcare
2. the research questions and scope of the registry are clearly defined
3. there is a proper governance set up and framework agreement to involve stakeholders in a constructive dialogue and efficient collaboration
4. the methodology and data collected are of defined high quality, appropriate, accurate and available on-line to all relevant parties
5. the financing is fair, transparent, sustainable and agreed by all parties

¹ MedTech Europe definition of payer: Individual, governmental unit or organization that constitutes the allocation of funds to provider organizations and/or individual, governmental unit or organization who influences purchasing decisions of others because of their responsibility, knowledge, position, or relationship.

6. relevant education is ensured to allow effective implementation and utilisation of the data collected

Medtech Europe also acknowledges the ongoing and published work on registries on European and country level. We acknowledge that this work aims to improve quality, usability and acceptance of registry data and some of this published work might be used as a reference to express our reflection. That being said, we believe that with this reflection paper, we can further contribute to the discussion on registries for medical technologies and on key principles to be considered when collecting registry/real-world data.

Background

Epidemiological and real world data are increasingly important to improve the knowledge of diseases, clinical effectiveness of interventions, quality of care, effectiveness of medical technologies, healthcare outcomes, and health system performance and of the socio-economic consequences of different interventions. With the growing ability to connect data sources and build “big” data, registry information might provide the ability to **measure the outcome of investment** made in healthcare and guide policy and decision making.

Registries are typically prospectively defined. A medical technology registry may be supported by manufacturers, professional societies, patient advocacy groups, physicians, payers, government agencies, provider groups or a combination thereof. As for patient registries, multiple definitions exist.

Registry is “an organised 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 pre-determined scientific, clinical, or policy purposes”. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical technologies. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalisation. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure.²

Six Key Principles

In this paper MedTech Europe suggests 6 Key Principles to focus on when European public health authorities request to set up registry to inform healthcare decisions (e.g. reimbursement, coverage with evidence development, population/sub-population access). We believe that by following these principles, applicable European regulations and national laws, the quality, acceptability, efficiency of collecting and analysing of this data can improve research and decision making.

The 6 Key Principles are:

1. Define the SCOPE
2. Set up the right GOVERNANCE
3. Establish fair and transparent FINANCING amongst all the parties

² Gliklich R, Dreyer N, Leavy M, eds. Registries for Evaluating Patient Outcomes: A User's Guide. Third edition. Two volumes. (Prepared by the Outcome DEcIDE Center [Outcome Sciences, Inc., a Quintiles company] under Contract No. 290 2005 00351 TO7.) AHRQ Publication No. 13(14)-EHC111. Rockville, MD: Agency for Healthcare Research and Quality. April 2014. <http://www.effectivehealthcare.ahrq.gov/registries-guide-3.cfm>.

4. Ensure collection of QUALITY data and data PROTECTION
5. Make data AVAILABLE AND REPORT the data
6. Guarantee the right EDUCATION AND QUALIFICATION

1) Define the SCOPE (informing and guiding the other principles)

Registries offer many opportunities to potentially help answer several clinical and economic questions. However, limitations and challenges of registry data must be understood by all parties. Every design of a registry needs to be fit for a defined objective. **When designing a registry the scope needs to be the central element.**

Due to the high level of investment and support needed to establish and operate registries, both in terms of funding and resources, any new registry must be set up and designed to **answer unmet information needs and to close defined evidence gaps**. Collecting quality data can be costly and time-consuming for healthcare professionals, and this burden needs to be matched to the value of the information that will be obtained in addressing justified research questions.

Registries should be established when the public health value and benefit of the data derived from a registry is greater than the burden of establishing and maintaining a registry. If adequate information related to the question is available from other sources or if there is no clear and specific research question, establishing a registry should be questioned.

Recommendations

When thinking about setting up a registry, we encourage the public health authority to answer the following questions:

- What is within the scope of the registry and what is not?
- Has a robust evidence assessment been completed to ensure that the data to be collected by the registry is needed and clinically meaningful?
- Are there better ways to go about the investigation and are there other activities in the field that are on-going already?
- What is the main research question (clinical or economic) and can it effectively be answered by the data collected in the registry (what registry can and cannot do, what are the endpoints)?
- Will answering the question have a significant impact on public health or patient care to warrant the investment in the registry?
- Is the data identified to be collected in the registry sufficient to address the questions - is there too much or not enough data being collected for the appropriate period of time to answer the question?
- Is there a minimum set of data to be collected that was agreed internationally in this field to potentially allow for cross-country comparisons?
- How will new and/or innovative medical technologies be treated after the set-up of the registry?

2) Set up the right GOVERNANCE

Registries have the potential to become powerful tools. However, this cannot happen if the right governance is not put in place. A good registry will appoint a commonly accepted, trusted and approved “coordinator” (which could be a “steering committee”, depending on the initiator of the registry and its defined scope) who should act on commonly defined rules of collaboration according to “Best Practice” principles.

Registries should set up proper mechanisms including transparent procedures to involve relevant stakeholders, as defined by the scope of the registry (including scientific community, payers, scientific societies, healthcare authorities, health economists, patients' associations, medical technology manufacturers, healthcare professionals, hospitals etc.). Registry holder(s) should engage in a constructive dialogue and efficient collaboration with all relevant stakeholders as each of them has unique and valuable insights.

To ensure registries interoperability in a cross-border setting we support European initiatives which could facilitate linkage among different data sources. We support a coordinated, harmonized and agreed by all parties approach to the development of registries with a common methodology and using the same core/minimum data sets. Further initiatives are needed to ensure the development of harmonised and standardised measures using validated instruments, such as comprehensive patient reported outcomes questionnaires, health-related quality of life questionnaires, measures for (socio) economic impact, and harmonised indicators to have a common basis of information.

Special provisions should be made in the governance on how and who can change the data generated to make sure that unauthorised manipulation with data is not allowed. Keeping the registry manual (rules) on data manipulation should be one of the responsibilities of the governing body.

Recommendations

When thinking about setting up governance for registries, we encourage the relevant bodies to take into consideration the following points:

- Commonly accepted, trusted and approved coordinator should be appointed.
- Data governance committee and written procedures for data ownership, data access, data analysis and data use before initiation of registry should be developed.
- Appropriate quality assurance plans including plans for periodic auditing of the registry should be set up.
- Broadly inclusive forums to engage with different stakeholders should be created.
- Potential synergies with other national or international registries should be explored.
- Successful on-going registry experience and efforts should be leveraged.
- Internationally agreed minimum data sets should be created to be able to share data across registries

3) Establish fair and transparent FINANCING amongst all the parties

As it is in all stakeholders' interest but primarily in the public's interest to set up a registry, appropriate public funding and possibly public-private partnerships should be put in place for the registry to properly function, including registry design, quality data collection, data analysis & reporting, and appropriate education. Multiple stakeholders have an interest in the creation of registries and the data which these registries generate. These multiple interests lead to the question of who actually wants to be involved and benefit from the creation of such a registry and the data it will provide. Looking at successful and sustainable registries, funding and in-kind support is a fundamental issue that needs to be managed and agreed upon early on in the process.

Ideally all future sponsors of a registry are interested in the data for active use e.g. for clinical and/or economic decision making. Ideally also, all stakeholders are included early on in the discussions and testing

procedures to define all the relevant parameters, the creation of the registry and follow-up period, as appropriate.

Funding should be agreed upon amongst all stakeholders, must be sustainable throughout the duration of the registry and should be proportionate to the research question and value received from the registry. The budget should be sufficient to provide for the set-up, data collection, and maintenance for the time needed (possibly several years) to sustainably create relevant data measurement, analysis and viewpoints. A registry should be re-evaluated periodically in line with its scope and stopped if it is not fulfilling its objectives. The true commitment of each stakeholder will be to manifest by their ability and willingness to co-fund or contribute to the registry. Funding or contribution to the registry should be a pre-requisite for the access to the predefined data sets.

Activities funded by a single stakeholder tend to be considered biased by the public and other non-industry stakeholders. Therefore funding by multiple parties, and involving public bodies, robust methodologies and strong governance will further contribute to the quality and objectivity of the registry.

Recommendations

- Address the funding challenges of a registry from the beginning.
- Make sure that funding is sufficient for the set-up and sustainable running of the registry.
- Make sure that all stakeholders interested in participating in the registry and in the data it produces are considered and consulted on funding or contributing to the registry.

4) Ensure the collection of QUALITY DATA and data protection

Quality data collected in line with applicable national laws and following recognised standards will allow answering the questions asked. Collaborative stakeholder engagement on emerging methodological approaches will result in evidence that meets the required goal of better balancing quality and cost as well as defining the value of medical technologies.

Aspects of data quality include accuracy, completeness, relevance, reliability and consistency of the records. In addition, other factors have to be considered to achieve an optimal quality-standard such as appropriate duration, well-defined end-points, and strong methodology addressing potential biases & missing data.

The registry needs to be conducted in accordance with a pre-defined & robust data management plan allowing the quality of data to be monitored and maintained throughout the duration of the registry. Modern information and communications technologies should be leveraged, minimizing additional human resources for collection and consolidation. The registry structure must contain all measures for ensuring data protection.

Recommendations

- Develop methodological guidance to provide the opportunity for obtaining reliable data to contribute to high-quality evidence.
- Conduct in-depth risk analysis to assess the registry's ability to obtain the quality data necessary for a pre-defined robust analysis and frequent reporting.
- Leverage experience and expertise from other types of activities like e.g. clinical trial data collection.
- Develop an automated data quality assurance system to verify adherence to the data quality monitoring plan which was developed prior to enrolment.

5) Make data AVAILABLE AND REPORT the data

Published peer-reviewed registry data, key findings and annual registry reports should be accessible on-line, and understandable to a wide audience.

Key findings of registries shall ideally be communicated to relevant stakeholders, for example at clinical congresses, to increase the awareness about how registries work and how adherence to agreed principles leads to better acceptance and participation.

Recommendations

- Provide definitions, explanations and methodologies on how data has been collected
- Establish clear roles regarding access to data for different users (primary users, secondary users)
- Establish the form in which data will be made available to primary and secondary users, including level of detail, numerical presentation and statistical analyses
- Establish publication policy plan
- Publish an on-line annual report including a patient-specific summary
- Establish a process for data requests

6) Ensure the right EDUCATION AND QUALIFICATION

Given the interest in registries across Europe and potential benefit that they could provide and that there is a wide variety and use of registries, it is essential that the staff involved with the registries and those assessing and using registry data are knowledgeable.

Standardised and certified education programs should be developed and included in the curriculum of students and professionals in research institutions, and clinical research organisations to ensure a common understanding and basis for collaboration.

Recommendations

- Standardised training programs should be developed and made available to
 - the staff involved in registries to ensure quality of data entered
 - other stakeholders involved in analysing and assessing registry data to help them understand the limitations and benefits of registry data
 - students as part of their curriculum to ensure proper qualification for possible future participation in registries
- Instruments to motivate entering complete data sets should be in place.