Using medical registries: Switzerland’s implant registry SIRIS as a successful model

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With the increasing use of implantable medical devices, registries are critical for conducting post-market surveillance and identifying long-term safety risks. Switzerland’s national implant registry SIRIS is an outstanding example of the benefits a well-managed registry can provide to different players in healthcare. The SIRIS registry also illustrates how to ensure high-quality registry data.

SIRIS registry: The largest implant registry in Switzerland

In recent years, there have been several high-profile scandals involving defective implants, such as poorly produced versions of silicone breast implants, metal-on-metal hip implants, or vaginal meshes. The European Commission and European Union countries therefore established a joint action plan that included support for developing implant registries in order to better identify safety issues and allow long-term monitoring of the safety and performance of medical devices.

The Foundation for Quality Assurance in Implantation Medicine (SIRIS), founded by swiss orthopaedics, Swiss Medtech, and santésuisse, initiated the SIRIS registry for hip and knee prostheses in 2012. Today, the SIRIS registry is the largest implant registry in Switzerland, with data collected from 186 institutions.

Participation is compulsory for all hospitals and clinics that perform knee and hip arthroplasties and have signed the National Quality Agreement with the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ). As a result, the coverage of hip and knee implants is high: around 95% of arthroplasties are reported.

High-quality data is crucial

Registry data must be of excellent quality to be useful for continuous quality improvement and implant-related clinical research. In order to analyse registry data correctly and draw valid conclusions, relevant quality requirements must be met. This is the only way to justify the significant organisational efforts, time, and costs involved in setting up and operating a registry. A badly managed registry with low data quality is not only useless but can even lead to unreliable information, wrong conclusions, and possibly inappropriate decisions.

There are several prerequisites for a high-quality registry. On an organisational and structural level, it is sustainability: a registry needs a clear aim, the partners who participate must be defined, the finances should be secured for several years, the governance must be defined, and bodies (e.g. a scientific board, an operator) need to be set in place. Another central aspect is the relevance of the information collected. When setting up a registry, its general objectives and expected outcome or results should be declared; the data to be collected should be defined accordingly. There is a high risk of implementing a registry with great personal effort, passion, and scientific eagerness but with no long-term plan on how to run and maintain it or how to analyse and report the registry's data.

On the data level, high quality depends on coverage, completeness, and correctness. Coverage evaluates the number of cases matching the inclusion and exclusion criteria recorded in the registry with external numbers of potential cases. This is a challenge, as the total number of cases are often not easily available and estimations rely on sales data (e.g. of implants), official administrative data, and internal data from clinic information systems. Completeness is a measure of how much of the requested information is entered into the registry. Having a user-friendly design for electronic data capture forms helps to achieve this with precise definitions of variables, ranges of valid data, distinct categories of answers, mainly mandatory fields, only a few optional fields, and the appropriate handling of potential missing data. The correctness of registry data is evaluated by central data monitoring and on-site audit visits.

Uses of registries

In recent years, patient-reported outcome measures (PROMs) have gained relevance as tools to describe treatment outcome from the patient's perspective. For example, patients provide their assessment of the level of pain or limitations in their daily activities before and after the implantation of a medical device.

However, even an optimally managed registry with complete, current, and relevant data makes little sense if the information contained in it is not systematically analysed. In the implant field, registries are often the only feasible or ethical way to collect long-term data on safety and the risk of revisions. Although randomised controlled trials (RCTs) are considered the gold standard for evaluating medical treatments, a long-term evaluation of implants (over many years after implantation) with an RCT is often unfeasible.

The information derived from registries can be useful for:

- patients who want to decide for or against a given implant
- doctors who want to know which implant and implant combinations to use in routine clinical practice
- researchers who work on projects related to long-term effectiveness
- regulators who make decisions about implants.

Hereafter we discuss the advantages and disadvantages of registry data for different user groups.

1. Feedback on the performance of products and clinics – benchmarking
In Switzerland, about 800 doctors regularly perform arthroplasty surgeries. They implant around 22,000 artificial hip joints and 18,000 artificial knee joints each year. Despite all the prophylactic measures taken, complications and revisions cannot always be completely avoided.

The Swiss implant registry SIRIS provides detailed quarterly reports (http://www.siris-implant.ch/en/) to all participating hospitals for quality assurance and publishes an annual report. These reports make it possible to compare hospitals (see **Figure 1**) and implants; detected outliers lead to thorough investigations and possibly to corrective actions.

For manufacturers of implantable medical devices, registries are a powerful tool for performing post-market surveillance and clinical follow-up.

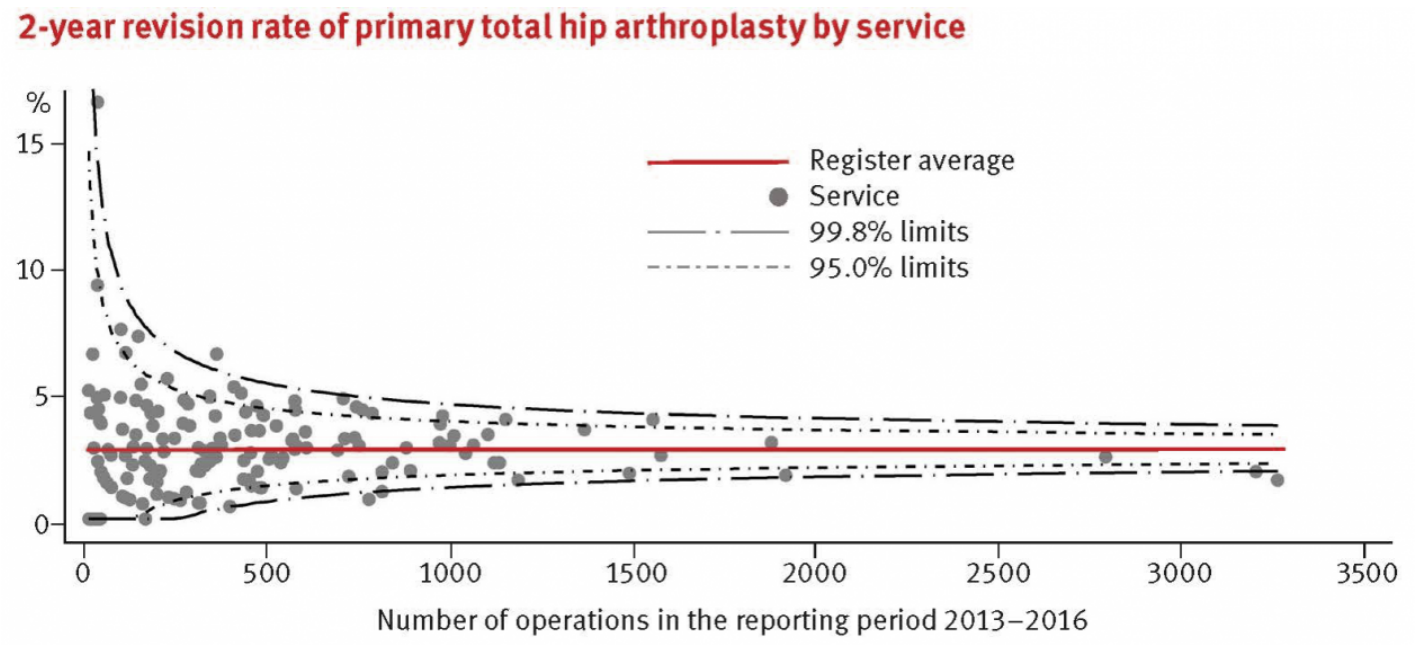

Figure 1: Example from SIRIS's 2019 annual report showing the revision rate by number of operations and clinic

2. A data basis for research

The availability of data on often large patient populations over many years makes registries an attractive platform for additional research activities. Registry-based research is usually less expensive and performed more quickly than projects, which need de novo data collection, especially if long-term outcomes are of interest. In addition, clinical data registries often include individual demographic data.

However, there are limitations on using registry data for research. Data are mostly collected for reasons unconnected to the specific research question of interest and, for practicability reasons, include only the most important variables. The information relevant for a study may not be available in the registry.

A possibility to increase the use of registry data in research is linking it with additional information from external databases. In order to allow for linkage with, for example, routinely collected administrative data such as mortality, several requirements must be met. For example, a registry must have individual patient identifiers with a corresponding legal basis or an informed consent statement from the patients. Harmonisation of data between registries and routine data and linkability are crucial for the future use of registries in the health sector. Since 2017, the Swiss Personalized Health Network (SPHN) has been actively promoting and funding projects which "enable the exchange of health-related data necessary for research". In the future, it would be ideal to use a uniform, non-speaking identification number in the various registries and routine data. To achieve this, the legal and data protection aspects need to be clarified.

3. A basis for decision-making for medical device regulators

Registries, especially in the area of implants, are also a valuable and important resource for regulatory

decisions concerning safety and are therefore crucial for approval. The effective use of well-organised registries can potentially lead to better health outcomes at a lower cost to society. In general, small registries with few data are of limited use to regulators. It is therefore often necessary to compare and combine data across registries, but this requires coordinated standardisation and harmonisation of the data collection procedures.

Conclusion

In summary, registries play an important role in the health sector and serve many needs. However, they are not a quick, easy, or cheap method to identify performance issues, answer research questions, and clarify questions from the regulators. Yet the SIRIS registry demonstrates that they can be worth the effort.

Further reading

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