EAR Handbook
for Register
Development

Handbook for the Development and Operation of an Outcome Register for Medical Devices

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Introduction and Background

Summary

This handbook summarises the experience collected in the establishment of Arthroplasty Registers within the framework of the European Arthroplasty Register (EAR).

EAR is a project by EFORT (European Federation of National Associations of Orthopaedics and Traumatology; www.efort.org) and has its legal basis in the Austria-based scientific non-profit association of EFORT-EAR.

EAR is a coordinating centre in a volontary cooperation of National Arthroplasty Registers, supports the development of national projects, supranational cooperation, for example, by process standardisation, and conducts scientific research focused on outcome research methodology.

The present handbook is designed to serve as a source of basic information of practical relevance, references primarily relate to recent publications with good publication lists. The list of references given in this handbook is not intended to be exhaustive.

Even though the present handbook primarily deals with Arthroplasty Registers, the results are also applicable to other medical devices if the following requirements are fulfilled:

1. The product concerned is a permanently-implanted medical device that can only be removed, exchanged or repaired by means of a revision operation.

2. There is a causal and logical relationship between a malfunction of the medical product and a revision operation. This means that every serious malfunction of or around the implant sooner or later leads to a revision operation, and every revision operation represents an undesirable result of the previous intervention.

3. The failure leads to an intervention or end-point which is documented in routine procedures in the medical service, for example, revision operations.

Thus the statements of this handbook cannot be applied to their full extent and without adaptation to essential areas in orthopaedics, such as fracture treatment (revision operations such as metal removal do not constitute a failed therapy per se), or anterior cruciate ligament repair (transplant rupture as a failure endpoint does not automatically lead to a documented medical intervention).

Introduction and Background

Development of Registers in Europe and World-wide

The world-wide development of Arthroplasty Registers can be traced back to initiatives in Scandinavia in the last quarter of the 20th century, where also the most important basic principles were developed with respect to methodology.

Since the turn of the millennium a multitude of national projects have been observed world-wide.

Country	Founded in	Status	Data collection
Sweden – Knee	1975	active	nationwide
Sweden – Hip	1979	active	nationwide
Finland	1980	active	nationwide
Norway	1987	active	nationwide
Denmark – Hip	1995	active	nationwide
Denmark – Knee	1997	active	nationwide
New Zealand	1998	active	nationwide
Hungary	1998	active	incomprehensive
Australia	1999	active	nationwide
Canada	2000	active	nationwide
Czech Rep.	2001	active	incomprehensive
Romania	2001	active	nationwide
Slovakia	2002	active	nationwide
Moldovia	2002	active	incomprehensive
Turkey	2002	in reorgansiation	in reorgansiation
Austria	2002	active	pilot phase (about 30% coverage; Register in the Province of Tyrol comprehensive)
England & Wales (NJR)	2003	active	nationwide

Introduction and Background

Development of Registers in Europe and World-wide

Country	Founded in	Status	Data collection
Lithuania	2005	pilot phase	pilot phase
France	2006	pilot phase	pilot phase
Portugal	2006	pilot phase	pilot phase
Netherlands	2006	pilot phase	pilot phase
Italy	2006	regional registers to be combined	not homogeneous with regard to the development in the regions; Lombardia and Emilia Romagna comprehensive
Croatia	2006	project	project
Bulgaria	2006	project	project
Spain	2006	pilot project	pilot project in the region of Catalonia
Switzerland	2008	pilot phase	pilot phase
(30% coverage)	2000	active	nationwide
Israel	2008	pilot phase	pilot phase
Luxembourg	2008	project	project
Poland		project	project
Germany	submitted for agreement	project	project

Apart from the ones listed above, there are numerous regional and other registers in the field of Orthopaedics that have not been included in this overview.

Introduction and Background

General Principles

Definition and Aim of an Outcome Register

- **Registration of ALL primary and revision operations in a defined area in a central database.**
- **Follow the implant until it has to be revised, the patient dies or emigrates.**
- **Definition of Revision (= Failure): at least one part of the implant has to be revised.**

Data collections which do not correspond to these criteria should be designated as surveys or multicentre studies.

This results in several essential differences as compared to other sources of information:

1. **Clinical studies:**
   They are usually sample-based, which makes bias factors inevitable. It would be sensible to examine whether the bias factors have a relevant influence on outcome and conclusions.
   In arthroplasty, bias factors in comparative analyses occur to a significant and relevant extent with respect to one of the most important indicators, the revision rate.

2. **Data sources from the public health sector:**
   These data sources are usually complete but mostly do not cover all contents that would be required to make statements of equal value and quality as compared to Registers. Since these data have primarily been collected for purposes other than outcome research, they should be validated before including them in comparative analyses. Outcome measurement reflects a very complex process with a variety of influence factors. The process is very changeable, therefore comprehensive datasets preferably covering all relevant factors are needed for making concrete decisions for improvement. Hence evaluations for outcome measurement put much higher demands on the selectivity of the basic data than, for instance, evaluations regarding structure and process indicators. As a matter of course, since processes in therapy and the structure of health-care do have an influence on the outcome, such data should therefore be incorporated in these evaluations. As a sole core dataset, however, such data (e.g. discharge records) are usually insufficient.

Rationale for the Decision to Set up a Register

- The organisation of a National outcome register is a complex task requiring high commitment by the persons involved and resources. Nevertheless National arthroplasty registers originating from Scandinavia have become established as valuable data sources that can provide an essential contribution to quality improvement.

- Valid data for day-to-day decisions are the basis for targeted quality improvement. Outcome research puts high demands on data sources since a variety of potential influence factors must be considered to achieve clear and selective results. Data currently collected in the health system, such as discharge records, mostly do not sufficiently contain all factors since they are collected for other purposes.

- The quality of data from comprehensive registers is clearly superior to those obtained from clinical studies and surveys. In comparison with registers, clinical studies to a considerable extent exhibit statistically significant deviations in revision rates and can therefore not be regarded as reliable.

  In conclusion it must be said that only an outcome register is able to provide clear and valid information as regards essential indicators such as revision rates.

- By way of longitudinal analyses, registers are able to initiate a structured bench-marking process and thus support a continuous improvement process.

- The experience with outcome registers in Scandinavia has demonstrated that.

  - by a continuous improvement process the revision rate can be reduced considerably; in total hip arthroplasty in Sweden, for example, by 50%.

  - This effects relevant cost savings, in Sweden, for example, an average of 14.000.000 US dollars in THA per year, pitted against costs of 400.000 US dollars for running a register. This corresponds to direct cost savings in hospitals effected due to non-incurred costs for complications that are 35 times the cost of a register.

- Registers are able to provide highly selective statements on the outcome quality of products and surgical techniques much more rapidly than other data sources.

- Registers are thus in a position to serve as a suitable early-warning system not only covering the outcome of implants in view of design and user-friendliness, but also with respect to the detection of relevant problems in the production process and the supply chain (e.g. loss in product sterility due to transportation).

Rationale for the Decision to Set up a Register

- The analysed examples of product deficiencies have shown that the present post-marketing surveillance procedures are inefficient. Registers are able to compensate for the deficits and make an essential contribution to improve patient safety.

- In case of product recalls or need for following up patients at closer intervals, a register can provide data about the patients and departments concerned.
  Registers can yield substantial improvements in vigilance control.

Success Factors for a National Outcome Register

Data Collection

- To allow for clear and reproducible evaluations and results, the data collections must comprise the most important factors influencing the outcome. These differ for different areas, that is why a particular questionnaire is required for each pathology. With regard to arthroplasty the most important contents are summarised in the EFORT Minimal Dataset, which is accessible via the EFORT website at www.ear.efort.org. A core dataset can be supplemented by further contents after approval by the National steering board; thus, additional aspects of National relevance can be covered.

- The workload for hospital staff resulting from documentation requirements is a critical factor. If it is too high, compliance is diminished, thus impairing the most important objective of data collection, the complete registration of all cases. The questionnaires should therefore be kept short and simple while asking for well-defined and objective contents.

- As a supportive measure, the use of facilities such as automatic read-out systems for the data already collected could be considered, for instance, by automatic detection of data already contained in the system, such as personal and product data, if the documentation is carried out via the hospital information system. However, solutions of this kind either require a largely standardised IT structure in the entire register area, or interface solutions.

- The primary goals of a register are longitudinal analyses with regard to the indicator of revision rate. The basic requirement for such evaluations is the collection of personal data to be able to assign primary and revision operations. This personal identification should be unambiguous and remain stable over a person's lifetime. The numbers of the statutory health insurance or fiscal codes meet these requirements, surnames or addresses do not. Trust centres represent an alternative if no unambiguous indentification number is available or its direct storage is not possible for reasons of data protection.

Organisation of an Outcome Register

- Since it is a fundamental goal of an outcome register to record all relevant cases in a defined geographical area, it is essential to control patients crossing the boundaries of a register.

- In this context it is a matter of particular interest to register patients whose primary intervention has been recorded in a register, whereas a potential revision operation is performed beyond the bounds of register collection.

- At present, linguistic and administrative hurdles represent a considerable barrier for National registers in Europe. The number of border crossings are negligible. Regional registers, however, should definitely take this aspect into account and publish the validation. In the course of an increasing availability of medical services in a common EU market, this aspect could generally become more important. In such a case obligatory reporting of the intervention to the register of the home country should be required, which is already practised in some cases. Since the costs of the intervention are usually covered by a National institution of the home country, autonomous monitoring is basically possible for the patient's country of origin.

- Supranational cooperation in data exchange and the provision for European identification numbers could help simplify the organisation of data collection in such cases.

- A central factor for the success of an outcome register is the cooperation between scientific societies and public health institutions. According to their focus of activity, both of them can make essential contributions to the overall performance:

  - Public health institutions usually have access to reference datasets, such as discharge records or official registration data / mortality records, which are essential for running a register. The public health sector is a major beneficiary of outcome improvements through registers. It can be expected that also public health institutions have a clear interest in being involved in the development and operation of registers in order to at least concomitantly monitor progress and make use of the results for their own tasks. Therefore, it is reasonable to utilise the specific background of the National public health system, incorporate existing structures, and ensure long-term and adequate funding.

  - Scientific societies have two primary competences:
    - Interpretation of the data requires broad expertise in the field, as well as detailed knowledge of the common surgical techniques and basic pre-requisites in the area covered in order to draw correct conclusions. Recourse to the pooled knowledge and experience of a multitude of physicians can provide essential contributions.
    - To tap the potentials for improvement identified by means of register results, comprehensive discussion within the networks of service providers is essential. Scientific societies provide an ideal forum for this process.
      Experience in Scandinavia has shown that improvements can be implemented in a sufficient

Organisation of an Outcome Register

and economic way via an autonomous process within the scientific societies. Delegating these tasks to the scientific societies and confining public health institutions to concomitant monitoring leads to an overall increase in efficiency.

An essential factor for the impact of an outcome register is an ample discussion of results. Physicians and health institutions have different needs; in a cooperation of public health institutions and scientific societies the option should be considered to compile specific reports for the different interest groups. In this context the individual partners' expertise and their networks for dissemination should be taken into account. Even if responsibilities for reports adapted to the respective target group are shared, all reports should be consensually agreed and decided on in a joint committee.

- The composition of a National register's steering group should take practical requirements into consideration. All major stakeholders should be involved; however, the group should not be too big in order to allow for efficient procedures. Perhaps a multi-level hierarchy should be chosen, with a core group running the day-to-day activities and a supervisory board responsible for strategic decisions and activity monitoring. It should be taken into account that the day-to-day activities, particularly data evaluation and validation for reports, are time-consuming. Well-established personalities from the scientific societies should be involved, but they usually have a variety of tasks to fulfil. Younger colleagues, who can concentrate on their tasks in registers and carry out detailed as well as preliminary work, are an option to share the workload and keep it at a bearable level for all parties involved. These persons, however, need time to familiarise themselves with the subject matter and build their reputation within the scientific societies for this responsible task. Qualified collaborators should therefore be already involved at an early stage of the project.

- Organisational details strongly depend on the legal environment, in particular on the data protection provisions regulating the comprehensive and routine storage and evaluation of personal data. In countries where this is possible, as is the case in Scandinavia, for instance, the establishment of registers in academic institutions supported by public funds has proved to be a successful approach. Also the establishment of registers in public health institutions represents a feasible option. In this case it is of crucial importance to involve all stakeholders, particularly the scientific societies.

- The organisation of registers should follow the principles of subsidiarity.

- In their datasets registers reflect the circumstances in the area monitored with respect to the implants used, the surgical techniques applied, or the conditions prevailing in the public health system. Merging the data or evaluating pooled data would dilute this effect and reduce the

quality of conclusions. For conclusions and longitudinal analyses (e.g. the analysis of the impacts of changes) on a national scale, National register data must therefore basically be regarded as superior.

- This also applies to evaluations at a level below the register, e.g. at the departmental level.
- The complexity of the organisation of register projects increases along with the size of the area to be monitored.
- In certain cases, however, supranational evaluations based national datasets do have advantages:
  - if the datasets of National registers do not reach sufficient size, as is the case with new or rarely used implants;
  - in supranational comparisons with respect to various variables, e.g. the impacts of different public health systems or procedures on the quality of treatment, or the performance of surgical standards or implants.

Evaluations, Feedback and Publications

The evaluation procedures applied should largely be structured in a standardised way in order to be able to track developments in the reports and simplify the evaluation process. Evaluations for physicians/departments are usually divided in two parts:

- a publicly accessible annual report, and
- a confidential departmental report. This report contains the results of the respective department including benchmarks relative to the average without diclosure of the results of other departments.

The structure of the reports is largely oriented at the data collected. There are many examples from established registers available. Basically, a raw report should first be compiled which should be as comprehensive as possible.

This raw report should be analysed by a core team of the register in order to

- Define relevant and sound data for the public report. In the course of the development of a register the increasing quality of the dataset allows for additional evaluation options and improved statement quality.
- To recognise irregularities such as increased failure rates of individual implants and perhaps analyse them in detail. This step should not be carried out on an exclusively mathematical basis, and must consider potential influence factors. Not every statistically significant result is actually relevant in practice. To achieve the highest possible sensitivity, it is necessary to proceed aggressively in the statistical methodology applied. As a consequence, however, factors such as a surgical learning curve or cluster formations by individual departments leading to a relative increase in revision rate could compromise the results. Even if special emphasis is put on high sensitivity in the mathematical approach, the issue of interpretation should be handled with great care. Statements made by registers should be valid and well-founded to avert any damage from the register, products and departments.
  The reliability of register data is an important commodity worth protecting.

On the basis of register data also scientific studies can be conducted, which has several advantages for the register:

- As a rule, manpower is made available free of charge, and additional insights are obtained.
- For scientific studies the basic data are usually validated so that concomitant validation of the entire dataset can be supported without additional allocation of means.
- The publication and discussion of results fosters the pre-occupation of physicians with the register, a crucial factor for the effectiveness of a register.

Evaluations, Feedback and Publications

- Constant feedback to physicians and departments is also important for the register's effectiveness. This should preferably be started at a very early stage of register development, even if only limited data such as epidemiological evaluations are available in the beginning.

  In the course of feedback also statistical interpretations and general information concerning the interpretation of data should be offered.

- Since the data of the departmental report are confidential, it is essential to impart the necessary basic knowledge for data interpretation. Contact persons should be available for further queries to interpret results. However, this should exclusively be understood as an offer. The addressee of the departmental report should decide autonomously whether or not and which of the confidential data shall be disclosed.

  For data interpretation a wide variety of data can be used, for instance, data from registers of other countries to asses the outcomes of implants applied. This, however, requires profound knowledge of the quality and comparability of the respective data – complex knowledge that should not be expected of every user.

Funding

- Physicians and departments often are the primary points of contact for outcome registers. Even if physicians are bound to check and improve the quality of their performance within the scope of their general duties, from an economic point of view it is the healthcare system which draws the greatest financial benefit from quality improvements due to registers.

- Outcome registers are cost-efficient, despite the fact that it takes several years until significant data are available. Registers by definition have no end-point and should be run on a long-term basis and continuously, with the benefit increasing in the course of time. Therefore, a long-term continuous financial basis should be ensured.

- As a rule, scientific societies cannot offer such a basis independently. They are usually directly or indirectly financed by the producers of medical devices and pharmaceuticals – i.e. by the manufacturers of the products whose quality should be controlled. This could raise the issue of the independence of results.

- It is advisable to maintain outcome registers by public funding.

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Links

EAR

- http://www.ear.efort.org/

EFORT

- http://www.efort.org/

Closing Words

The development of a register is a very complex and time-consuming task during which a variety of problems and details have to be solved. Working groups dedicated to such a task should actively attempt to cooperate with working groups in other countries, either via networks such as EAR or directly.

The challenges in the development of an outcome register are usually similar in all countries, incorporating experience and solutions from other countries allows for concentrating the resources available.

An outcome register should form an integral part of the respective health-care system. A simple adoption of global solutions from other countries would therefore not make sense. However, taking recourse to the experience and solutions in other countries and adapting them to the particular environment is a promising approach.

The expenditure and personal commitment required are often underestimated. However, the achievements and benefits for the quality of medical performance justify this commitment.

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Many registers publish reference lists on their websites, partly also in full text. An overview of these websites is available at http://www.efort.org/getdoc/1b923b01-41d2-4587-bac2-7ca7a11e613e/Arthoplasty-Registers.aspx.

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