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Characterising Registries for reviewing purposes

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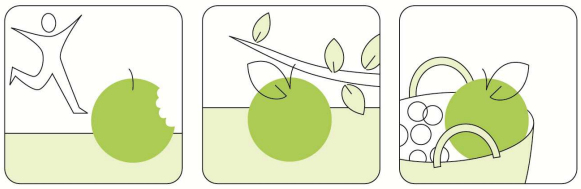

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Summary

Characterising registries for reviewing purposes

Background

An undisputable practice of decision making in healthcare is including existing scientific knowledge by critically appraising the best available evidence [1]. Recently medical registries have reached increasing interest by reviewers [2]. One reason is, that registries provide information on the real world use (effectiveness) of health services (do interventions perform as expected?) as opposed to information on efficacy (do interventions work?). Another reason is that medical registries have the potential to address questions that can not always be answered by clinical studies because of their design (clinical studies usually show the advantage of one intervention compared to another, but are not designed to give background information or reasons). Registries are seen to be valuable tools to give additional information alongside clinical studies [3], [4], [5]. The EUPHORIC project aims to support the function of registries by coordinating registry activities along the member states and by presenting useful indicators and necessary practical and methodical tools [www.euphoric-project.eu].

However, there are a couple of difficulties to include information from registries into reviews. Taking these difficulties into account creates the need for a scheme to characterise registries before adding them to the knowledge base of a review.

Objective

This paper describes the development of a characterising scheme for registries that are considered for a review of the scientific evidence. It is supposed, that a list of few critical features to be evaluated would be sufficient to guide the selection decision adequately. It is aimed that the impact of each feature can be demonstrated by citations from technical literature on the work with registries. An overview of the technical literature is attached.

Method

A search for current active cardiovascular, neurological and spine-related registries in selected countries was performed and a database was created from the results [6]. From the descriptions of the registries, common characteristics were extracted. Examples for these features are: the primary question, the types of main data fields, the type of results given, the kind of stakeholder, etc. At the same time a review on the literature of the work with registries was performed. 23 Publications were finally selected and analysed. Essential statements by the authors were collected and formed to good practice strategies for the work with registries [6]. Subsequently 9 characteristics were chosen in an iterative process by means of importance according to the knowledge from the technical literature. The characteristics were grouped into tree domains. To validate the scheme, it was applied to a sample of registries and its practicability was evaluated.

Results

The scheme consists of nine characteristics. The scheme is shown in table 1. The characteristics are grouped into three domains: context, design and result. Every characteristic is specified by guiding questions. Additionally, a more detailed description of every characteristic is available together with citations from technical literature.

The validation process (the scheme was used to characterise a sample of registries) showed good applicability. Most of the characteristics could be taken from the publicly available registry information.

Conclusions

Registries used in medicine have variations in their context, design and results. This is a barrier for the usage of results within reviews of evidence. It is possible to assess the variations by applying a scheme to characterise registries by these domains. The examination of the main characteristics can ease the inclusion/exclusion process to reviews and therefore help to utilise valuable scientific knowledge from registries to the level of health care decision making.

1 Background

An undisputable practice of decision making in healthcare is including existing scientific knowledge by critically appraising the best available evidence [1]. The number of scientific papers has increased rapidly in the last decades. Therefore systematically reviewing the literature has reached a level of tremendous importance for an easier access to information. Systematic reviews help decision makers to find the right information in the right form. Most of the systematic reviews are performed by EBM (evidence based medicine) or HTA (health technology assessment) researchers. The number of such departments and institutes is growing.

The sources of information (i.e. the evidence) are publications of studies, but although other resources (reports, information from databases) are also taken into account (according to the principle of looking for the best available evidence). Recently medical registries have reached increasing interest by reviewers [2]. One reason is, that registries provide information on the real world use (effectiveness) of health services (do interventions perform as expected?) as opposed to information on efficacy (do interventions work?). Another reason is that medical registries have the potential to address questions that can not always be answered by clinical studies because of their design (clinical studies usually show the advantage of one intervention compared to another, but are not designed to give background information or reasons). Registries are seen to be valuable tools to give additional information alongside clinical studies [3], [4], [5].

However, there are a couple of difficulties to include information from registries into reviews. First, initiatives indicating themselves as a "registry" are tremendously heterogenic in their design [8]. Many of them would neither fit the epidemiologic definition [9] nor to AHRQs (Agency for Healthcare Research and Quality) definition of patient registries [2]. They may focus various types of questions and often many questions in parallel [4]. They may run in different settings and with different interests. Therefore it is not easy to work out, if a registry has valuable information or not. Second, the registry may address questions from two or even three very distinct scientific fields. Registries can focus public health questions, clinical questions or even questions of an ideal individual treatment [10]. Third, the way of information output varies in registries. While many of the current registries publish their result in scientific journals others offer only limited information to the public (which can also be also a problem when trying to identify it). There is no system of registration for registries as it exist for clinical studies.

Taking these difficulties into account creates the need for a scheme to characterise registries before adding them to the knowledge base of a review.

2 Method

Within the scope of a project [6] at the Ludwig Boltzmann Institut Health Technology Assessment a search for current active cardiovascular, neurological and spine-related registries in selected countries was performed and a database was created from the results. From the descriptions of the registries, common characteristics were extracted. Examples for these features are: the primary question, the types of main data fields, the type of results given, the kind of stakeholder and many others. At the same time a review on the literature of the work with registries was performed. 23 Publications were finally selected and analysed. Essential statements by the authors were collected and formed to good practice strategies for the work with registries [6]. A selection of these strategies is available in Appendix 3. Subsequently 9 characteristics were chosen in an iterative process by means of importance according to the knowledge from the technical literature. The characteristics were grouped into tree domains. To validate the scheme, it was applied to a sample of registries and its practicability was evaluated.

3 Results

The scheme consists of nine characteristics. The scheme is shown in table 1. The characteristics are grouped into three domains: context, design and result. Every characteristic is specified by guiding questions. Additionally, a more detailed description of every characteristic is available together with citations from technical literature.

The validation process (the scheme was used to characterise a sample of registries) showed good applicability. Most of the characteristics could be taken from the publicly available registry information.

Table 1. Characteristics of registries

Domain Characteristic	Questions	Notes/Comments	Good practice strategy
1. Context			
Problem	What is the main problem focused by the registry? [2]	A clear definition of the main problem as well as the aims of the registry is essential to all following decisions in performing the registry. This can be, choosing the appropriate design, select the necessary core data, plan the analysis and plan the reporting strategy.	See good practice strategies in appendix 3: ⇒ **Define the objective(s)**
Health service catchment area	Does the registry address input, throughput, output or outcome?	Considering the catchment area of the registry gives an overview on the context. A better understanding of the registries role in the system should be possible by analysing this characteristic.	See good practice strategies in appendix 3: ⇒ **Determine the level of action**
Adherence	Are there any laws, contracts or promises to which the registry adheres? Who are the stakeholders?	This characteristic may help to recognise main aspects that determine the registries structure and the potential to utilise it's information	See good practice strategies in appendix 3: ⇒ **Identify stakeholders**
2. Design			
Data	What primary data objects are used? (individuals, cases, devices) What data groups are used? (demographic data, exposure data, intervention data, outcome data) What registry type appears according to the scheme published in [7] Which aggregation level is covered (individual level data, aggregated data)?	Data elements are the essential core of the registry. The utilisation of any valuable information depends on the chosen data elements. If a reviewer works on a question of safety, the register must have data about adverse effects to be included.	See good practice strategies in appendix 3: ⇒ **Select data elements according to standards** ⇒ **Define a core data set**
Population	Which population is recorded by the registry?	For a reviewer a description of the population is essential to estimate the external validity (i.e. the transferability of the findings).	
Scheme of analysis	What kind of comparison is used? Is the design longitudinal or cross-sectional?	The design gives information about the internal validity of the registry.	See good practice strategies in appendix 3: ⇒ **Apply a scientific design for the registry**

Table 2. Characteristics of registries *(continued)*

Domain Characteristic	Questions	Notes/Comments	Good practice strategy
3. Outcome and dissemination			
Result	What kind of numbers, ratios or rates (or indicators or key figures) are used to describe the outcome [11]? Has the main problem been addressed by the chosen parameters?	For registry results to be included into a review, they must provide outcomes that are able to contribute to the question of the review.	See good practice strategies in appendix 3: ⇒ **Select data elements according to standards**
Reports (Reporting strategy?)	What kinds or formats of reporting are used? What is the frequency of reporting? Are publications available?	The most important aspects of outcomes may be, if they are comparable with other reports or data sources. Information on the quality of the outcomes should be included.	See good practice strategies in appendix 3: ⇒ **Define the format of reporting**
Dissemination	Who is addressed by the reports? Are feedback mechanisms defined for beneficial changes to the problem area? [12], [13], [14]	This characteristic indicates the practical value of the registry in it's operational area	See good practice strategies in appendix 3: ⇒ **Let results act as feedback to the system**

The following section gives a more detailed description of each particular characteristic.

3.1 Context

• Characteristic: Problem

What is the main problem focused by the registry?

A clear definition of the main problem as well as the aims of the registry is essential to all following decisions in performing the registry. This can be, choosing the appropriate design, select the necessary core data, plan the analysis and plan the reporting strategy.

See good practice strategies in appendix 3:

⇒ **Define the objective(s)**

• Characteristic: Health service catchment area

Considering a black box model of the health system - does the registry address input, throughput, output or outcome?

Considering the catchment area of the registry gives an overview on the context. A better understanding of the registries role in the system should be possible by analysing this characteristic.

See good practice strategies in appendix 3:

⇒ **Determine the level of action**

- **Characteristic: Adherence**

Are there any laws, contracts or promises to which the registry adheres?

Who are the stakeholders?

See good practice strategies in appendix 3:

⇒ **Identify stakeholders**

3.2 Design

- **Characteristic: Data**

Data elements are the essential core of the registry. The utilisation of any valuable information depends on the chosen data elements. If a reviewer works on a question of safety, the register must have data about adverse effects to be included.

What primary data objects are used? (Individuals, cases, devices)

What data groups are used? (Demographic data, exposure data, intervention data, outcome data)

What registry type appears according to the scheme published in [7]

Which aggregation level is covered (individual level data, aggregated data)?

See good practice strategies in appendix 3:

⇒ **Select data elements according to standards**

⇒ **Define a core data set**

- **Characteristic: Population**

For a reviewer a description of the population is essential to estimate the external validity.

Which population is recorded by the registry?

- **Characteristic: Scheme of analysis**

The design gives information about the internal validity of the registry.

What kind of comparison is used?

Is the design longitudinal or cross-sectional?

See good practice strategies in appendix 3:

⇒ **Apply a scientific design for the registry**

3.3 Outcome and dissemination

- **Characteristic: Result**

The most important aspects of outcomes may be, if they are comparable with other reports or data sources. Information on the quality of the outcomes should be included.

What kind of numbers, ratios or rates (or indicators or key figures) is used to describe the outcome?

Has the main problem been addressed?

• Characteristic: Reporting strategy (Reports?)

What kinds or formats of reporting are used?

What is the frequency of reporting?

Are there publications?

See good practice strategies in appendix 3:

⇒ **Define the format of reporting**

• Characteristic: Dissemination

Who is addressed by the reports?

Are feedback mechanisms defined for beneficial changes to the problem area?

See good practice strategies in appendix 3:

⇒ **Let results act as feedback to the system**

4 Conclusions

Registries used in medicine have variations in their context, design and results. This is a barrier for the usage of results within reviews of evidence. It is possible to assess the variations by applying a scheme to characterise registries by these domains. The examination of the main characteristics can ease the inclusion/exclusion process to reviews and therefore help to utilise valuable scientific knowledge from registries to the level of health care decision making.

5 Appendices

5.1 Summary of the LBI HTA projekt "Register für klinische und gesundheits ökonomische Fragestellungen"

Project report on
"Clinical and health economic registries in the field of cardiovascular, spinal and neurologic diseases. Methods and good practice strategies"
Link to the full report:
http://eprints.hta.lbg.ac.at/788/1/HTA-Projektbericht_011.pdf
(Report language is German)

Executive summary:

Clinical and health economic registries in the field of cardiovascular, spinal and neurologic diseases. Methods and good practice strategies

Background: The increasing demand for a better understanding of the health care system and ways to its improvement resulted into a diversification on the method of epidemiological registries. In regard to this additional registries developed in clinical fields with variable methodology and goals. Additional factors for an increasing usage of registries are improved information technologies and the need for information for policy making in health care. The application of registries was therefore extended from population based coverage to other areas. Different application fields, definitions, questions and methods of existing registries complicate the question, where registries can be applied effectively and what factors would be critical to a successful implementation. This implies also the question, how registries can produce scientifically accepted information that is also useful for health policy making.

Policy and Research Question of assessment: Questions of this assessment are (1) in what fields are registries recently additionally applied, (2) what kind of questions are processed in these registries and (3) what are the factors that make a registry work efficiently and what is needed to make them producing scientific valuable and health political relevant results.

Method: For each sub question different methods were used. A systematic literature search and a complementary search discovered active registries in selected medical fields by publications resulting from these registries. An iterative deductive method was applied to generate a scheme to characterise registries. With these scheme types of questions in registries can and have been systematically assessed. A second systematic literature search was performed to identify good practice strategies for the work with registries.

Results: The results are presented in three parts:

1.) The results from the systematic identification process for active registries in the cardiovascular, neurological and spine-related field are 42 registries that are presented in the report in tabular view and in a database.

2.) A scheme for the characterisation of registries was developed. A description of 4 cases of registries helped to demonstrate the scheme and to deepen the knowledge about questions and the organisation of the cases.
3.) In about 250 citations in methodological and reflexive publications about registries were compacted to form good practice strategies for the work with registries. Also a category system evolved.

Discussion: The analysis of application fields of registries confirmed their usage for differential observations of the gap between experimental research and real life application. This can be interpreted as an increased need for information about the health care system. For the work within registries various biometrical and epidemiological methods can be applied and these methods are described plentiful in the technical literature for registries. A scientific design is recommended in registries and can improve the significance of the results. Beside recommendations regarding the scientific design plenty advices could be identified in the area of information processing and project management. Risks in performing registries to be considered concern data privacy and protection aspects and the need for (often underestimated) complex statistical analyses of the registry's data. An important aspect is also the strategy for dissemination. Many recommendations to connect the results tightly to feedback channels into the related health area implicate, that results of registries are often not sufficiently considered in health policy decisions. A methodology for the evaluation of the quality of the evidence from registries - as it is needed in Health Technology Assessment - is rudimentary available.

Conclusion:

- Registries can be seen as a reaction to the expanded information needs about the health care system
- Registries are used increasingly in the field of quality work, in initiatives of specialists and initiatives to connect research and real life application
- Registries can be seen as a complementary tool to clinical studies
- Data security aspects and complex statistical analyses are resource critical aspects of registry ventures
- Prerequisites should be arranged in a way that registry results are able to act as feedback to the system
- Methodological knowledge from classical study designs and biometrical methods can enhance the significance of the evidence from a registry
- For the assessment of the quality of the evidence from registries rudimentary methodological guidance is available.

5.2 Appendix 2: A method to identify registries by citations - poster presented on the HTAi 2008, 6th-8th of July.

Link to the poster:
http://eprints.hta.lbg.ac.at/788/2/RegisterPosterHTAi2008-07-02.pdf
The list is part of the LBI HTA project # 11

Abstract:

Registries – What for?
Evidence from international registries in cardiovascular, spine related and neurological fields

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Ludwig Boltzmann Institut für HTA

Background: For the appraisal of benefit of health technologies from the view of health decision maker different sources of evidence can be used. An important complementary approach to experimental studies is using registries. They can give a more population based view to a health problem and allow certain analyses that can not be addressed in clinical studies – for example the identification of rare side-effects. Here we present a project that aims to evaluate the benefit of registries for health decisions. In the first step an exhaustive amount of active registries in three clinical fields are identified to get an overview about types of questions and results that are addressed by registries.
Methods: A systematic search was performed in Medline and Scopus to identify publications that present results from registry projects. In the next step a web search for the identified registries and a collection of basic data to the registry was done. Additionally an email-request was sent to experts to identify registries.
Results: 365 cardiovascular, 366 neurological and 64 spine specific articles were identified in the search. 159 of the cardiovascular, 108 from the second group and 64 spine specific articles mention registries. These registries were located and underwent a selection by exclusion criteria (only registries that have been active during the past 3 years with periodic reports, certain countries). Finally an amount of about 90 cardiovascular, 20 spine and 30 neurological registries could be identified. Additionally 8 registries were identified by the experts.
Conclusion: The applied search to identify registries helped to get an overview over active registries and their working topic. One of the ways to appraise the potential of registries to offer evidence for HTA is the amount of their publications. Registries according to national guidelines seem to be more efficient by means of having a greater publication output.

5.3 Appendix 3: Good Practice Strategies for the work with registries and references to the technical literature

In this appendix a collection of "good practice strategies" is listed. Sources from the technical literature for each strategy are cited. The chapter topics of the list are based on the chapter structure of the handbook "Registries for Evaluating Patient Outcomes" [2]. This was also the main technical document used as source of good practice strategies. The good practice strategies are printed in bold letters.
The list is part of the LBI HTA project # 11:
http://eprints.hta.lbg.ac.at/788/

5.3.1 Phase of planning

⇒ **Define the objective(s)**

"key steps in planning ... articulating the purpose of the registry" [2]
"The purpose or purposes should be clearly stated. A registry must have a clear purpose that can be articulated by the sponsoring organisation" [15]
"The fact that there were fairly explicit goals in the original registry establishment funding contract documentation for monitoring this aspect of the system has enabled the project to focus on specific objectives rather than just collecting data, in the hope that some of it will be useful." [16]
„… Zweck der Erhebung allen Beteiligten transparent und einsichtig…" [17]
[Translation: „The aim of the data collection is transparent and understandable to every participant"]

⇒ **Determine whether a registry is the appropriate strategy**

"determining whether the registry is an appropriate means for addressing the research question" [2]
"Determine if the registry is an appropriate strategy to achieve the purpose and how the data from the registry will fit into the overall evidence programme for the sponsor's product. Alternative evidence development approaches, including randomised trials or existing datasets, might be compared or contrasted" [15]

⇒ **Identify stakeholders**

"key steps in planning a patient registry ... identifying stakeholders" [2]
Identify the stakeholders. Internal stakeholders include organisational ' owners' of the registry as well as other influencers. Sufficient resources should be allocated. External stakeholders should also be determined and potentially engaged." [15]
"For a registry to function optimally there must be a collective will for it to work at the political, administrative and clinical levels." [16]

⇒ **Register as much as necessary – as little as possible**

"The scope is also affected by the degree of uncertainty that is acceptable to the primary stakeholders, with that uncertainty being principally driven by the quantity, quality, and detail of the data collection balanced against its considered importance and value." [2]

⇒ **Sufficient funding for main period**

"key steps in planning ... assessing feasibility, and securing funding"[2]
"Funding must be sufficient to enable long-term commitment from an expert group to oversee the registry and experienced staff to focus on sustainable collection and analysis of data."[16]

"If register data are requested because they can help in making relevant assumptions about cost-utility and cost-effectiveness in spine surgery and thus in setting priorities among healthcare activities, then it should be obvious that all involved should be given the time and financing necessary to accomplish the task. This issue is a matter of urgency, at least in Sweden."[10]

„Bis zu diesem (vorläufigen) Endpunkt müssen ausreichende Kapazitäten, insbesondere auch für die planmäßige Auswertung und Veröffentlichung, bereitgestellt sein." [4]

[Translation: „Until the (preliminary) endpoint [comment: endpoint ot the planning period] there must be sufficient resources particularly for the planned analysis and public presentation of the results"]

⇒ **Provide incentives for data collection**

"Factors that motivate participation include the perceived relevance, importance, or scientific credibility of the registry, as well as the risks and burdens of participation and any incentives for participation."[2]

"...Belgian example by making verifiable data submission a prerequisite for reimbursement of the procedure." [18]

"Strong determinants may also be reimbursement associated with registering. Non-participating departments may encounter economic disadvantages on the healthcare market."[10]

⇒ **Determine the level of action**

"The intention may be to give local, regional, or national support, or
international services ..." [10]

5.3.2 Design of the registry

⇒ **Apply a scientific design for the registry**

"key points to consider in designing a registry include ... choosing a study design" [2]

⇒ **Combine the registry with a clinical study**

„Register und Studien sollten idealerweise aufeinander bezogen, möglichst sogar verzahnt geplant, durchgeführt und ausgewertet werden" [4]

[Translation: Registries and studies should be planned, performed and evaluated in a interrelated, interleaved i.e. synergistic way

⇒ **Test the design by an ethical board**

"As a rule it is a good idea to test the future registry's design with an ethical review board."[12]

⇒ **Select data elements according to standards**

"Specific data elements then are selected with consideration for established clinical data standards, common data definitions, and the use of patient identifiers." [2]

"In choosing measurement scales for assessing patient-reported outcomes, it is preferable to use scales that have been appropriately validated, when such tools exist." [2]

⇒ **Perform a pilot test for the design**

"Once data elements have been selected, a data map should be created, and the data collection tools should be pilot tested. Testing allows assessment of respondent burden, accuracy, and completeness of questions, and potential areas for missing data." [2]

5.3.3 Data elements

⇒ **Define a core data set**

"... preferable for spine surgeons to agree on the use of a basic set of core outcome instruments, preferably suggested by the Spine Society of Europe (SSE), to allow relevant comparisons with data from other registers." [10]

"The data elements collected by trauma registries internationally varies considerably and recommendations have been made to minimize the number of core variables collected due to the potential for incomplete datasets." [16]

„Es hat sich bereits in der Vergangenheit gezeigt, dass die durch die Kerndokumentation etablierte Dokumentationsstruktur äußerst günstige Voraussetzungen für die Durchführung großer multizentrischer Studien, sowohl klinischer Phase- III- und -IV-Studien als auch epidemiologischer Prognosestudien, bietet." [17]

[Translation: "history shows that a document structure that is characterised by a core documentation is an advantageous base for performing further big multicentre clinical studies (of phase III and phase IV) as well as prognostic epidemiological studies"]

⇒ **Variables should be easy to measure**

"The variables shall be well defined and easy to measure" [12]

5.3.4 Data sources

⇒ **Knowledge is necessary about the formation of secondary data**

"Secondary data are comprised of information that has been collected for purposes other than the registry, and they may not be uniformly structured or validated with the same rigor as primary data. "[2]

"Furthermore, a solid understanding of the original purpose of the secondary data and how they were collected is advised, because the way that those data were collected and verified or validated will help shape their use in a registry." [2]

„So ist eine systematische Verfälschung zu erwarten, wenn auf Diagnosen Bezug genommen wird, die zu Abrechnungszwecken dokumentiert wurden." [19]

[Translation: „Systematic bias has to be expected when using diagnostic data that comes from administrational accounting documentation"]

5.3.5 Ethics, data ownership, privacy

⇒ **Orientation on the EC directive 95/46 data protection[20] when considering privacy and data security aspects**

"The objective of the Personal Data Act is to protect people from personal integrity violation through the processing of personal data. This law, which went into effect in October 1998, builds on an EC directive and replaces the Data Act." [12]

"Ownership of and access to databases require clarification" [7]

⇒ **Assess the risk of collecting data**

"The balance between the benefits of using such data [comment: routine data] for research and the risks of abuse needs to be continually assessed."[7]

5.3.6 Recruitment and Management

⇒ **Communicate relevance and importance to all participants**

“The motivating factors for participation at each level and the factors necessary to achieve retention differ according to the registry. Factors that motivate participation include the perceived relevance, importance, or scientific credibility of the registry, as well as the risks and burdens of participation and any incentives for participation.” [7]

⇒ **Plan the recruitment method**

“Well-planned strategies for enrolment and retention are critical”[7]

⇒ **Share profits with participants**

„Für die Qualität eines Registers ist es hilfreich, die beteiligten Institutionen und Wissenschaftler unmittelbar von dem erzielten Erkenntnisgewinn profitieren zu lassen.“ [4]

[Translation: For the quality of a registry it is helpful to share the gathered knowledge accession directly with the participation institutions and scientists”]

5.3.7 Data collection and quality assurance

⇒ **Use an integrated software system**

“The integrated system for collecting, cleaning, storing, monitoring, reviewing, and reporting on registry data determines the utility of those data for meeting the registry’s goals.” [2]

“As a solution, the national Spine Society decided that a less work-intensive and automated web-based register solution should be developed. The goal should be to ensure the import and export of data, to simplify statistical analyses and to facilitate online feedback and annual reporting with a minimum of effort.” [10]

⇒ **Place the physical registry system by practical considerations**

“The registry’s physical placement (Registry Manager and database) is guided by practical considerations. The placement should for example not be perceived as a threat or as a competitor to established research groups.” [12]

⇒ **Train the people that collect the data**

“Therefore, all data collectors must be trained appropriately to ensure data quality.” [16]

“To improve data quality, standardized definitions for all data fields are provided to the nurses in an operations manual, and extensive training of data-entry personnel is necessary.” [21]

„Alle Beteiligten sollten eine klare Vorstellung von den Informationen haben, die aus jedem einzelnen Eintrag auf dem Datenblatt entnommen werden.“ [22]

[Translation: „Every participant should have a clear understanding of the concept of the information that is taken from each entry on the datasheet.”]

⇒ **Provide a support service**

“There were numerous questions regarding registration procedures from the participating departments and in order to ensure compliance, a readily accessible support function should be available during working hours.” [10]

⇒ **Do documentation timely**

„Die genannten Verfahren, wie das Schreiben von Arztbriefen und die Planung von Chemotherapien, können besonders erfolgreich eingesetzt werden, wenn die Daten möglichst frühzeitig im Behandlungsablauf und nicht erst nachträglich erhoben werden, so zum Beispiel in Nachsorgesprechstunden oder onkologischen Tageskliniken. Hier deckt das GTDS einen nennenswerten Anteil der durch die Ärzte in der Routine benötigten Funktionen ab, so daß es in einigen Zentren bereits in der Routine benutzt wird."
[23]
[translation: Named procedures as writing the medical documentation or writing a dosage plan for a chemotherapy can successfully be performed, if data are entered in the earliest possible moment during the treatment process, instead of entering the data subsequently (as in aftercare consultations or in oncology outpatient centres"]

⇒ **Standardise data collection**

"Data collectors must be able to collect all data items in a standardized manner with specific protocols to ensure data validity and reliability." [16]

⇒ **Use web-based data entry systems**

"New National Quality Registries should strive to be web-based from the start." [12]

⇒ **Make questionnaires patient-based**

"The early paper-based model was static and heavily dependent on the work of secretaries at both the data processing departments and the data administrative centre. In addition, since spine surgeons—at least in Sweden—have limited time for (or interest in) completing forms, the registration procedure was problematic. In times of economic restrictions and increasing workload, data reports were not frequently delayed and incomplete registration was a problem. As a solution, outcome questionnaires were reorganised and made entirely patient-based." [10]

⇒ **Define data quality attributes**

"Before designing a plan for quality assurance of registry data, a clear description of what attributes constitute data quality is necessary." [24]

⇒ **Perform audit and monitoring as like in clinical studies**

"Therefore, there are requirements for benchmarking and comparative audit as tools for quality control that are both essential and urgent." [18]
„Plausibilitätsprüfungen, Data Monitoring und Audits kommt deshalb in Registern dieselbe Bedeutung zu wie etwa in RCTs." [4]
[„Registries require the same efforts for plausibility checks, data monitoring and audits as for randomised controlled studies."]

5.3.8 Adverse events

⇒ **Implement a system to handle adverse events**

"AE-Detection: Although AE reporting for all marketed products is dependent on the principle of "becoming aware," collection of adverse event data falls into two categories: those events that are intentionally solicited (meaning data that are part of the uniform collection of information in the registry) and those that are unsolicited (meaning that the AE is volunteered or noted in an unsolicited manner)." [2]

5.3.9 Analysis and Interpretation

⇒ **Include relevant co-variables**

“Evaluation of an exposure often includes the exposure of interest as well as information that affects or augments the main exposure, such as dose, duration of exposure, route of exposure, or adherence.” ...
“Other exposures of interest include independent risk factors for the outcomes of interest (e.g., comorbidities, age), as well as variables, known as potential confounding variables, that are related to both the exposure and the outcome and are necessary for clarifying analyses.“ [2]

⇒ **Define a data analysis plan**

“The utility and applicability of registry data heavily rely on the quality of the data analysis plan and the ability to interpret the results.” [2]

⇒ **Let results act as feedback to the system**

“The National Quality Registries vary as to their objectives, as well as to how and when they arose, but have in common that they were started by representatives of the medical profession and were built up as aids to quality development at the users’ own treatment facilities.” [12]
“data collection or feedback on outcomes ... associated with .. greater ability to use data and make positive changes in stroke care” [13]

⇒ **Define the format of reporting**

“A plan for using the data, from internal purposes to publications to regulatory reporting, should be clear before the data is collected.” [15]
“If the programme is primarily for safety monitoring, it should be clear how the data will be reported (for example, periodic safety update report)” [2]
“The VSTORM project has developed a reporting policy that enables provision of information in a standardized, routine and regular format for others to access.” [16]

⇒ **Let a statistician perform the analysis of data**

„Die Auswertung eines Registers ist also entgegen einer häufig naiv geäußerten Vermutung umfangreicher, langwieriger und teurer als die einer RCT.“ [4]
Die Auswertung gehört deshalb in die Hand eines professionellen Statistikers oder Epidemiologen.“ [4]
[“The analysis of a registry is (contrary to commonly naively assumed) more extensive, time consuming and more expensive as it is for a randomised controlled trial.”
“The analysis must therefore be performed by an experienced statistician.”]

5.3.10 Evaluation

See [2], section III (page 179-188)

5.3.11 Good practice strategies from other categories

⇒ **Integrate register functions into existing care information systems**

“Systems can be tailored locally to produce feedback in the form of screen prompts that help participants to prescribe the correct therapy or refer patients for an appropriate service or surgical intervention” [25]

6 Literature

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