

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” [1]. 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/>

1 Phase of planning

⇒ **Define the objective(s)**

“key steps in planning ... articulating the purpose of the registry” [1]

“The purpose or purposes should be clearly stated. A registry must have a clear purpose that can be articulated by the sponsoring organisation” [2]

“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.” [3]

„... Zweck der Erhebung allen Beteiligten transparent und einsichtig...” [4]

[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” [1]

“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” [2]

⇒ **Identify stakeholders**

“key steps in planning a patient registry ... identifying stakeholders” [1]

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.” [2]

“For a registry to function optimally there must be a collective will for it to work at the political, administrative and clinical levels.” [3]

⇒ **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.” [1]

⇒ **Sufficient funding for main period**

“key steps in planning ... assessing feasibility, and securing funding“[1]

“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.”[3]

“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.”[5]

„Bis zu diesem (vorläufigen) Endpunkt müssen ausreichende Kapazitäten, insbesondere auch für die planmäßige Auswertung und Veröffentlichung, bereitgestellt sein.“ [6]

[Translation: „Until the (preliminary) endpoint [comment: endpoint of 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.”[1]

“...Belgian example by making verifiable data submission a prerequisite for reimbursement of the procedure.” [7]

“Strong determinants may also be reimbursement associated with registering. Non-participating departments may encounter economic disadvantages on the healthcare market.”[5]

⇒ **Determine the level of action**

“The intention may be to give local, regional, or national support, or international services ...” [5]

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” [1]

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

„Register und Studien sollten idealerweise aufeinander bezogen, möglichst sogar verzahnt geplant, durchgeführt und ausgewertet werden“ [6]

[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.”[8]

⇒ **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.” [1]

“In choosing measurement scales for assessing patient-reported outcomes, it is preferable to use scales that have been appropriately validated, when such tools exist.” [1]

⇒ **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.” [1]

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.” [5]

“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.” [3]

„Es hat sich bereits in der Vergangenheit gezeigt, dass die durch die Kern-dokumentation etablierte Dokumentationsstruktur äußerst günstige Voraussetzungen für die Durchführung großer multizentrischer Studien, sowohl klinischer Phase-III- und -IV-Studien als auch epidemiologischer Prognosestudien, bietet.“ [4]

[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“ [8]

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. “[1]

“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.” [1]

„So ist eine systematische Verfälschung zu erwarten, wenn auf Diagnosen Bezug genommen wird, die zu Abrechnungszwecken dokumentiert wurden.“ [9]
[Translation: „Systematic bias has to be expected when using diagnostic data that comes from administrative accounting documentation”]

5 Ethics, data ownership, privacy

⇒ **Orientation on the EC directive 95/46 data protection [10] 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.” [8]
“Ownership of and access to databases require clarification” [11]

⇒ **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.” [11]

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.” [11]

⇒ **Plan the recruitment method**

“Well-planned strategies for enrolment and retention are critical” [11]

⇒ **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.“ [6]
[Translation: For the quality of a registry it is helpful to share the gathered knowledge accession directly with the participation institutions and scientists”]

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.” [1]
“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.” [5]

⇒ **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.” [8]

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

“Therefore, all data collectors must be trained appropriately to ensure data quality.” [3]

“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.” [12]

„Alle Beteiligten sollten eine klare Vorstellung von den Informationen haben, die aus jedem einzelnen Eintrag auf dem Datenblatt entnommen werden.“ [13]

[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.” [5]

⇒ **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.“ [14]

[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.” [3]

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

“New National Quality Registries should strive to be web-based from the start.” [8]

⇒ **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.” [5]

⇒ **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.” [15]

⇒ **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.” [7]

„Plausibilitätsprüfungen, Data Monitoring und Audits kommt deshalb in Registern dieselbe Bedeutung zu wie etwa in RCTs.“ [6]

[„Registries require the same efforts for plausibility checks, data monitoring and audits as for randomised controlled studies.”]

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).” [1]

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.” [1]

⇒ **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.” [1]

⇒ **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.” [8]

“data collection or feedback on outcomes ... associated with .. greater ability to use data and make positive changes in stroke care” [16]

⇒ **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.” [2]

“If the programme is primarily for safety monitoring, it should be clear how the data will be reported (for example, periodic safety update report)” [1]

“The VSTORM project has developed a reporting policy that enables provision of information in a standardized, routine and regular format for others to access.” [3]

⇒ **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.“ [6]

Die Auswertung gehört deshalb in die Hand eines professionellen Statistikers oder Epidemiologen.“ [6]

[“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.”]

10 Evaluation

See [1], section III (page 179-188)

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” [17]

Literature

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