

# Evaluation of Neurological Patient Registries

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Can J Neurol Sci. 2013; 40: Suppl. 2 - S60-S61

Over the past decade, there has been an appreciable increase in the number of national as well as international registries for a variety of neurological conditions, with corresponding increase in the amount of publications arising from these efforts [ref]. The registries were established for determining the natural history of a specific disease, the effectiveness of new treatments, the quality of care and/or other patient-related outcomes. The purpose of this chapter is to provide an approach to registry evaluation and quality assessment.

In preparation of this chapter, we reviewed current literature and consensus guidelines on registry evaluations. We also consulted with medical experts and registry/database specialists as part of a national registry meeting to provide feedback and consensus on criteria to be used for evaluation of disease registries in Canada.

## RELEVANT LITERATURE

Despite the importance of registry evaluation, there is currently a paucity of reports related to neurological disease registry evaluation. Other examples were related to diseases such as rheumatoid arthritis,<sup>270</sup> trauma,<sup>271</sup> liver transplantation,<sup>104</sup> and cancer<sup>272</sup>. Domains of the registries that were evaluated include recruitment numbers, missing data, reporting, audit of guidelines, access to national and institutional health databases, patient involvement and collaborations. Key references and tables are provided as resources to assist with registry evaluation.

## Research Quality

Detailed discussion of registry quality assurance and quality control can be found in Chapter 7 of this guideline. A further discussion on the validation and interpretation of registry data including from a quality perspective can be found in Chapter 8 of this guideline.

## Existing Guidelines for the Reporting of Research Studies

The Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) statement<sup>273</sup> is a 22-item checklist

intended for use with observational studies. The list provides 18 general and 4 specific guidelines for complete reporting of cohort, case-control and cross-sectional studies. The authors had intended for the statement to be a tool (instead of a rigid standard) to help assess the quality of reports arising from observational-based studies. They acknowledged the inherent limitations of the STROBE statement, including an inability to address the reporting of all types of studies. Nonetheless, for registries based primarily on observational methods, the STROBE statement is a useful guide.

Similar guidelines are available for the reporting of randomized clinical trials, meta-analysis, and systematic reviews. The QUOROM (Quality of Reporting of Meta-analyses)<sup>274</sup> and the CONSORT (Consolidated Standards of Reporting Trials)<sup>275</sup> statements are guidelines for assessing the quality of reports that were developed at separate consensus meetings. Like the STROBE statement, these guidelines are consisted of checklists of domains that should be considered as part of the evaluation. These domains are pre-defined and the ways in which they should be assessed are described. Similarly, guidelines on how best to report perform systematic reviews include SQUIRE (Standards for Quality Improvement Reporting Excellence) and STREGA (Strengthening of Reporting of Genetic Association Studies); the latter is an extension of the STROBE statement.<sup>276</sup> Other types of publications should be graded based on strength of the evidence as presented in the research articles.<sup>277</sup>

In reality, there are often variations in the reporting of observational studies. In the article titled Issues in the reporting of epidemiological studies: a survey of recent practice<sup>271</sup>, seventy-three articles in observational epidemiology were reviewed in search of limitations in reporting. The articles were picked from 20 journals, and included 37 cohort, 25 case-control, 10 cross-sectional, and one case-cohort studies. For the most part, the articles investigated cancer or cardiovascular disease with 31% of the articles investigating other diseases. The authors found a variety of issues that may have led to erroneous conclusions, including insufficient information on participant

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FINAL REVISIONS SUBMITTED JANUARY 28, 2013.

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selection process, data quality, sample size consideration, and rationale for grouping and sub-analyses. Adjustment for potential confounders (or effect modifiers) and multiple comparisons were at times inadequate. As well, the epidemiological literature in general may be prone to publication bias. Additional attention to details and efforts are needed to avoid similar bias in the reporting of disease registries.

### ***Quality of Evidence: Consistency, Precision and Avoidance of Bias***

It is important to have clear guidelines for grading the strength of evidence. According to one publication<sup>278</sup>, evidence should be graded according four domains: risk of bias, consistency, directness and precision. The reference includes recommendations on how to rate the evidence for each of the four domains. Additional considerations included dose-response association, potential confounding factors, strength of the association, and publication bias. The authors recommended that these assessments should be incorporated into an overall grade of the strength of the evidence; as well, the report should provide an explanation of the reasoning for the grade and which domains played the most important role in influencing the overall grade.

### ***Data Comparability, Validity, and Timeliness***

In a review article on data quality in the cancer registries<sup>279</sup> is based on experience from a cancer registry. Part 1 highlighted the importance of the comparability, validity and timeliness of data. Comparability is the extent to which statistics generated by different groups are to be compared to one another. In order to have data comparability, it is important to have consistent definitions and adherence to mutually agreeable standards and operational procedures. Validity refers to the proportion of cases in the registry that actually have a particular characteristic. Validity depends on accurate abstracting, coding/recoding, as well as the precision of documentation. Common methods of assessing validity include re-abstracting and recoding, diagnostic criteria (or histological) verification, missing information analyses, and internal consistency assessments. More information on Validation of Registry Data can be found in Chapter 8 of this guideline.

Re-abstracting involves independently collecting data from the source and comparing it to the initial data abstraction that has been recorded in the registry. Greater degree of agreement is associated with greater validity of data. Recoding involves reassigning codes to the abstracted information and assessing the agreement with records in the database. While this method is easier and less expensive, it will not allow one to detect problems with abstraction. Reliability studies involve multiple people coding identical source documents under controlled conditions to assess the level of agreement. Histological verification involves assessing the accuracy of a diagnosis through a histological examination by a pathologist. This method is particularly relevant for disease based on tissue biopsies or pathological analyses. Death certificate only (DCO) registrations involve registering patients post mortem based only on a death certificate which mentions some form of cancer. The problem with this method pertains to the degree of accuracy of death certificate. One possible solution is to minimize the amount to

death certificate only registrations. Death certificate notification registrations involve identification of a cancer patient through a death certificate and verification of the information through other sources. This practice is generally more accepted than death certificate only registration due to the increased validity.

Lack of access to source documents, problems with items and code values, misapplication of coding rules and inadequate case histories can often lead to unknown values or missing information. Internal consistency, item validity and inter-record consistency are all important concepts to evaluate the quality of evidence in a registry. Timeliness deals with access to current data; the more current the data, the more likely it is to be complete and accurate. While there is no formal definition of timeliness, some guidelines suggest that capturing within 6-23 months is considered as "timely". Efficient procedures, well trained staff and electronic data capture can all enhance timeliness.

### ***Comprehensiveness of Data***

Comprehensiveness is the extent to which the information of the registry is representative of the population.<sup>280</sup> To assess comprehensiveness it is important for the incident rates and survival proportions generated by the registry to be as close as possible to those of the general population. Both semi-quantitative and quantitative methods were outlined in this review to help determine the completeness of data in a cancer registry.

## **OTHER CONSIDERATIONS**

### ***Registry Impact***

The impact and cost-effectiveness of disease registries remains largely undetermined. As well, the potential impact of registries on patients, families as well as the scientific communities will require further studies. Timely dissemination of available information will help disease registries to achieve their greatest impact.

## **RECOMMENDATIONS**

- ✓ Assess registry quality with the registry purpose in mind.
- ✓ Criteria for evaluating the outcomes and/or success of the registry are available and should be specified as part of registry planning.
- ✓ Research and evidence quality will depend on available resources and budget. These should be planned accordingly to achieve the desired quality.