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GUIDELINES

Development of the standards of reporting of neurological disorders (STROND) checklist: a guideline for the reporting of incidence and prevalence studies in neuroepidemiology

Derrick A. Bennett[1] · Carol Brayne[2] · Valery L. Feigin[3] · Suzanne Barker-Collo[4] · Michael Brainin[5] · Daniel Davis[6] · Valentina Gallo[7] · Nathalie Jetté[8] · André Karch[9] · John F. Kurtzke[10] · Pablo M. Lavados[11,12] · Giancarlo Logroscino[13,14] · Gabriele Nagel[15] · Pierre-Marie Preux[16] · Peter M. Rothwell[17] · Lawrence W. Svenson[18]

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Abstract Incidence and prevalence studies of neurological disorders play an important role in assessing the burden of disease and planning services. However, the assessment of disease estimates is hindered by problems in reporting for such studies. Despite a growth in published reports, existing guidelines relate to analytical rather than descriptive epidemiological studies. There are also no user-friendly tools (e.g., checklists) available for authors, editors and peer-reviewers to facilitate best practice in reporting of descriptive epidemiological studies for most neurological disorders. The Standards of Reporting of Neurological Disorders (STROND) is a guideline that consists of recommendations and a checklist to facilitate better reporting of published incidence and prevalence studies of neurological disorders. A review of previously developed guidance was used to produce a list of items required for incidence and prevalence studies in neurology. A three-round Delphi technique was used to identify the 'basic minimum items' important for reporting, as well as some additional 'ideal reporting items'. An e-consultation process was then used in order to gauge opinion by external neuroepidemiological experts on the appropriateness of the items included in the checklist. Of 38 candidate items, 15 items and accompanying recommendations were developed along with a user-friendly checklist. The introduction and use of the STROND checklist should lead to more consistent, transparent and contextualised reporting of descriptive neuroepidemiological studies resulting in more applicable and comparable findings and ultimately support better healthcare decisions.

Keywords Neurology · Epidemiology · Incidence · Prevalence · Reporting · Checklist

Suzanne Barker-Collo, Michael Brainin, Daniel Davis, Valentina Gallo, Nathalie Jetté, André Karch, John F Kurtzke, Pablo M. Lavados, Giancarlo Logroscino, Gabriele Nagel, Pierre-Marie Preux, Peter M. Rothwell and Lawrence W. Svenson authors are in alphabetical order.

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✉ Derrick A. Bennett
derrick.bennett@ctsu.ox.ac.uk

[1] Clinical Trial Service Unit and Epidemiological Studies Unit, Nuffield Department of Population Health, University of Oxford, Old Road Campus, Oxford OX3 7LF, UK

[2] Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK

[3] National Institute for Stroke and Applied Neurosciences, AUT University, Auckland, New Zealand

[4] Department of Psychology, University of Auckland, Auckland, New Zealand

[5] Department for Clinical Medicine and Preventive Medicine, Danube-University, Krems, Austria

[6] Faculty of Population Health Sciences, University College London, London, UK

[7] Centre of Primary Care and Public Health, Blizard Institute, Queen Mary, University of London, London, UK

[8] Department of Clinical Neurosciences and Hotchkiss Brain Institute, Department of Community Health Sciences and O'Brien Institute for Public Health, University of Calgary, Calgary, AB, Canada

[9] Research Group Epidemiological and Statistical Methods, Helmholtz Centre for Infection Research, Braunschweig, Germany

[10] Georgetown University, Washington, DC, USA

Background

Neurological diseases are becoming more prevalent as the world's population ages and their burden is expected to increase globally [1]. These conditions are often subtle in their clinical manifestation and are prone to misconceptions and misinterpretations. [2] In epidemiological studies neurological conditions can provide particular challenges including: (1) the diagnostic criteria tends to be variable, or subjective, or prone to misclassification; (2) the diagnosis of the condition is based on the clinical phenotype but also on data that may require the use of sophisticated technology such as magnetic resonance imaging or measuring biomarkers from plasma and cerebrospinal fluid. This may require both access to such equipment and specialist skills in order to accurately determine whether an individual is a case (and it is subject to a certain degree of operator-dependent error); (3) there can be considerable heterogeneity in latency periods resulting in variable and long gaps between disease onset and manifestation of symptoms; (4) pathological confirmation in vivo may be difficult or unavailable for certain neurological conditions; and (5) many neurological conditions are rare.

High quality prevalence and incidence studies of neurological conditions that follow a systematic approach are essential for estimating the burden of disease globally, for comparison of estimates between various countries and populations, for priority setting, resource allocation and planning public health approaches. For neurological conditions descriptive epidemiological studies can provide important information on (a) trends and gaps in the health service needs; (b) estimates of morbidity, mortality and economic burden from these diseases; and (c) can be used for generating new hypotheses on causation or natural history of the disease. Descriptive epidemiological studies are particularly useful for estimating prevalence, incidence, morbidity and mortality time trends for studies where global health is of concern [3]. For instance there is usually more information available for high-income countries (HIC) but for low- to middle-income countries (LMIC) the number of descriptive epidemiological studies conducted is sparse. However studies from both HIC and LMIC can be of poor quality, either due to poor reporting, poor methodology or both [4, 5]. It is becoming increasingly important to collect high quality routine information on neurological disorders from LMICs in addition to those from HIC because these populations are likely to be the ones where the greatest future need for health services and treatment will be required by the middle of this century [6].

Any approach to attempt to bridge the gap worldwide would require methods or guidelines that reduce inconsistencies in reporting that may identify health disparities between resource-rich and resource-poor regions that are disseminated widely. [7, 8] Good reporting strategies for neuroepidemiological studies can be used to facilitate meta-analyses and systematic reviews, and are therefore of critical importance. General quality checklists and reporting standards are common for particular types of studies (and, increasingly, expected) in health services research—see for example CONSORT for randomized controlled trials [9], PRISMA for systematic reviews [10] and SQUIRE for quality improvement studies [11]. They have two main purposes: to help researchers design, undertake and report robust studies, and to help reviewers and potential users of research outputs assess risk of bias (in terms of validity and reliability). The Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines [12] are well known and widely used but were devised for analytical epidemiology (i.e. case–control studies, cohort studies, and cross-sectional studies).

We aim to develop a reporting guideline that outlines the key information to be reported for descriptive health policy research, [such as Global Burden of Disease and Injuries type studies (GBD)] [13], as studies which are not necessarily obviously population based, particularly those from settings where there are few data, might be of greater value to projects such as the GBD that needs to synthesise evidence, if they were reported better. For example in a systematic review of incidence and prevalence of multiple sclerosis across the Americas found that there were inconsistencies in methodologies and reporting quality among the published studies [14]. A review of dementia in Parkinson's disease (PD) found that PD and the prevalence rates of dementia (PDD) were usually reported in the different age groups, and age-specific prevalence rates of PDD were usually not reported which made comparisons

[11] Vascular Neurology and Stroke Unit, Neurology Service, Department of Medicine, Clínica Alemana de Santiago, Universidad del Desarrollo, Concepción, Chile

[12] Department of Neurological Sciences, Institute of Neurosurgery, Universidad de Chile, Santiago, Chile

[13] Neurodegenerative Diseases Unit, Department of Basic Medicine, Neurosciences and Sense Organs, University Aldo Moro, Bari, Italy

[14] Department of Clinical Research in Neurology Presso Fondazione Card Panico, University Aldo Moro, Bari, Tricase (LE), Italy

[15] Institute of Epidemiology and Medical Biometry, University of Ulm, Ulm, Germany

[16] Institute of Tropical Neurology, University of Limoges, Limoges, France

[17] Stroke Prevention Research Unit, University of Oxford, Oxford, UK

[18] School of Public Health, University of Alberta, Edmonton, AB, Canada

between studies infeasible [15]. Another review of the most populous countries found that it was not possible to make a distinction between burden based on the absolute number of cases of PD and burden based on the relative mix of severity of disease as this was poorly reported. [16] The recent GBD 2013 report on all-cause and cause-specific mortality noted that the estimates of Alzheimer's Disease would be improved by more population-based prevalence studies that use and report standardized definitions and methods [17]. The primary objective was to develop reporting guidance for incidence and prevalence studies specifically related to neurological disorders using a consensus-based process, but this information may also be of interest to a general epidemiological audience.

Methods

We followed the Guidance for Developers of Health Research Reporting Guidelines [18] and developed a three-phase consensus process (Fig. 1).

Phase I

The process consisted of empirical work, split into four different components (a) a systematic review of reporting guidelines for incidence and prevalence studies in general and reporting guidelines specific to a common neurological condition (we used stroke as an example for our initial investigations); (b) production of a core set of important items for the reporting of incidence and prevalence studies based on the review of the evidence; (c) assess the quality of reporting of a random sample of published incidence and prevalence studies of the common neurological condition (stroke), (d) proposed an initial checklist of a 'core set of items' that were then discussed with members of The Standards of Reporting of Neurological Disorders (STROND) collaborative group. The eAppendix summarizes the results of phase I of the development of the STROND guideline.

Phase II

A three-round Delphi process was conducted using a group of individuals that had expertise in neuroepidemiological research (that were not members of the STROND group), that agreed to take part in a series of three consecutive rounds of questionnaires designed to achieve increasing consensus of opinion on which items should be included in the checklist [19]. The Delphi process participants were identified by contacting members of neurological societies via e-mail. An on-line questionnaire (that included tick boxes and free text comments), was devised based on the relevant version of the questionnaire (and took no more than 15 min to complete). This questionnaire was circulated to participants that had agreed to take part in each of the three rounds of the Delphi process. Participants remained anonymous which enabled them to comment freely, but they were required to give their initials and a memorable date when completing the questionnaire for tracking purposes. Respondents were asked to suggest additional items, that they believed were important, that were missing from the initial checklist. After each round, the results were summarized (both quantitative and free text information was summarized) and fed back to the respondents along with the updated version of the checklist that had been revised in the light of the comments received.

Phase III

Once consensus had been reached on the items to be included in the checklist based on Phase I and II findings, then a group of internationally recognised experts on neurological disorders, (as nominated by members of the STROND collaborative group) were contacted as part of a further e-consultation process in order to assess their views on the contents of the checklist. Once this three-phase consensus process was completed a 'final checklist' was produced based on the feedback received from all the individuals that had participated.

Results

The initial checklist based on a systematic review of the evidence yielded 27 items that were used as part of the first round of the Delphi exercise. Another 11 items that were not included in the initial checklist were included based on feedback from the first round. Table 1 gives details of the background of the participants in the Delphi and the e-consultation processes. Seventy-nine individuals participated in the first round of the Delphi process and described their area of expertise as clinical (80 %), research (77 %), policy (10 %) or methodological (20 %) [Delphi process respondents were allowed to check more than one general area of expertise in the on-line questionnaire]. The seventy-nine individuals were from a variety of countries and with contributions from respondents based in high-income (52 %), middle-income (30 %) and low-income (18 %) countries. Of the seventy-nine individuals that completed the first round, sixty-five individuals took part in the second round (82 %) and 61 took part in the third and final round (77 %). Consensus was deemed to be reached when $\geq$70 % of the respondents were in agreement about the utility of a particular checklist item in each successive round of the Delphi process. The e-consultation process

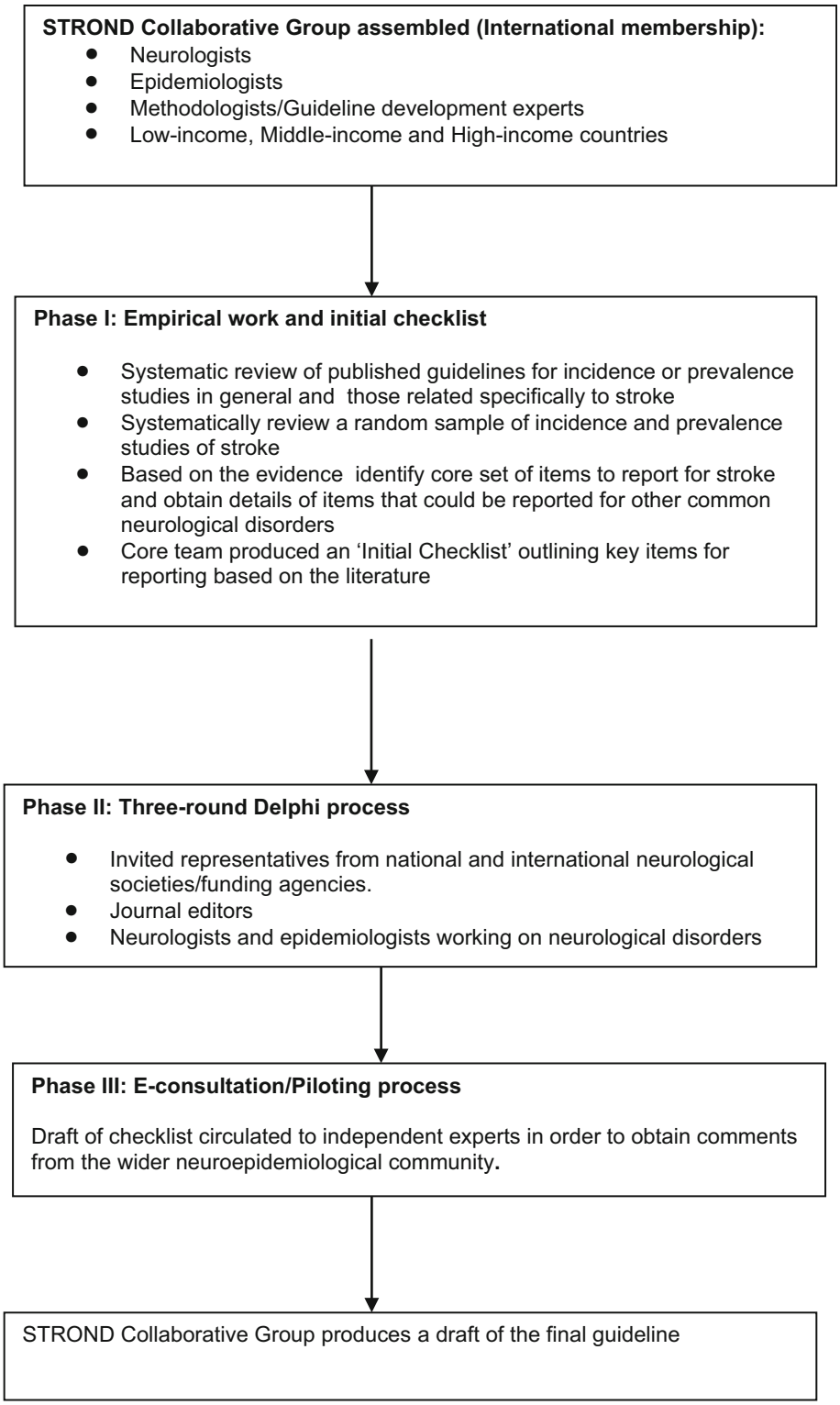

Fig. 1 Structure of the guideline development process

invited thirty individuals that were prominent researchers, policymakers, or methodologists in the field of neuroepidemiology. Of the thirty invited individuals eighteen (60 %) agreed to participate in the e-consultation/piloting process.

The responses received from the e-consultation/piloting process were then used to construct STROND guideline checklist. The STROND checklist is given in Table 2 and was structured to correspond to key components that should be reported in the final manuscript in a similar

Table 1 General area of expertise of the Delphi and e-consultation process respondents

Self-identified area of expertise	Delphi process			E-consultation/piloting process (N = 18)
	Round 1 (N = 79)	Round 2 (N = 65)	Round 3 (N = 61)	
Clinical, N (%)*	63 (80 %)	51 (80 %)	50 (82 %)	10 (55 %)
Research, N (%)*	61 (77 %)	45 (70 %)	44 (72 %)	16 (89 %)
Policy, N (%)*	8 (10 %)	6 (9 %)	7 (11 %)	2 (11 %)
Methodology, N (%)*	16 (20 %)	18 (28 %)	15 (24 %)	6 (33 %)

* Respondents were allowed to identify more than one area of expertise

manner to the STROBE checklist [12]. The checklist has 15 key items and distinguishes between items that are deemed to be 'basic minimum reporting' requirements (items in non-italic font), and items that are deemed to be 'ideal reporting' requirements (items in italic font). For example, the item on the source population (item 6) used in the study has three basic minimum reporting requirements: using several different sources for case identification; the core data used to identify individuals (e.g. medical records, administrative databases), and a description of dropouts or exclusions from the source population. The ideal reporting requirements would also have details on: the rate of admission for the neurological condition in the population, details of the healthcare system in the country where the study was conducted, and details of filters on how the person with the neurological condition is referred. The checklist also distinguishes between items that relate specifically to incidence or prevalence studies of neurological disorders.

Discussion

We envisage that the STROND checklist will only be used to assess the reporting of prevalence and incidence studies of neurological disorders. Although this checklist is aimed at reporting of descriptive epidemiological studies neurological disorders we believe that it would also be of interest to researchers wishing to report their descriptive epidemiological studies of non-neurological disorders. The 15-item checklist provides a framework to satisfy the need for completeness and transparency of reporting of incidence and prevalence studies of neurological disorders. We attempted to strike a balance between adequate detail and concise reporting so we incorporate both 'basic minimum reporting' standards as well as 'ideal reporting' criteria in the checklist. There is substantial evidence that reporting guidelines improve the completeness of published reports based on natural experiments [20, 21]. As has been done with other reporting guidelines [22] we aim to develop a more detailed explanation and elaboration report that provides more detail on the rationale for each item included in the checklist and provides some empirical evidence of good reporting of incidence and prevalence studies for neurological disorders. The preliminary aims and objectives of the guideline have been posted on the EQUATOR network [23, 24] and we plan to post the checklist and the explanation and elaboration report on the EQUATOR website (http://www.equator-network.org).

The limitations of this project are that the STROND reporting guideline was developed using a consensus process and thus may only represent the opinions of the participants. However, consensus was reached on both the 'basic minimum reporting' standards and the 'ideal reporting standards' with >70 % of respondents in agreement on the items included in successive rounds of the Delphi exercise. Furthermore, the independent group of experts that participated in the e-consultation were all in broad agreement about the items included. In addition, the Delphi technique has been used widely in medical research as a survey method to gain consensus among a group of respondents [25]. For example, a Delphi exercise process was employed by the Consolidated Standards of Reporting Trials (CONSORT) investigators when developing this widely used reporting guideline. [22].

Large-scale projects like the Global Burden of Disease and Injuries Study [26] need to utilise prevalence and incidence studies that use consistent methods and terminology and also require high quality reporting in order to provide the required information for their disease-modelling algorithms to adequately estimate disease burden due to these disorders. It is well known that rigorous population-based studies from LMIC are sparse for neurological disorders (even for stroke), and the quality of reporting in LMIC as well as HIC is in need of improving [13]. We will aim to translate the checklist into languages other than English as required as well as aiming to conduct and support research that investigates the impact of the guidelines on the reporting quality of incidence and prevalence studies in neurological disorders [7]. We hope that the introduction and use of the STROND checklist will lead to more consistent, transparent and contextualised reporting of population-based prevalence and incidence studies of neurological disorders and that these more applicable findings will lead ultimately to better healthcare decisions.

Table 2 Standards of reporting of neurological disorders (STROND): a guideline for the reporting of incidence and prevalence studies in Neuroepidemiology

Section/topic	Number	Recommendation
Title and abstract		
Title and abstract	1	(a) Give the type of study design employed using a widely recognised term in the title or abstract
		(b) The abstract should give an accurate summary of how the study was conducted and the main findings
Introduction		
Background	2	Details of the scientific rationale for the study should be reported
Aims and objectives	3	State the specific aims and objectives of the study
Methods		
Study design	4	Give a full description of the study design
	4a	*Give details of any study protocol (published or unpublished that gives additional useful information on the study design)*
	4b	*If a pilot study has been conducted to inform the main study design then the findings should be referenced*
Setting	5	Clearly defined (usually, but not always, on a geographic basis), and stable, with reliable information on in- and out-migration
Source population	6	Description of how all eligible members of the population were identified and through what data sources (e.g. hospitals, outpatient clinics, death certificates)
	6a	Source of data used for the study (e.g. administrative database, medical records). *If administrative database used algorithms for data extraction should be described*
	6b	*Description of the rate of hospital admission, (if applicable), for the neurological condition in the population*
	6c	*Details of health care system in the country (study region) where the study was conducted (e.g. public versus private health care system)*
	6d	*Description of how a person with the neurological condition is referred (with the filters) in the country (study region) where the study was conducted*
	6e	Description and characteristics of response rate/drop outs and exclusion rate if applicable
Participants	7	Definition of cases is clearly identified and presented in sufficient detail
	7a	Details of the sampling method are described (are participants representative of the source population)
	7b	Fully validated source of diagnosis or "reference-standard" criteria applied
	7c	Definition and justification of disease severity (preferably using a standardized scale) or staging of the disease
	7d	Description of how types/subtypes of the neurological disorder of interest are distinguished (if relevant)
	7e	Description of how completeness of case-ascertainment was assessed
	7f	*Description of whether completeness of case ascertainment was adequate*
Ethical approval	8	*Details of ethics approval/informed consent/data governance should be reported*
Measurement	9a	Incidence studies
		Give details of how incidence was determined (based on timing of data collection either prospectively or retrospectively)
		Definition and justification of timing of measurements
		The data presented to some specified time period (usually whole years or person-time)
		Raw numbers are reported in sufficient detail to calculate the appropriate rates (e.g. by age or gender)
	9b	Prevalence studies
		Give details of specific time points over which estimates are derived (usually defined as the number of cases existing in a specific time point)
		The data presented to some specified time period (usually whole years)
		Raw numbers are reported in sufficient detail to calculate the appropriate rates (e.g. by age or gender)
	9c	*If disease burden is to be assessed the study should report details of burden due to a variety of sources* (*e.g. disability, DALYs, symptoms, financial, caregiver* etc.…)
	9d	*Report any arrangements for quality checks/data verification/triangulation*
	9e	*Report details of the training of the person administering the instruments*

Table 2 continued

Section/topic	Number	Recommendation
Statistical methods	10	If rates have been standardised (e.g. by age or gender), then the details of the standard population used should be given
	10a	*If possible two standard populations should be used one with local relevance and the other to facilitate international comparisons*
	10b	Description of any assumptions made in the calculations should be reported
	10c	An explanation of how missing data was addressed in the analyses
	10d	*Provide* a priori *estimates of: sample size/power assessment/precision of estimates assessment*
	10e	Description of any sensitivity analyses
Results		
Main findings	11	Consider a flow diagram that describes how participants were included in the study [useful in order to assess how a person with the neurological condition of interest is referred (with the filters)]
	11a	Give appropriate rates with their associated 95 % confidence intervals
	11b	Report results of any sensitivity analyses
Discussion		
Key findings	12	Summarise the key findings in relation to the study aims and objectives
Limitations	13	Discuss potential limitations of the study
	13a	*Include details of risk of bias (e.g. selection bias), completeness of case ascertainment, and data quality (assessment of its probability, size and potential importance)*
Interpretation	14	Interpret the results in the context of the evidence from other well performed studies with similar designs and objectives
	14a	Reliability of the estimates (i.e. based on the reporting of the statistical methodology, and study design, measurement of key information)
Generalizability	15	Discuss the external validity of the study findings
	15a	Are the results consistent with meta-analyses of descriptive epidemiological studies on the same topic that cover different settings (if applicable)?

Basic minimum reporting items are in non-italic font

Ideal reporting items are in italic font

Appendix

Core standard of reporting of neurological disorders (STROND) development team

Dr Derrick Bennett (Nuffield Department of Population Health, University of Oxford, Oxford, UK); Professor Carol Brayne (Department of Public Health and Primary Care, University of Cambridge, Cambridge, UK); Professor Valery Feigin (National Institute for Stroke and Applied Neurosciences, AUT University, Auckland, New Zealand), Helen McDonald. National Institute for Stroke and Applied Neurosciences, AUT University, Auckland, New Zealand).

Standard of reporting of neurological disorders (STROND) collaborators

Professor Michael Brainin (Department for Clinical Medicine and Preventive Medicine, Danube-University Krems, Austria; Professor Pierre-Marie Preux, Institute of Tropical Neurology, University of Limoges, Limoges, France; Professor Peter Rothwell, Stroke Prevention Unit, University of Oxford, Oxford, UK; Dr Pablo M. Lavados, Vascular Neurology and Stroke Unit, Neurology Service, Department of Medicine, Clínica Alemana de Santiago, Universidad del Desarrollo and Department of Neurological Sciences, Universidad de Chile, Institute of Neurosurgery, Santiago, Chile; Emeritus Professor John F Kurtzke, Georgetown UniversityUSA.; Dr Suzanne Barker-Collo (Department of Psychology, University of Auckland, New Zealand). Dr Daniel Davis (Faculty of Population Health Sciences, University College London, UK.); Dr Valentina Gallo, Centre of Primary Care and Public Health, Blizard Institute, Queen Mary, University of London, UK; Dr Nathalie Jetté, Department of Clinical Neurosciences and Hotchkiss Brain Institute, Department of Community Health Sciences and O'Brien Institute for Public Health, University of Calgary, Canada; André Karch, Research Group Epidemiology and Statistical Methods, Helmholtz Centre for Infection Research; Lawrence W. Svenson, School of Public Health, University of Alberta, Canada; Professor Giancarlo Logroscino, Neurodegenerative

Diseases Unit, Department of Basic Medicine, Neurosciences and Sense Organs, and Department of Clinical Research in Neurology presso Fondazione Card Panico. Tricase,University Aldo Moro, Bari, Italy.; Gabriele Nagel, Institute of Epidemiology and Medical Biometry, University of Ulm, Ulm, Germany.

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