

# BMJ Open Multicentre collection of uniform data on patients hospitalised for transient ischaemic attack or stroke in the Philippines: the Philippine Neurological Association One Database-Stroke (PNA1DB-Stroke) protocol

Philippine Neurological Association One Database - Stroke, Disease Study Management Group

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## ABSTRACT

**Introduction** For scientific advances to translate into improved patient outcomes, systems of care must be in place to facilitate delivery of care. There is scarce information on quality of care and clinical outcome in our stroke patients. We aim to collect uniform data from patients with first or recurrent transient ischaemic attack (TIA) or ischaemic or haemorrhagic stroke to determine in-patient caseload, patient profile, types of diagnostic and therapeutic procedures, outcomes and overall quality of care among patients hospitalised for acute stroke in the Philippines.

**Methods and analysis** This multicentre observational study and standing database will include patients diagnosed with first or recurrent TIA, ischaemic or haemorrhagic stroke or cerebral venous thrombosis, ≥18 years old, and admitted in any of the country's 11 accredited adult neurology residency training institutions. Anonymised data on sociodemographics, medical history, stroke subtype, in-hospital management and discharge outcomes will be collected and entered in a database using a secure online data platform. Outcomes include in-hospital complications, functional, neurological and vital (alive or dead) status at discharge. We intend to capture data from all TIA and stroke cases in participating sites. Based on 2017–2019 census, approximately 10 000 cases each year may be included. Collective data spanning 3 years will be extracted, summarised and analysed every year.

**Ethics and dissemination** Approval from ethics committees or institutional review boards (EC/IRB) was obtained from the Single Joint Research Ethics Board and all participating institutions. As this study involves no more than minimal risk to patients, waiver of informed consent was requested. Written information about the study will be provided to patients or legal representative. If site EC/IRB requires written consent, only approved consent forms will be used.

To identify areas of improvement and guide public health policies, data on 'real-world' situation are needed. The Philippine Neurological Association One Database-Stroke

## Strengths and limitations of this study

- ⇒ Study intends to capture uniform data from all cases of first or recurrent transient ischaemic attack or stroke admitted in participating hospitals.
- ⇒ Real-world data on type and quality of care received by patients will be collected.
- ⇒ Collection of complete data and data quality will be challenging yet crucial in arriving at valid analyses.
- ⇒ Study sites may not be directly representative of all hospitals in the country.

initiative may become a model that can be implemented in other designated stroke-ready hospitals.

**Trial registration** NCT04972058; ClinicalTrials.gov.

## INTRODUCTION AND RATIONALE

The Global Burden of Diseases 2016 reported neurological disorders to be the leading cause of disability and second leading cause of death worldwide and that the overall burden continues to increase, with stroke as the largest contributor of neurological disability-adjusted life years.<sup>1</sup> In the Philippines, stroke is the second leading cause of death with a prevalence of 0.9%.<sup>2</sup> Ischaemic stroke comprises about 70% and haemorrhagic stroke about 30% of cases. About half a million Filipinos will be affected by stroke, with an estimated US\$350 million to US\$1.2 billion needed to meet the cost of medical care.<sup>2</sup> Healthcare in the country is largely private, and the cost is borne out-of-pocket by patients and their families. There is an unequal distribution of major stroke healthcare providers, with as much as 67% of

neurologists practicing in highly urbanised centres in the country.<sup>2</sup>

As populations grow and age, governments will face increasing demand for treatment, rehabilitation and support services for neurological disorders. To translate advances in scientific knowledge and innovations into improvements in patient outcomes, comprehensive systems of care must be in place to facilitate optimal delivery of stroke care. New recommendations support policies that standardise the delivery of stroke care, lower barriers to emergency care for stroke, ensure stroke patients receive care at appropriate hospitals in a timely manner and improve access to secondary prevention and rehabilitation and recovery resources after stroke.<sup>3</sup>

The difficulty is that there is scarce local information on the quality of care received, clinical outcome of hospitalisation and reasons for such quality and outcome in our stroke patients, especially among the resource-limited sectors. Local experiences in stroke and recommendations have been published.<sup>4–8</sup> Few, however, are related to overall quality of care. In one early study, late hospital arrival of acute stroke patients was identified as only one cause of delay in the provision of care.<sup>9</sup> Longer delays were seen due to healthcare-related factors such as delays in referral to a neurologist and neuroradiologic diagnosis. To address this, education of both the public and the medical community on the necessity of early neurologic evaluation and patient transport to ‘Stroke Centres’ equipped with CT scanner was recommended.

In an analysis of 1025 stroke patients from 11 hospitals in the Philippines, patients who were admitted to stroke units had better outcomes than those admitted to the general neurology wards.<sup>10</sup> For secondary prevention, a multicentre study on 262 Filipino patients taking aspirin for first-ever ischaemic stroke showed that the risk for stroke recurrence was 7.9% in the first year and 12.4% in the second year, while the risk for combined stroke, myocardial infarction and death was 8.9% in the first year and 17.9% in the second year.<sup>11</sup> How these patients with recurrent events are managed is unclear.

Reliance on few published studies may not be appropriate. Patient-level and system-level factors can be inconsistent across studies, providing little guidance for the development of models suitable for reporting of hospital-level stroke outcome.<sup>12 13</sup>

## Objectives

Primary objective is to collect uniform data on sociodemographics, medical history, in-hospital management and outcomes among patients with first or recurrent transient ischaemic attack (TIA) or ischaemic or haemorrhagic stroke admitted in accredited adult neurology training institutions in the Philippines.

Secondary objectives are:

1. To determine the in-patient case load.
2. To determine the profile.
3. To determine the types of diagnostic and therapeutic management.

4. To determine the outcomes.
5. To evaluate factors that predict outcome.
6. To assess the overall quality of care.
7. To perform other analyses that may improve the care of patients admitted for first and/or recurrent TIA or stroke.

## METHODS AND ANALYSIS

### Design

This is a pragmatic, multicentre, prospective, observational, non-interventional study and standing database of patients hospitalised for TIA or stroke (Protocol V.1.1 dated 1 May 2021).

### Patient population

This study endeavours to include all patients with first or recurrent TIA or ischaemic or haemorrhagic stroke admitted in the 11 accredited adult neurology residency training institutions in the Philippines. Patients are eligible to be included if they fulfil all inclusion and none of the exclusion criteria.

Inclusion Criteria:

1. Diagnosis of first or recurrent TIA, ischaemic or haemorrhagic stroke or cerebral venous thrombosis.
2. 18 years old or older.
3. Admitted in a participating hospital.
4. If required by the institutional review board/ethics committee, signed or verbal informed consent for participation in the study from the patient or a legal representative.

Exclusion criteria

1. Patients with previous TIA or stroke who are admitted to the hospital for medical conditions other than an acute stroke, for example, patient with non-acute stroke admitted for pneumonia, rehabilitation or procedures, such as gastric tube insertion, etc.
2. Any condition which, in the study investigator’s opinion, may jeopardise the patient by his/her participation in this study or affect the validity of the study results

### Study procedures

Data will be collected from each patient while they are admitted in the hospital and until hospital discharge. No additional posthospitalisation visit will be required.

All eligible patients will be assigned a case identification number and included in the site log kept confidentially in each site. Corresponding anonymised data on sociodemographics, medical history, index stroke subtype, in-hospital management and discharge outcomes will be collected from each patient and entered in the database using a secure online data collection tool. Patients who refuse or withdraw participation or are excluded by the investigator from participation for any reason will not have their clinical data collected or will have their data expunged from the database but will still be counted in the annual case load.

Collective data will be extracted, summarised and analysed for the secondary objectives every year with oversight provided by the Philippine Neurological Association (PNA). To be able to assess trends and changes over time, data collection for this study will span 3 years from study initiation, after which the utility of an extension or a reimplementation of the study will be assessed by the PNA.

Data collection commenced on 1 June 2021.

### Data collection and outcomes

The study team will be provided access to and trained on the use of a password-protected secured online system containing the electronic case report forms (eCRF) for data entry. The eCRF will be compliant with applicable data protection laws and will serve as source documents.

Completed eCRF in English will be required for each patient included in the database, which will be used to transmit the information collected to the sponsor. Data will be entered directly or from the original records onto the eCRF. When direct data entry onto the eCRF is inappropriate or impractical, information may be collected first on paper and subsequently transcribed into the eCRF.

The data fields to be completed are listed in [table 1](#). Outputs and outcomes collected in the study include the following:

- ▶ Number of cases admitted with first and recurrent TIA or stroke (total and subtypes).
- ▶ Vital status (ie, alive or dead) at the time of discharge from the hospital.
- ▶ Functional (assessed by modified Rankin Scale) and neurological (assessed by National Institute of Health Stroke Scale and Glasgow Coma Scale) status at the time of discharge from the hospital.
- ▶ Diagnostic and therapeutic management received during hospitalisation.

The site investigators will ensure the accuracy, completeness and timeliness of data recording to allow appropriate data queries and reporting. By electronically entering the data in the eCRF using their study log-in accounts, the investigators retain full responsibility for the accuracy and authenticity of the data entered in the eCRF.

As this is an observation study, no specific medication, procedure, treatment, supplement or diet are recommended or disallowed in this study. However, relevant predefined data variables on procedures and treatments will be collected. Data on compliance to predefined diagnostic or therapeutic procedures as planned or recommended by the treating physician and the reason for non-compliance to recommendations or non-performance of the procedures will be collected as these are important variables in meeting the objectives of the study.

Only prespecified outcome data that are relevant to the study objectives and may be related to stroke, for example, complications from stroke and discharge status, will be collected and analysed. Other adverse events, which may or may not be related to any clinical diagnostic or

therapeutic procedure, whether serious or non-serious, and regardless of severity, will not be captured and analysed in this study. They are considered part of standard independent audits or pharmacovigilance activity of that particular therapy or procedure.

### Data monitoring and quality

The investigators and the PNA will be responsible for implementing and maintaining quality assurance, quality control and overall integrity in the study. The PNA and the study team will have access to the anonymised data in the eCRF. Neither the central study team nor the PNA will have access to the individual patient's medical records or documents, although the respective participating hospital study team may have access to them according to their standard practice.

The study investigators and data manager will review study data in the eCRF for consistency of data entered. All efforts will be exerted to minimise missing and spurious data. Any failure to collect subject data (apart from the reasons of death, withdrawal and being truly 'unknown' or 'unmeasurable') will be considered protocol deviations. The site study team will be retrained on study procedures to avoid further loss of data.

System checks will be built into the eCRF. After completion of the data entry process, system logic checks will run to identify potential errors, such as inconsistent dates, missing data and questionable values. A study monitor will follow this study closely and may visit the study site at periodic intervals, in addition to maintaining necessary telephone contact and written communications. The eCRF will be reviewed for completeness and acceptability. Queries may be issued by the study monitor, data management personnel or the principal investigator for study sites to answer.

Regular monitoring of collective data for outliers and possible errors will be performed by the data manager to assess reasonable validity of entered data. Outliers and potentially erroneous data will be verified with the site study team and corrected, if necessary.

Every effort will be made to ensure that the data are accurate and complete prior to database lock. If database unlocking is required to implement any modification to data in the eCRF, authorisation from the sponsor and full valid reason will be required and formally communicated to the study team.

Study data will be available for review by the sponsor and regulatory authorities. Quality assurance auditors, employees of the sponsor or its designated representative may evaluate the conduct of the study at the study site. These entities will have access to all available study reports and source documentation. The sponsor audit reports will be kept confidential.

### Sample size estimates

No formal sample size calculation was performed since the objectives of this study are to determine the case load of stroke and assess/audit the overall quality of care

**Table 1** PNA1DB-Stroke data fields

Data fields	First event case	Recurrent event case
Case ID number	X	X
Initials	X	X
Sociodemographics form		
Birthdate	X	X
Sex	X	X
Race	X	X
Ethnicity, if Asian	X	X
Occupation	X	X
Latest occupation	X	X
City, province, region (current residence)	X	X
Migrant from another region?	X	X
Marital status	X	X
Number of household members (excluding hired help) in current residence	X	X
Number of hired help (maid, driver, caregiver, etc.) in current residence	X	X
Approximate annual total household income (monthly x 12, in Php)	X	X
Hospital or clinic full name (where data are collected)	X	X
Was this patient transferred from another hospital?	X	X
Medical history form		
First or recurrent TIA or stroke?	X	X
Primary subtype of current stroke	X	X
If TIA or ischaemic, primary cause	X	X
if ICH, primary cause	X	X
if SAH, primary cause	X	X
if unknown, reason	X	X
Does the patient have a regular doctor (seen at least once a year) prior to this stroke?	X	X
Number of previous TIA or strokes		X
Number of previous TIA		X
Number of previous ischaemic strokes		X
Number of previous ICH		X
Number of previous SAH		X
Number of previous CVT		X
Number of previous unknown stroke subtype		X
Was antithrombotic medication prescribed for previous stroke (may choose more than one)?		X
If yes, was patient taking medication regularly?		X
If no, why not?		X
Known history of hypertension	X	X
If yes, was patient prescribed medication?	X	X
If yes, was patient taking medication regularly?	X	X
If no, why not?	X	X
Known history of diabetes mellitus	X	X
If yes, was patient prescribed medication?	X	X
If yes, was patient taking medication regularly?	X	X
If no, why not?	X	X
Known history of dyslipidaemia	X	X
If yes, was patient prescribed medication?	X	X
If yes, was patient taking medication regularly?	X	X

Continued

**Table 1** Continued

Data fields	First event case	Recurrent event case
If no, why not?	X	X
Known history of heart disease (may choose more than one)?	X	X
If yes, was patient prescribed medication?	X	X
If yes, was patient taking medication regularly?	X	X
If no, why not?	X	X
Known history of other major diseases or conditions?	X	X
If yes, was patient being treated for all these conditions regularly?	X	X
If no, why not?	X	X
Family history of stroke?	X	X
Current smoker?	X	X
Alcohol consumption of $\geq 4$ servings on $\geq 5$ days in past month?	X	X
Index stroke details and diagnostics form		
Date and time of stroke	X	X
Date and time of arrival in emergency room	X	X
NIHSS total score—first one performed in the hospital	X	X
GCS score—first one performed in the hospital	X	X
If ICH, ICH score on admission	X	X
Brain scan and types done?	X	X
Date and time first procedure was performed	X	X
ECG done?	X	X
Date and time first procedure was performed	X	X
Echocardiogram and types done?	X	X
Date and time first procedure was performed	X	X
Vascular studies and types done?	X	X
Date and time first procedure was performed	X	X
Was testing for SARS-CoV-2 performed during this admission?	X	X
If yes, what was the result?	X	X
Treatments and hospital course form		
Admitted to stroke unit?	X	X
If no, why not?	X	X
Admitted to intensive care unit or monitored bed?	X	X
Was revascularisation attempted?	X	X
If no, why was revascularisation not attempted?	X	X
If yes, any complication from revascularisation?	X	X
Did the patient undergo any surgical procedure?	X	X
Was anti-thrombotic medication given in the hospital?	X	X
Did patient receive prophylaxis for DVT?	X	X
Did patient receive any 'neuroprotectant' agent in the hospital?	X	X
Did patient receive any health supplements for stroke in the hospital?	X	X
Did patient undergo physical therapy while in hospital?	X	X
If no, why not?	X	X
Did patient undergo occupational therapy while in hospital?	X	X
If no, why not?	X	X
Did patient undergo speech therapy while in hospital?	X	X
If no, why not?	X	X
Was patient included in any investigational drug or device clinical trial?	X	X
Did patient have a healthcare directive implemented?	X	X

Continued



**Table 1** Continued

Data fields	First event case	Recurrent event case
Did the patient experience any of the following while in the hospital?	X	X
Recurrent stroke or TIA	X	X
Cardiovascular event	X	X
Pneumonia/chest infection	X	X
Fall	X	X
Skin breakdown/decubitus ulcer	X	X
Urinary tract infection	X	X
Seizures	X	X
Deep venous thrombosis	X	X
Pulmonary embolism	X	X
Joint disorder (eg, frozen shoulder, contracture, etc.)	X	X
Discharge status form		
Date of hospital discharge	X	X
Discharge type	X	X
mRS on day of discharge	X	X
NIHSS total score on day of discharge	X	X
GCS total score on day of discharge	X	X
Was patient prescribed any of the following agents on discharge?	X	X
Anti-platelet	X	X
Warfarin/coumadin	X	X
Newer oral anticoagulant	X	X
Anti-hypertensive	X	X
Oral hypoglycaemic	X	X
Insulin	X	X
Statin	X	X
Non-statin hypolipidemic	X	X
'Neuroprotectant'	X	X
Health supplement	X	X
On discharge, where was patient instructed to follow-up for next visit?	X	X
Was clinical summary or referral letter given to patient?	X	X
On discharge, was patient instructed to undergo any rehabilitation?	X	X

CVT, cerebral venous thrombosis; DVT, deep venous thrombosis; GCS, Glasgow Coma Scale; ICH, intracerebral haemorrhage; mRS, modified Rankin Scale; NIHSS, National Institute of Health Stroke Scale; PNA1DB, Philippine Neurological Association One Database; SAH, subarachnoid haemorrhage; TIA, transient ischaemic attack.

provided to patients admitted in participating hospitals with TIA or stroke. The study intends to capture data from all TIA and stroke cases that are admitted for hospital care in participating sites. Based on data received by the PNA from the project sites for years 2017–2019, approximately 10 000 cases of stroke may be included in the database each year once all sites are activated.

### Statistical analyses

Data processing will be conducted according to the data extraction and analysis plan that will be defined by the investigators and/or the PNA prior to any data analysis. The resultant data sets will be produced by the study data manager. Data will be summarised using descriptive statistics, for example, means, SD, medians, minimums

and maximums for continuous variables and frequency distribution and percentages for discrete variable. Comparative analyses may be performed as necessary using appropriate statistical methods, such as chi-square for comparison of proportions and t-tests for comparison of means.

The number of stroke cases will be compared with the total number of patient admissions in participating sites. Outcomes will be compared with data from the previous years (whenever available) and rates from published studies. Utilisation of diagnostic procedures and therapies provided to cases will be compared with recommendations by international and local guidelines on stroke management and data from the previous years (whenever

available). Stratification by baseline factors, for example, sociodemographic factor, site, etc, may be performed.

Other proposed analyses, for example, determinants of outcomes, analyses that may improve knowledge on the care of stroke patients, etc maybe be performed after review and approval of the proposal by the PNA.

## ETHICS

The conduct of this study will be guided by the principles of Good Clinical Practice as described in the International Council for Harmonization Guideline E6 (R2), the National Ethical Guidelines for Health and Health-Related Research 2017 and in accordance with local regulations.<sup>14 15</sup> Approval from the EC/IRB of the study site will be obtained prior to initiating the study or implementation of any important protocol amendments.

The protocol was approved by the Single Joint Research Ethics Board of the Department of Health, Philippines (SJREB-2021–20) as well as by the EC/IRB of each institution, that is, Baguio General Hospital and Medical Center Research Ethics Committee, Chong Hua Hospital Institutional Review Board, East Avenue Medical Center Institutional Ethics Review Board, Jose R. Reyes Memorial Medical Center Institutional Review Board, Makati Medical Center Institutional Review Board, Quirino Memorial Medical Center Research Ethics Board, St. Luke's Medical Center Institutional Ethics Review Committee, The Medical City Institutional Review Board, University of the East Ramon Magsaysay Memorial Medical Center Ethics Review Committee, University of the Philippines Manila Research Ethics Board, and University of Santo Tomas Hospital Research Ethics Committee.

As this is an observational, non-interventional study that (1) involves no more than minimal risk to subjects, (2) the principal risk of harm to the subject would be a breach of confidentiality and (3) the subject's signature on the informed consent document will be the only record linking the subject to the research, a waiver of informed consent was requested and approved based on the same principles underlying provisions in the National Ethical Guidelines for Health and Health-Related Research 2017 and the Code of Federal Regulation (Federal Policy for the Protection of Human Subjects or the 'Common Rule').<sup>8 16</sup>

If the waiver of written consent is affirmed by the site EC/IRB, a standardised written information about the study will be provided to all subjects or legal representative on inclusion into the study. If the site EC/IRB resolves to require written consent, site participation will be assessed by the steering committee as inclusion bias and the potential effect on the overall data may lead to failure to meet the study objectives. If allowed to proceed, only the informed consent form that is approved by the EC/IRB will be used prior to any study-related data collection.

## DISSEMINATION

There is a huge gap in our understanding of the quality of care and factors that may improve outcome in our stroke patients. Challenges remain in the delivery of adequate support to rural communities and the under-privileged sectors. The mission, commitment and onus of working to reduce the health burden of stroke fall on the PNA and the Stroke Society of the Philippines (SSP), two major stakeholders in the provision of stroke care in the country. Towards this goal, the SSP came out with management guidelines on the prevention, treatment and rehabilitation of stroke in 1999, which has since been updated in 2014 with the publication of the sixth edition.<sup>17</sup> While internationally guidelines on prevention and management of acute stroke, both ischaemic and haemorrhagic are available,<sup>18–21</sup> the aim was to make the guidelines applicable and relevant in the local setting with its strategy of 'Thinking Globally, Acting Locally'. Nevertheless, different factors may influence their implementation, such as availability of resources, patient economic status and other sociopolitical and cultural factors.

In order for the PNA to understand and take the lead in identifying areas of improvement, guiding public health policies on stroke and recommending/directing resources to areas in need, standardised data collection on 'real-world' practices and observation of clinical outcomes are needed. The PNA and investigators may prepare a joint presentation of the results of analyses in scientific or public conferences or publication in scientific journals.

The PNA1DB-Stroke initiative may become a model that can be implemented in other designated stroke-ready hospitals.

**Collaborators** PNA1DB-Stroke Disease Study Management Group members and participating sites—Robert N. Gan (Chair), Raquel M. Alvarez (Makati Medical Center), Maria Teresa A. Cañete (Chong Hua Hospital), Christian Oliver C. Co (Quirino Memorial Medical Center), Maria Epifania V. Collantes (University of the Philippines—Philippine General Hospital), Cyrus G. Escabillas (Jose R. Reyes Memorial Medical Center), John Harold B. Hiyadan (Baguio General Hospital), Dan Neftalie A. Juangco (East Avenue Medical Center), Johnny K. Lokin (University of Santo Tomas Hospital), Maria Cristina Z. Macrohon-Valdez (St. Luke's Medical Center), Monique Therese S. Punsalan (University of the East—Ramon Magsaysay Memorial Medical Center), Gemmalynn B. Sarapuddin (The Medical City).

**Contributors** The authors, all members of the PNA1DB-Stroke Disease Study Management Group, have contributed substantially to the conceptualisation, design and writing of the study protocol.

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**Competing interests** PNA1DB is a not-for-profit initiative. Committee members, investigators and collaborators may have been involved in previous works wherein potential conflicts of interests were declared within the original publications.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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