

**FINAL DRAFT**

# **Clinical Guidelines for Stroke Management**

**Administrative report**

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## 1 Background

The Stroke Foundation has been developing stroke guidelines since 2002. The existing *Clinical Guidelines for Stroke Management 2017* were approved by the National Health and Medical Research Council (NHMRC) in July 2017 with further approvals for changes in November 2017 and July 2018.

In order for the Australian Government to ensure up-to-date, best practice clinical advice is provided and maintained to healthcare professionals, the NHMRC requires clinical guidelines be kept current and relevant by reviewing and updating them at least every 5-years. As a result, the Stroke Foundation in partnership with Cochrane Australia is testing a model of continually reviewing and updating recommendations in response to new evidence. This project commenced in July 2018 and is currently being funded by the Australian Government Department via the Medical Research Future Fund.

Several topics are currently under review following identification of important new evidence since the last major systematic review in mid 2016. Three topics have been completed.

This Administrative report details the information required by the NHMRC in accordance with the requirements of the *Standards for developing clinical practice guidelines 2011*.

## 2 Content Development Working Group

In September 2018, the Stroke Foundation called for an Expression of Interest (EOI) for healthcare professionals to be involved in the development of the Guidelines. Requests for EOI were sent to all previous people involved in the 2017 update as well as stroke care related professional organisations. The EOI was also advertised on the Stroke Foundation's website and in our healthcare professional newsletter. The criteria for selection was:

- Good working relationship with their professional organisation,
- Extensive networks of peers to seek input as needed,
- Strong clinical expertise/experience with a very good practical knowledge of current practice,
- Detailed knowledge of research design and critical appraisal of evidence,
- Familiar with systematic reviews and development of clinical guidelines, and
- Willing and able to commit to the necessary time commitment of this project (over a minimum 24 month period).

Applications in writing were assessed against the selection criteria by members of the Stroke Foundation Project Team and discussed with the co-chairs who also co-chaired the previous update: Professor Bruce Campbell and Associate Professor Coralie English.

The CDG and associated Working Parties are responsible for:

- Reviewing the framework of the existing guidelines;
- Determining the clinical questions for the guideline update;
- Identifying, reviewing and classifying relevant literature;
- Extracting data from the literature and inputting that information into the guideline development platform (MAGICapp);

- Developing the draft Guidelines;
- Evaluating and responding to feedback from the consultation process; and

An overview of the roles and responsibilities and guidelines governance is provided in the Methodology Paper.

Review of the current topics (thrombolysis, acute antiplatelet therapy and PFO closure) was undertaken by the work group members outlined in Table 1. All consumers and specifically the acute medical working group were asked to review draft changes and provide comments. Finally the Content Steering group signed off on the content prior to public consultation and discussed and agreed final copy after feedback was considered.

Table 1: Content Development Working Group Members specifically involved in the current topics

|                                                       |                          |                                                                          |
|-------------------------------------------------------|--------------------------|--------------------------------------------------------------------------|
| Prof Bruce Campbell                                   | Neurologist              | Royal Melbourne Hospital and University of Melbourne, VIC                |
| Dr Nawaf Yassi                                        | Neurologist              | Royal Melbourne Hospital and University of Melbourne, VIC                |
| A/Prof Tim Kleinig                                    | Neurologist              | Royal Adelaide and Lyell McEwin Hospitals and University of Adelaide, SA |
| Prof Thanh Phan                                       | Neurologist              | Monash Medical Centre, VIC                                               |
| Dr Lauren Sanders                                     | Neurologist              | St Vincent's Hospital, VIC                                               |
| A/Prof Andrew Wong                                    | Neurologist              | Royal Brisbane & Women's Hospital, QLD                                   |
| Sue Bowden, Karen Bayly                               | Consumers (thrombolysis) |                                                                          |
| Sue Bowden, Clive Kempson                             | Consumers (antiplatelet) |                                                                          |
| Toni Arfaras, Sam Owen, Kim Draper, Stephen Carpenter | Consumers (PFO)          |                                                                          |

### 3 Consumer involvement

Based on feedback from consumers on the Stroke Foundation Consumer Council an innovative model of consumer involvement is being used which involves involving a panel of consumers as 'lived experts' and who are active members of the Content Development Group. The Guidelines Content Development Group (CDG) Consumer Panel will ensure options, values and preferences of consumers are central to the review and update of any clinical recommendations.

For each topic being updated, 2-4 individuals from the panel with experience of the topic are co-opted to join clinical experts to update the recommendations. The whole panel will then be invited to review and comment on the draft changes.

#### Responsibilities

People involved on the panel will be responsible for:

- Periodically providing input into questions the guidelines answers (and the research literature is searched specifically for). This may involve helping rank the most important outcomes we want to search for in the research.

- Review and comment on updated summaries of research, specifically information related to patient values and preferences
- Input into draft updates to any background text, specifically related to practical considerations and consumer considerations
- Respond to feedback from the public consultation (in cooperation with the interdisciplinary group).
- Assist in the evaluation of the model as needed

#### 4 Managing conflicts of interest

The Guidelines are managed in accordance with the Stroke Foundation *Conflict of Interest Policy*, which is based on the NHMRC *Identifying and Managing Conflicts of Interest of Prospective Members and Members of NHMRC Committees and Working Groups Developing Guidelines* documents. Working group members were asked to review and update their previously disclosed potential conflicts of interest (COI). The form and policy will be provided to NHMRC for review along with summary of potential COIs.

#### 5 Systematic literature review

An overview of the systematic review process is provided in the Methodology Paper. Overarching PICO's and search terms used in the current updating process is listed below –specific PICO's for each individual intervention is found in the Technical report. Search dates were from June 2016 (from last search for the previous guidelines) to the end of February 2019. Additional scanning was undertaken up to end of May particularly for thrombolysis due to known new evidence published.

Evidence surveillance is being conducted monthly with new evidence being considered where relevant. Advice from the CWG will determine the potential impact of the evidence and workflow as outlined in the Methodology paper (evidence deemed to have a possible impact will be rapidly reviewed and incorporated).

| Clinical question                                                                              | Population                       | Intervention                    | Comparator         | Outcomes                                                                 | Search terms used                                                                                                                                                  |
|------------------------------------------------------------------------------------------------|----------------------------------|---------------------------------|--------------------|--------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Does the administration of thrombolysis improve outcomes after acute ischemic stroke?          | All people with ischaemic stroke | Thrombolysis                    | No thrombolysis    | Death<br>Institutionalisation<br>rate                                    | thrombolysis<br>tissue plasminogen<br>thrombolysis (tPA)<br>intravenous thrombolysis<br>intra-arterial thrombolysis<br>Mechanical clot removal<br>Sonothrombolysis |
| Does the use of antithrombotic therapy within first 48 hours improve outcomes in acute stroke? | All people with stroke           | Antithrombotics within 48 hours | No antithrombotics | Death<br>Institutionalisation<br>rate<br>Recurrent /<br>secondary stroke | aspirin<br>acetylsalicylic acid<br>antiplatelet                                                                                                                    |

|                                                                                                              |                                |                              |                 |                                                        |                                                                              |
|--------------------------------------------------------------------------------------------------------------|--------------------------------|------------------------------|-----------------|--------------------------------------------------------|------------------------------------------------------------------------------|
| What interventions in patent foramen ovale management lower the risk of further strokes in stroke survivors? | All people with stroke and PFO | surgical closure, medication | No intervention | Death<br>Institutionalisation rate<br>Secondary stroke | antiplatelet therapy; anticoagulation therapy; surgery, percutaneous closure |
|--------------------------------------------------------------------------------------------------------------|--------------------------------|------------------------------|-----------------|--------------------------------------------------------|------------------------------------------------------------------------------|

## 6 Practice Statements (Consensus-based recommendations) and Practice Points

The Guidelines have a number of Practice Statements (Consensus-based recommendations) and Practice Points.

For some topics, a systematic review of the available evidence was conducted, but there was either a lack of evidence or insufficient quality of evidence on which to base a recommendation. In cases where the CWG determined that recommendations were important, statements and advice about topics were developed based on consensus and expert opinion (guided by any underlying or indirect evidence). These statements were labelled as 'Practice statements', and correspond to the 'consensus-based recommendations' outlined in the NHMRC procedures and requirements. These statements should be regarded with greater discretion by guideline users.

For topics outside the search strategy (i.e. where no systematic literature search was conducted), additional considerations are provided. These are labelled 'Info Box' and correspond to 'practice points' outlined in the NHMRC procedures and requirements.

Final decisions about Practice Statements (Consensus-based recommendations) and Practice Points were made using informal group processes after open discussion facilitated by the Co-Chairs. If there was divergent opinion with respect to Practice Statements (Consensus-based recommendations) and Practice Points, they were not included in the guideline.

## 7 Public consultation

The Stroke Foundation conducted the public consultation process in accordance with Section 14A of the *Commonwealth National Health and Medical Research Council Act 1992* and accompanying regulations.

We advertised the 'Notice of public consultation' publicly on the Stroke Foundation websites – [www.strokefoundation.com.au](http://www.strokefoundation.com.au); [www.informme.org.au](http://www.informme.org.au) and [www.enableme.org.au](http://www.enableme.org.au) from 31 July to 30 August 2019. Electronic communications were also sent on 1 August to all organisations identified by the NHMRC as being mandatory to consult with, advising of the public consultation period (refer to Appendix 2 for a list of these organisations). Electronic communications were also sent to all professional and consumer organisations via the Australian Stroke Coalition. Feedback was received email.

The Stroke Foundation received a small number of responses from individuals and organisations. No changes were deemed to be necessary but some additional information was provided in practical considerations section.

All individuals and organisations that provided feedback during the public consultation period will be contacted via letter and thanked for their input and advised of the action taken by the CWG in response to their feedback.



## Appendix 1: Names of organisations contacted for Public consultation

|                                                                                                                |
|----------------------------------------------------------------------------------------------------------------|
| <b>Organisation</b>                                                                                            |
| The Director-General, Chief Executive or Secretary of each state, territory and Commonwealth health department |
| Therapeutic Goods Administration (TGA)                                                                         |
| Pharmaceutical Benefits Scheme (PBS)                                                                           |
| <b>Australian Stroke Coalition</b>                                                                             |
| Stroke Society of Australasia (SSA)                                                                            |
| Australasian College for Emergency Medicine                                                                    |
| Australasian Faculty of Rehabilitation Medicine                                                                |
| Australian College of Nursing                                                                                  |
| Australian Physiotherapy Association                                                                           |
| Australian Psychological Society                                                                               |
| Council of Ambulance Authorities                                                                               |
| Dietitians Association of Australia                                                                            |
| Occupational Therapy Australia                                                                                 |
| Royal Australasian College of Physicians                                                                       |
| Speech Pathology Australia                                                                                     |
| NSW agency of clinical innovation Stroke Network                                                               |
| Northern Territory Stroke Unit Network                                                                         |
| South Australian Stroke Department                                                                             |
| Queensland Statewide stroke Clinical Network                                                                   |
| Safer Care Victoria                                                                                            |
| Stroke Clinical Advisory Group of WA                                                                           |