Governance and methodology

Outline of the process for the development of the **National Heart Foundation of Australia (Heart Foundation) and Cardiac Society of Australia and New Zealand (CSANZ): Australian Clinical Guidelines for the management of Atrial Fibrillation (AF) 2018**

Introduction

The National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand have developed the Australian Clinical Guidelines for the management of Atrial Fibrillation (AF). These guidelines have been developed to assist clinicians in the diagnosis and management of adult patients with AF. They are informed by recent evidence interpreted by local experts to optimise application in an Australian context.

The guidelines were developed within a governance structure commensurate with the evolving landscape of rigorous guideline development. This is the first Australian guideline on the topic of Atrial Fibrillation.

This document seeks to outline the roles and responsibilities of contributors to this process for the Heart Foundation and Cardiac Society of Australia and New Zealand. These guidelines were developed by leading Australian experts who contribute to the Heart Foundation in an honorary capacity. These experts often have overlapping commitments and hence the importance of both transparency and appropriate management of Conflicts of Interest (COI). The governance processes employed by the Heart Foundation aimed to ensure the integrity of guideline developers and to strike an appropriate balance between the existence of 'interests' in a topic under review and the expertise required to make sound and meaningful recommendations.

1. Structure

Membership

Key experts involved in writing the AF guideline comprised of a reference group and a working group. A detailed description of the membership of the groups is included below. The approach to development and consultation was designed to ensure appropriate representation and engagement in the guideline writing process.

Working group

1) <u>Responsibilities</u>

- To advise on the scope and processes of the project;
- To provide advice and guidance on the content and structure of the project;
- To evaluate and consider all relevant evidence-based literature appropriate to the formulation of the project;
- To evaluate and consider other relevant international guidelines;
- Define the initial questions to be submitted for literature review;

- Provide a structured environment for discussion and debate of relevant evidence for assimilation into recommendations;
- Drafting the guideline manuscript;
- Provide quality of evidence and strength of recommendation classification for recommendations;
- To identify opportunities for implementation and promotion of the guideline; and
- Consult on other project specific activities as necessary.

2) The writing committees

The working group consisted of three writing committees (see Appendix 1 and below). An executive writing committee comprised of one member of each writing committee. Based on the determined scope, guideline writing committees were established to cover the following topics: screening and prevention, epidemiology, and multidisciplinary management; arrhythmia management; and stroke prevention. For each writing committee, a primary writer was appointed by group consensus, on the basis of expertise and previous experience in guideline development. Other members of the writing committees comprised of members with recognised expertise, from stakeholder groups and the clinical community, and a consumer representative. The writing committees met on several occasions to discuss the content of the guideline during the development process.

The reference group

The reference group comprised of nominated representatives from identified key stakeholder organisations/bodies with national relevance in the provision of AF care in Australia. Members of the reference group were asked to engage in the guideline development process, including review of draft content of the guideline. Specific requests of the reference group included:

- Review the guideline in terms of acceptability and relevance;
- Provide consultation and commentary with respect to evidence-based clinical content in the guideline;
- Advise on the implementation planning of the guideline;
- In the case of organisational representative members, represent the parent endorsing body to facilitate the process of endorsement where appropriate. Organisational representatives have the responsibility of keeping the organisation they represent informed and up to date through the development process.

If any disagreement or dispute about the content arose through the reference group review, this was resolved by the executive writing committee which had final approval of content.

Endorsing organisations

Where endorsement was sought from an organisation which was a member of the reference group, the relevant reference group member facilitated endorsement. In some cases, endorsement was sought from some organisations not on the reference group. In these cases, the chief executive officer of the endorsing body was contacted to co-ordinate review of the guideline.

2. Heart Foundation governance structure

The draft guidelines produced by the working group were approved by the Heart Foundation and CSANZ through the clinical approval committees. For the Heart Foundation this included the Clinical Issues Committee (CIC) and the Cardiovascular Health Advisory Committee (CVHAC), and the Board of the Heart Foundation. CSANZ approval was by the Quality Standards Committee and the National Board.

Please refer to Appendix 1 for more information.

3. Working group operations and communication

- Tenure of the chair and working group members was for the period of the guideline development project.
- All working group members were honorary.
- The executive writing committee members were decided upon and nominated by the chair of the working group and the Heart Foundation prior to the first meeting. The working group members volunteered for writing committee(s) according to their expertise and interests.
- The writing committee chairs in collaboration with the writing committee members were responsible for the delivery of scope, clinical questions, a process to receive and review evidence summaries, draft updates to the guideline and draft clinical recommendations for open consultation, and review of responses to these.
- Working Group Chairs (Writing Committees and Reference Group) were responsible for managing COI of their group. All members were expected to disclose COI at commencement and throughout membership and continuously review their disclosure to the working group and the Heart Foundation during the project. COI disclosure was a standing agenda item at each working group meeting. A register was maintained as a record (including emails and relevant papers and documents). The conflict of interest register is available on the Heart Foundation website.
- Where the chair disclosed a COI, responsibility for the meeting/actions of the working group related to the specific topic at issue was delegated to another member of the working group, or Heart Foundation staff.
- Working group meetings were via teleconference or face-to-face. The frequency of meetings and contact was determined by the working group based on project requirements.
- Correspondence between meetings was via email and/or telephone.
- Clinical questions were approved by NHFA and CSANZ internal clinical committees. The draft manuscript was presented for public consultation.

Communication with CSANZ

- Updates were given via NHFA Clinical Issues Committee Chair to CSANZ board, and quarterly reports were provided to the CSANZ CEO
- A CSANZ representative member was on the AF Guideline reference group.
    - In this capacity as representative for CSANZ his role was to keep CSANZ appraised of the guideline development progress and facilitate the process of CSANZ endorsement/ approval of the completed guideline.

Communication with reference group organisations

The Heart Foundation generated quarterly reports on progress for circulation through organisational representatives to their parent organisations

4. Literature search and evidence methodology

The literature search required to inform the AF guideline development was out-sourced. An organisation was commissioned after expressions of interest were sought and applicants rigorously reviewed (via a selective tender process). The executive committee was consulted in making the final decision. The organisation commissioned was the Joanna Briggs Institute at the University of Adelaide.

In addition to reviews of published trials and systematic reviews, guideline content was informed by other clinical guidelines and local clinical expertise. Grading of Recommendations Assessment, Development and Evidence (GRADE) methodology was used to formulate recommendations. Refer to Appendices 2 and 3. GRADE highlights the strength of a recommendation for or against an intervention. This is determined by considering the quality of evidence, balance between benefits and harms, trade-offs between improving survival and quality of life, uncertainty or variability in patient values and preferences, and resource considerations. This methodology is increasingly being used by guideline developers in Australia and worldwide.

5. Public consultation

- There was a public consultation period on the final draft, advertised on the Heart Foundation website and through clinical networks in April 2018 for 21 days.
- The chair reviewed every item of feedback received, and a face to face working group meeting was constituted to run through feedback and agree on any required changes to the manuscript.

6. Conflict of Interest

The AF Guideline working group acknowledges the importance of both transparency and appropriate management of COI. A COI arises in any situation in which a member or related person has an interest which influences, or may appear to influence, the proper performance of the members' responsibilities. An apparent COI may be as important as an actual conflict of interest.

Each AF guideline working group member was expected to disclose in writing to the Heart Foundation the fact, nature and extent of any interest of the Individual and any associate of the Individual which was or may be or become in conflict with the duties or obligations of the Heart Foundation in relation to the Project, whether direct or indirect, and whether as a partner, contractor, servant, shareholder, principal, agent, officer or otherwise.

A register was maintained by the Heart Foundation as a record of COI (including emails and relevant papers and documents). This register is available on the Heart Foundation website.

What is considered a relevant Conflict of Interest?

A relevant COI was a financial/other relationship (including intellectual) with an entity that either does, or could be perceived to, influence what has been incorporated into the guideline.

What should be disclosed?

Interest statements comprised a declaration of any interests that may be capable of influencing advice or decisions relating to the update of the guideline, or that may affect the integrity and reputation of the Heart Foundation and the Cardiac Society of Australia and New Zealand. An interest statement included interactions with any entity that could broadly be considered relevant to the work, including non-financial intellectual property. Intellectual conflict of interest included "enhanced academic or practice profile and prestige" related to guideline content or other work outside of the guideline.

Classification of Conflicts of Interest

Conflicts of interest were considered within a framework that considered both the *relationship* of the participating individual, combined with the *nature* of the potential conflict specific to the topic under consideration within the guideline development process.

The *Relationship* to the individual was considered as either:

1. Personal: Directly pertaining to the individual or family, where the benefit was received personally.

2. Non-personal: Pertaining to the individual's employing institution (but where the benefit was not received personally), where the individual had some managerial responsibilities and influence over the interaction between that institution and organisations that may seek to exert influence. Examples include:

- A grant from a company for the running of a unit or department for which a member was responsible.
- A grant or fellowship or other payment to sponsor a post or member of staff in the unit for which a member was responsible.
- The commissioning of research or other work by, or advice from, staff who work in a unit for which the member was responsible.

The *Nature* of the potential conflict of interest was considered in the following classifications.

High-level pecuniary interest

1. Any directorship, position in or work in the healthcare industry (including research and pharmaceutical industry) that attracted regular or occasional payments in cash or in kind, having been undertaken within the 36 months of the project.

2. Any shareholdings, or other beneficial interests, in shares of a healthcare industry entity (including research and pharmaceutical industry) that was either held by the individual or for which the individual had legal responsibility.

3. The holding of a fellowship endowed by the healthcare industry (including pharmaceutical industry). Examples include:

- a grant from a company for the running of a unit or department for which a member is/was responsible
- a grant or fellowship or other payment to sponsor a post or member of staff in the unit for which a member is/was responsible

Low-level pecuniary interest

1. Membership of advisory boards.

2. Speaker Fees for presentation at educational events that have sought sponsorship or were sponsored by the health care industry.

3. Expenses or hospitality provided by a healthcare industry company for accommodation, meals and travel to attend meetings and conferences, which have been undertaken within the 36 months preceding the release of the guidelines.

4. Commissioning or funding of research from the healthcare industry (referring to pharmaceutical, medical device or technology companies) or other work by, or advice from, staff who work in a unit for which the member is/was responsible.
5. Any payment or other support by the health industry, that does not convey any material benefit to an individual personally but that might lead to indirect benefit.

Non-pecuniary interest

- A clear opinion, reached as the conclusion of direct involvement in primary research projects or clinical trials, about the clinical and/or cost effectiveness of an intervention under review.
- A public statement in which an individual has expressed a clear opinion about the matter under consideration, which could reasonably be interpreted as prejudicial to an objective interpretation of the evidence.
- Holding office in an organisation or advocacy group with a direct interest in the matter under consideration.
- Other reputational risks in relation to an intervention under review.

Managing conflict of interest

Conflicting interests among the guideline development group required appropriate management to ensure clinical recommendations were not compromised. There was discussion relating to the management of COI during the guideline development process to minimise the risk of biases in the framing/formulation of clinical recommendations and final guideline content. Processes employed by the Heart Foundation aimed to ensure the integrity of guideline developers and to strike an appropriate balance between the existence of 'interests' in a topic under review and the expertise required to make sound and meaningful recommendations.

Conflicts of interests were managed by:

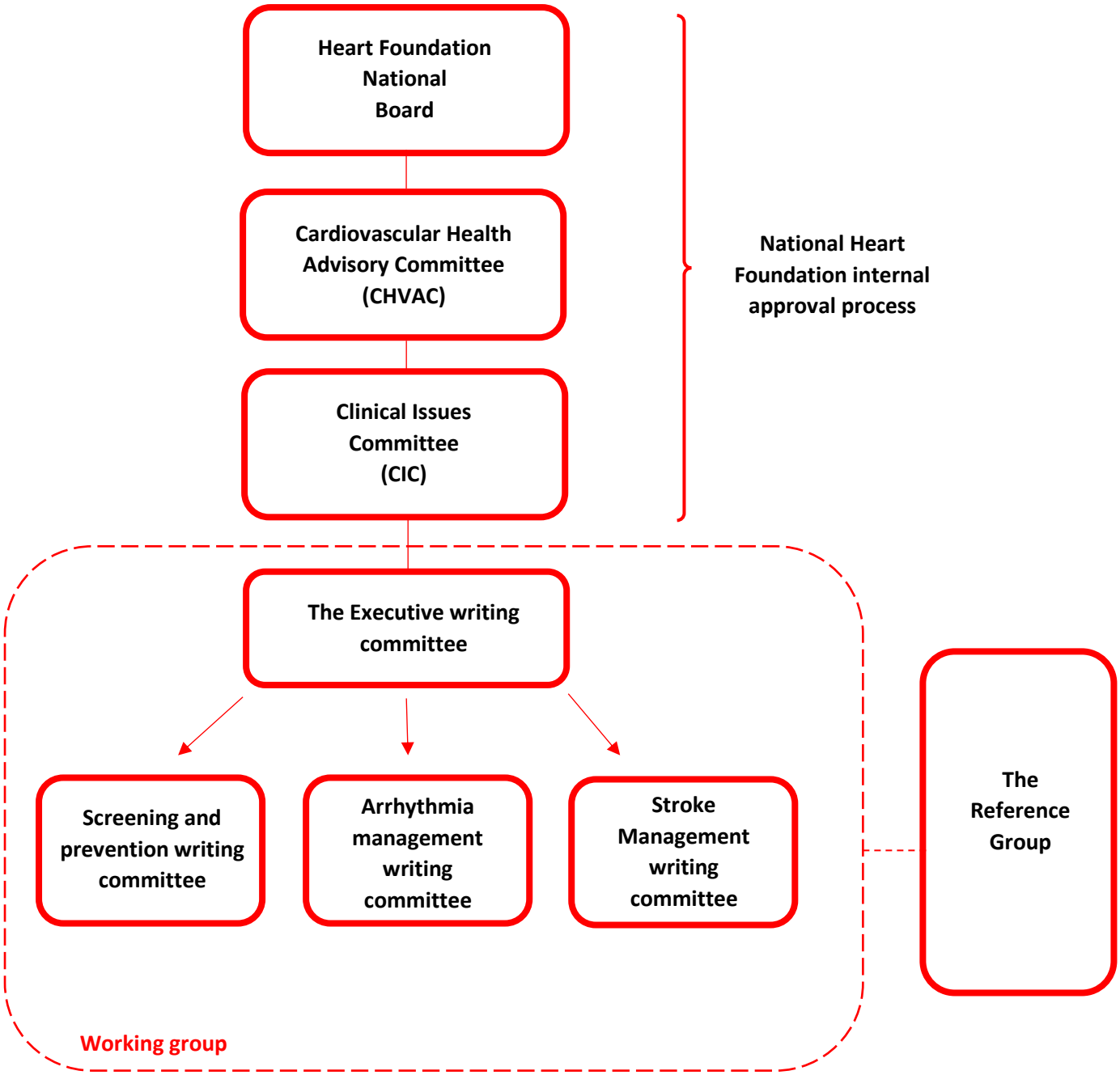
- Open disclosure of all COI to all members of the working group and public declaration of all COI in the guidelines. Members were expected to disclose COI at commencement of membership and also to update the working group during the project if there were any changes to this declaration.
- COI declarations were revisited at each working group meeting (including Executive and Writing Committees) to ensure new disclosures were recorded.
- The principal writer and the appointed senior writer in writing committees reviewed the COI that occurred within their group.

- If a COI disclosure was deemed significant, individuals may have been restricted from involvement in discussions and decisions on related topics. In circumstances where a COI was disclosed, the process of managing the disclosure included:
    - limited involvement in the deliberation of the evidence, with possibility of bias noted
    - limited involvement in discussions on the wording, structure or intent of the clinical recommendation
    - limited involvement in the formulation of the clinical recommendation relevant to disclosure of a conflict.

7. Confidentiality

Each Working Group and Reference Group member agreed to confidentiality obligations under the Terms of Reference. Working group members could not permit any of their officers, employees, agents, contractors, or related entities to, use or disclose to any person any information disclosed to them by the Heart Foundation or as a part of this project, without the prior written consent of the Heart Foundation. No breaches of confidentiality were noted.

Appendix 1: Heart Foundation Governance Process for the Heart Foundation/CSANZ Australian Clinical Guidelines for the Management of Atrial Fibrillation 2018



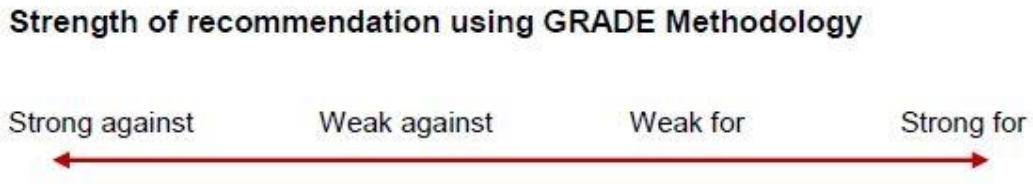
Appendix 2: Template for approving Recommendations

This template was used to ensure that the presentation of the guideline is consistent throughout. As there are many members writing sections it was important to ensure there was a consistent style.

Title: *Section of scope addressed*
Recommendation: *Clinical actions that are likely to be associated with the largest impact on patient important outcomes. GRADE methodology [2] used to provide strength of recommendation.*
Quality of Evidence: *GRADE* [1]
Rationale: *Very brief summary of the key evidence (Maximum 2-3 short paragraphs)*
Benefits and Harms: *Where possible estimates of the absolute changes in intervention specific outcomes or care related adverse events for the 'average' patient. These assist clinicians in their discussions with patients by quantifying the likely benefits or risks associated with each guideline recommendation.*
Resources and other considerations: *Commentary regarding the key economic implications or relevant system factors where appropriate. How the recommendations impact available resources geographically to the Australian context.*
Practice Advice: *Aspects of care associated with a very limited evidence base and reliant on consensus opinion, or where the impact of interventions on clinical outcomes are considered modest.*

The resources and other considerations section should, where appropriate, consider the cultural and linguistic diversity of the Australian community, in particular the Aboriginal and Torres Strait Islander population and those in rural and remote areas of the country.

Appendix 3: GRADE methodology for recommendations [1]



Within GRADE methodology there are two strengths of recommendation: “strong” or “weak/conditional”. The direction and strength of each recommendation is determined on the basis of four key factors: level of confidence in effect estimates (as determined by quality of evidence), balance between benefits and harms, uncertainty or variability in patients’ values and preferences, and resource considerations.

The strength of the recommendation is defined by the following principles:

GRADE METHODOLOGY	
Strong recommendation	High or moderate confidence in effect estimates AND Benefits clearly outweigh the harms or vice versa AND All or almost all fully informed patients will make the same choice AND Benefits of the intervention are clearly justified in all or almost all circumstances of resource allocation
Weak recommendation	Low or very low confidence in effect estimates OR Balance between benefits and harms is close OR Variability or uncertainty in what fully informed patients may choose OR Benefits of the intervention may not be justified in some circumstances of resource allocation

References

1. Grading of Recommendations A, Development and Evaluation (GRADE) Working Group,. GRADE Handbook. Introduction to GRADE Handbook. Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach. Updated October 2013. Available at: http://gdt.guidelinedevelopment.org/app/handbook/handbook.html. Accessed 21/02/18. 2013.