TSANZ CLINICAL DOCUMENT DEVELOPMENT PROCESS, PUBLICATIONS, AND ENDORSEMENT POLICY

Contents

Abbreviations

CCRS – Clinical Care and Resources Sub-Committee
COI – Conflict of Interest
EOI – Expression of Interest
SIG – Special Interest Groups

TSANZ-Commissioned Documents

There are two types of TSANZ clinical documents: clinical practice guidelines and position papers.

Clinical practice guidelines

Clinical Practice Guidelines are documents that foster best clinical practice and promote consistency and equity of health care in Australia and New Zealand. These guidelines should be based on the systematic identification and synthesis of the best available scientific evidence.

Guidelines are the only TSANZ documents in which recommendations for clinical practice can be made. Recommendations can be made because the rigorous process underpinning a clinical practice guideline allows the Society to be confident that the recommendations are robust and underpinned by sufficient evidence to guide clinical practice.

TSANZ guidelines should aspire to meet the requirements of the peak national bodies in Australia and New Zealand, such as the National Health and Medical Research Committee (NHMRC updated 2016).

Guidelines developed should follow the 2016 NHMRC Standards for Guidelines. Working parties should familiarise themselves with the NHMRC resources for guideline developers.

Requirements for TSANZ Clinical Practice Guidelines

The requirements for TSANZ Clinical Practice Guidelines are:

- the purpose of the guideline is clearly stated, including the intended users and the population of interest;
- a systematic review of the literature is conducted by a CCRS approved methodologist, which includes:
    - a documented methodology for the review;
    - appropriate research/clinical questions in PICO format;
    - inclusion and exclusion criteria clearly stated;
    - a documented search strategy, including the search period;
    - systematic synthesis and grading of quality of the body of evidence for each clinical question; and
    - the link between evidence and guideline recommendations is clearly documented;
- the recommendations are graded in accordance with the GRADE system (or equivalent for international collaborative guidelines);
- consumer representatives are included on the guideline development group, if appropriate;

- the guideline development group includes representatives from a range of professions and disciplines that are relevant to the scope of the guideline;
- there is evidence of peer review external to the guideline development group;
- a list of members of the guideline development group is included; and
- a conflict of interest statement for each of the members of the guideline development group is included.

Position papers

Position papers present TSANZ positions on:

- clinical practice, especially in the areas of emerging diagnostic and therapeutic modalities where insufficient data exists to write a formal clinical guideline;
- public health policy, including health service delivery and government policy; and
- clinical and basic science research relevant to the area of respiratory medicine.

Recommendations for clinical practice cannot be made in a position paper, although suggested approaches to clinical care can be outlined.

The working party may choose to include a systematic review and formal assessment of the quality of evidence, however this is not mandatory. A clear statement on the evidence that has been used, how this has been sourced and evaluated, and how conclusions have been made should be included. If a systematic review is included, the working party must include an experienced methodologist, approved by the CCRS.

Requirements for TSANZ Position Papers

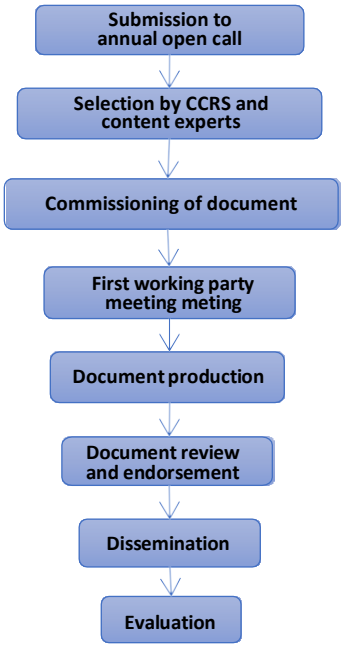
Requirements for TSANZ Position Papers are:

- the purpose of the position paper is clearly stated, including the intended users and the population of interest;
- the position paper development group includes representatives from a range of professions and disciplines that are relevant to the scope of the position paper;
- consumer representatives are included on the position paper development group;
- there is evidence of peer review external to the position paper development group;
- a list of members of the position paper development group is included; and
- a conflict of interest statement for each of the members of the position paper development group is included.

TSANZ clinical document development process

The process for clinical document development, from inception to fully disseminating the information and translating it into meaningful policy, should be controlled and transparent. At no time with the TSANZ accept sponsorship for guidelines or position papers from pharma, device or other companies with an actual or perceived conflict of interest. This overview contains a flow chart (Figure 1) of what is expected, coupled with a policy or template when appropriate.

Figure 1 *- Flowchart of the development process for TSANZ clinical documents*



Submission to annual open call

There will be an annual open call for proposal submissions for new documents or updates of existing documents in July of each year.

In general, TSANZ clinical documents should address issues applicable to all Australian States and Territories and New Zealand, unless there are important specific reasons to restrict them to certain states, territories or countries.

The TSANZ board and CCRS may identity priority areas for each open call, although proposal submission of all topics and document types is welcome.

The proposer should complete the Proposal for a New Clinical Document online for the submission. This is a requirement for TSANZ review. The proposal will include a list of proposed working party members, which will form part of the assessment. Guidance for selecting proposed working party members is provided in the Proposal for a New Clinical Document. Briefly, a working party is to be formed with the following considerations:

- appropriate number of members in the working party for the scope of work without being excessive;
- the selection of working group members should consider the content and methodology expertise required, and conflict of interests, as well as reflect the diversity of the Society and end users, considering geography, disciplines, gender, seniority and First Peoples;
- the predominance of working group members from one centre or state is discouraged;
- the stakeholder representation in the working party, including partner organisations and consumers (inclusion of consumers from the beginning of the process is strongly encouraged, to ensure that the document reflects their needs and priorities);
- the inclusion of other society members in the working party may be considered if deemed appropriate for TSANZ clinical documents and will be required for joint societies documents.
- the inclusion of experts outside Australia and New Zealand is only recommended when similar expertise is not available and should not exceed 10-20% of the panel.
- At least two co-chairs should be appointed for each document, with a maximum of 3 if including an early-career member. It is encouraged to appoint a co-chair who is in the early stages of their career to support the development of the document. The co-chairs should be from different institutes. One of the co-chairs should have no or minimal conflict of interest.

The proposed list of working party members will be reviewed as part of the proposal assessment (see next section). For proposals of updating TSANZ documents, it is encouraged to include both members from previous working party (50%) and new members (50%) to allow continuity as well as new perspectives. there will be an open call each year for members who are interested to participate in TSANZ documents. A database of interested members will be developed for CCRS to nominate and allocate suitable candidates to fill the gaps identified in the proposed memberships for successful proposals.

The proposal must include clearly defined, documented process for

- literature review for position papers or systematic review(s) for clinical practice guidelines
- procedure for reaching consensus and/or generating recommendations (e.g. the GRADE assessment, Delphi process, etc).

Selection by CCRS and content experts

Proposals received from each open call will be collated and considered by the CCRS and content expert reviewers based on greatest need, available evidence, and resources. Each proposal will be scored based on the 4 categories: Relevance, Methodology and proposed committee, Project scope and feasibility, and TSANZ need assessment. Score sheets will be released to all submissions.

Recommendations of changes (e.g. scope of work, composition of working party members) may be provided for successful proposals. Failure to address the recommendations of changes may result in

project termination. As all working parties will be formed concurrently, participation of a single member in multiple working parties in the same round will be discouraged.

Commissioning of a clinical document

Once the successful proposals are finalized, including addressing recommended changes by CCRS and content expert reviewers, they will be commissioned.

Conflict of interest

Proposed and other nominated working party members of the successful proposals will be asked to fill out and sign the TSANZ Conflict of Interest for Authors and Reviewers in reference to the clinical document prior to being accepted to join the working party. The CCRS will review the COIs to ensure suitable composition for the panel. The co-chair(s) of the working party will be responsible for ensuring all conflict of interest statements are kept up to date and all declared interests managed throughout the document development. A statement of conflict of interests must be included in all publications.

For further details regarding Conflict of Interest, see the TSANZ Conflict of Interest Policy.

Confidentiality Agreement

All content of TSANZ clinical documents should be kept confidential and not to be discussed outside of the working party, unless being approved by TSANZ. Working party members of the finalized successful proposals will need to sign a Confidentiality Agreement prior to the first working party meetings.

First working party meeting

The first working party meeting for the finalized successful proposals is aimed to be held at the TSANZ Annual Scientific Meeting. Representatives from each working party are required to attend a mandatory briefing session with the CCRS chair at the TSANZ Annual Scientific Meeting.

At the first working party meeting,

- the co-chairs of the working parties will be selected;
- the need of methodology support for document development will need to be discussed. Where the group feels that they do not have the required skills amongst their membership (e.g. methodology or systematic review skills), the CCRS will assist the group to access these skills amongst the broader TSANZ membership.

Document production

During the process of document production, working parties must adhere to the Guidelines for Clinical Document Working Parties. The co-chairs must provide a progress report to the CCRS every six-months.

If suitable resources are already available elsewhere (e.g. guidelines used in other countries), it may be more appropriate to adopt or modify these instead of generating new ones. Similarly, if relevant systematic reviews are already available, these should be used to underpin guideline development, rather than generating new ones.

TSANZ clinical documents are aimed for publication in Respirology, although this is subjected to independent peer reviewing of the journal. Should a clinical document not be accepted for publication in Respirology, the CCRS chair and working party co-chairs will discuss an alternative publication plan. The word limits for clinical documents published at Respirology are 8000 words for clinical practice guidelines and 2500 words for position papers, although this may be negotiated with Respirology.

The final document must be approved by the CCRS, who will recommend it to the TSANZ Board for endorsement. The submission of documents to the CCRS involves a thorough procedural and content review, and will usually include editorial suggestions, and the document may require revision before it is finally accepted.

Evidence used in clinical documents

It is anticipated that TSANZ guidelines and position papers will be read and considered by a broad audience including the membership of the society, but also other professionals, other professional bodies, government and non-government agencies. From that perspective it is clearly preferable that a consistent approach to assessing the quality of evidence and the strength of recommendations is applied. At this stage a standard approach has not been adopted by the NHMRC. In the interim the TSANZ will recommend that for guidelines (and where applicable position papers) that a system of assessment of both the evidence and the strength of recommendations be used. The recommendation currently is to use the GRADE system, as it is internationally recognised, clearly defines the difference between evidence and recommendations and specifies a transparent system for moving from evidence to recommendation.[1,2,3,4]

[1] Guyatt GH, Oxman AD, Vist GE, Kunz R, Falck-Ytter Y, Alonso-Coello P, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. Bmj. 2008 Apr 26;336(7650):924-6. PubMed PMID: 18436948. Pubmed Central PMCID: 2335261.

[2] Jaeschke R, Guyatt GH, Dellinger P, Schunemann H, Levy MM, Kunz R, et al. Use of GRADE grid to reach decisions on clinical practice guidelines when consensus is elusive. Bmj. 2008;337:a744. PubMed PMID: 18669566.

[3] Schunemann HJ, Oxman AD, Brozek J, Glasziou P, Bossuyt P, Chang S, et al. GRADE: assessing the quality of evidence for diagnostic recommendations. ACP journal club. 2008 Dec 16;149(6):2. PubMed PMID: 19071869.

[4] Schunemann HJ, Oxman AD, Brozek J, Glasziou P, Bossuyt P, Chang S, et al. GRADE: assessing the quality of evidence for diagnostic recommendations. Evidence-based medicine. 2008 Dec;13(6):162-3. PubMed PMID: 19043023.

Peer review and endorsement of clinical documents

Peer review

The manuscript will be reviewed by nominees of the relevant SIGs pertaining to the publication with a focus on the document content. The CCRS will review the document with a focus on process. The CCRS reserves the right to request additional reviewers from inside or outside the Society. All content-matter expert reviewers must fill in the Conflict of Interest for Authors and Reviewers and the TSANZ Confidentiality Agreement. Feedback will be issued to the working party for detailing any further requirements or recommendations required prior to endorsement.

For publications planning to publish with Respirology, the TSANZ and Respirology reviews may occur simultaneously.

Endorsement

Once the clinical document has been reviewed by the CCRS and relevant SIG(s), the CCRS will make a recommendation about whether the document should be endorsed in its current form. Each clinical document will be tabled for review by the TSANZ Board at their next Board Meeting. If there is a specific urgency for publication, this process may be fast-tracked and an out-of-session endorsement may be requested. The timeline for this is usually 2 weeks.

Endorsement will include:

- registration of Board endorsement by TSANZ Office; and
- badging (or co-badging if it is a joint paper) of the publication with the TSANZ logo.

Publication

Respirology will be the first consideration for all publications. Clinical documents are typically published as Open Access, which is funded by the Society with the publications being licensed as CC-BY-NC, or affiliated institution with the Wiley Open Access agreement of the authors (if applicable).

The TSANZ may assert copyright ownership over guidelines we commission.

Dissemination and further education requirements

A dissemination plan must be developed alongside each document.

- All working parties will be asked to host a TSANZ webinar to present their clinical document. This will be organised with the Professional Development Officer.

- The working party may propose and develop additional dissemination and education materials (such as PowerPoint slides for key summary points, pamphlets, checklists and posters), which will be reviewed and endorsed by the TSANZ.
- In order to enhance access to TSANZ guidelines and position papers, all clinical documents will be made available via the TSANZ website, either in full or as a link to the publication. Where a clinical document is published in a journal, it will not be published on the TSANZ website until the publication embargo has lifted.
- If applicable, representatives from selected clinical practice guidelines or position papers may be invited to present the documents at the TSANZ Annual Scientific Meeting.
- If applicable, a training course or workshop based on the clinical practice guidelines or position papers can be proposed by the working party for consideration of the Education and Training Sub-committee for the TSANZ Education Hub.
- For clinical practice guidelines, the working party will be invited to create an Audit Standards of Care Template as a companion to the guidelines. This template is to be made available to all TSANZ members. The template must be in the form of a checklist which provide questions for what is required to be compliant. E.g. For oxygen audits, there would be a yes/no question for whether a prescription has been written for patients requiring high flow nasal oxygen.

Evaluating impact

Each TSANZ document should have a plan to evaluate its impact, which is documented alongside the dissemination plan. The evaluation should consider process, clinical outcomes and policy. For instance, consider;

- number of downloads from TSANZ website;
- number of downloads from journal website;
- number of derivatives developed, e.g. training packages or quality standards;
- number of people undertaking training, where relevant;
- media mentions;
- evidence of impact on health care policy and clinical practice; and
- evidence of impact on patient outcomes.

Update

All TSANZ documents will be endorsed for a period of five years, unless agreed otherwise during the review process. Prior to five years, the CCRS will ask the relevant SIG and/or the original working party

to review the document for currency and the need for updating. Documents that required updating may form the priority areas in the annual open calls for proposal submissions.

Out-of-session commissioned documents

TSANZ may identify urgent areas or topics for out-of-session commissioned documents. The nominated topics will be reviewed and discussed by the TSANZ President and CCRS Chair for commissioning documents through an expedited process as follows:

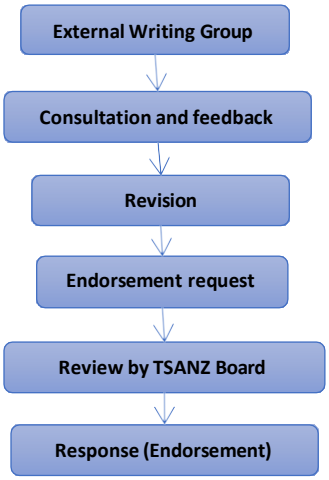
- commission to the relevant SIG convenors
- Nomination of up to 10 members for the working party by the SIG convenors or their representatives. A smaller working party is desirable for urgent documents to allow timely progress and completion.
- Development and submission of the document outline by the working party for review and approval by the TSANZ President and CCRS chair
- Submission of the document for simultaneous review by CCRS and Respirology within 6-9 months.

Documents from Other Organisations

TSANZ members who are involved in the development of documents for external bodies are encouraged to liaise with the CCRS to determine whether TSANZ endorsement might be relevant.

The process for endorsement of external clinical documents should allow for review and improvement of resources and covers both the guideline development process and content. This overview contains a flow chart (Figure 2) of what is expected.

Figure 2 *- Flowchart of the development process for clinical documents from external organisations*



Consultation request

The TSANZ will receive requests to review and consult on publications which have been produced external to the Society. All requests should be sent to the TSANZ Clinical Administrator to ensure tracking of requests and coordination of the review. The external organisation will be requested to complete the consultation checklist prior to the consultation. The consultation may or may not be accompanied by a request for endorsement.

The manuscript will be reviewed by a number TSANZ of reviewers including, but not exclusive to, two representatives of the relevant SIG/s. The CCRS will review the consultation checklist from a procedural view. Feedback will be issued to the external working party detailing any further requirements or recommendations required prior to endorsement.

All content-matter expert reviewers should fill in the Conflict of Interest for Authors and Reviewers.

Requests for TSANZ review should normally be regarded as a request to comment on and improve the document. Requests should therefore allow sufficient time for the sub-committee to do this. Requests not submitted with sufficient time to permit full evaluation, will usually not be considered.

Endorsement request

The CCRS Chair will determine the stance of the Society and if the external document will be considered with consideration to the information provided in the consultation checklist. The external document will enter review step once the following has occurred;

- The cost of consultation is agreed,
- The timeline of consultation is agreed,
- The document is registered by the Clinical Administrator, and
- The author list and completed COIs are noted by the TSANZ Office.

Review by TSANZ Board

The TSANZ Board will review the clinical document from a strategic point of view. Endorsement of the clinical document will be determined by the TSANZ Board, with a recommendation provided by the CCRS.

Dissemination via TSANZ

One the external document is published, it will be disseminated via the TSANZ eNews or Weekly update.