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Clinical Practice Updates: Purpose, Processes & Policies

This document has been created on behalf of the CCS Guidelines Committee to outline the policies and procedures that guide CCS and its affiliates in the development of Clinical Practice Updates (CPUs), including the processes of topic selection, co-chair selection, panel formation, format, review, approval and submission to the *Canadian Journal of Cardiology (CJC)*.

PURPOSE

What is a Clinical Practice Update?

Clinical Practice Updates (CPUs) are official CCS statements that serve as a practical and useful source of clinical expertise to assist practitioners to make appropriate care decisions. They focus on critical issues in cardiovascular medicine, evolving areas of clinical practice, and/or technologies that are widely available or new to the practice community, for which a body of evidence and/or expert opinion is available.

CPUs are evidence-based but are more focused and concise than guidelines, do not have formally voted recommendations and may have time sensitive elements that warrant "fast track" translation into clinical practice. In some cases, they may be documents presenting an approach to a particular clinical problem, based on the expert opinion of the writing group, in situations where either the evidence base is extensive and well-known but summary clinical guidance would be useful, or where there is no clear evidence (generally for very new approaches and/or techniques) and expert opinion is needed.

CPUs do not follow GRADE methodology. As CPUs require less time and resources to develop than guidelines, they can be developed relatively quickly in response to rapidly evolving areas of research and clinical care (see "Timelines", page 6).

CPUs will replace position statements, a format which CCS retired in 2019. Although their submission is not strictly open to affiliates, CPUs are intended to serve primarily as a voice for one or more CCS affiliates.

Depending on the scope of the topic and nature of the material covered, CPUs will be published in one of three formats:

- Full CPUs,
- Focused CPUs, or
- Practical CPUs (see "Content & Format", page 5)

The format appropriate for a given CPU will be defined by the CCS Guidelines Committee, based on the topic proposal and discussions with the chair(s) of the specific CPU writing group, and with guidance from the Editor-in-Chief of the *Canadian Journal of Cardiology*.

TOPIC SELECTION

How and when can I submit a topic?

There are two ways to submit a topic for consideration as a CPU:

- 1) Through the annual "Call for Guideline and Clinical Practice Update Topics,".
- 2) CCS affiliates can submit topics at any point during the year by email to guidelines@ccs.ca. Topic submissions on behalf of affiliates must be signed off by the President(s) of the respective Affiliate(s).

Although there is no limit to the number of topics that can be proposed, each Affiliate may be the lead on only one CPU at any given time.

The Guidelines Committee will review all submitted topics on a quarterly basis.

What is included in the topic proposal?

The proposal must include the topic, proposed scope of the document, information supporting why this topic should be covered and suggested co-chairs. Sign-off on the topic submission by contributing affiliates in writing (e.g., email) implies support on the suggested co-chairs.

How are topics selected and approved?

All submitted proposals are reviewed by the CCS Guidelines Committee, either during their annual topic review discussion or on a quarterly basis. The Committee considers the following when reviewing each topic:

- Does the submitting affiliate already have a CPU under development with CCS or have they had a topic accepted within the last 12 months?
- Has adequate progress on other previous topics from the submitting affiliate been made?
- Is there an immediate or emerging need for information on this topic?
- Is there a (potentially) competing or overlapping CCS document in progress?
- Is the proposed CPU consistent with the goals elucidated above, and would the CPU add new information to the existing literature?
- What other Affiliates may have potential input into the topic, and have they been contacted to participate?
- Does the CCS have within its membership (including associate members) the capacity to address the topic with recognizable content-expertise?
- Is the proposed topic already (being) addressed by another similar organization?

The Guidelines Committee also reviews the suggested co-chairs and partner Affiliates, and may provide alternate or additional considerations for co-chairs, as well as for the inclusion of new partner Affiliates.

Once approved by the Guidelines Committee, the topic proposals along with suggested co-chairs, will be brought forward (via e-mail) to the CCS Council for final review and approval.

Potential co-chairs must disclose all relationships with industry before being approved by CCS Council. Unless an exception is specifically granted by the Guidelines Committee, at least one of the co-chairs must have no relevant conflicts of interest related to the topic throughout the duration of the writing process.

Work cannot begin on the topic, including notifying co-chairs, until Council approval has been given.

CCS staff support

CCS staff will manage the submission intake process and prepare materials for CCS Guidelines Committee and Council review once the Guideline Committee has approved the topic(s).

Who oversees the CPU development process?

For each CPU, the Guidelines Committee appoints a member of the Guidelines Committee to oversee the development process and act as a liaison and information resource. The individual is accountable to the CCS Guidelines Committee and represents the interests of the Guidelines Committee during the CPU development process.

What are the responsibilities of the Guidelines Committee liaison?

- Ensures that all relevant affiliate groups are aware of the project and have been given the opportunity to be involved
- Ensures that sex and/or gender has been considered during the development process
- Provides insight and guidance to the selection of writing panel members
- Leads a kickoff teleconference with the co-chairs and writing panel members to provide an overview of the process and answer any initial questions
- Provides guidance as required and addresses any questions or concerns that panel members may have about conflict of interest and relationships with industry
- Ensures appropriate strategies and methods for rigor and transparency are followed during development
- Oversees the development timeline to ensure review and approval milestones are met
- Attends teleconferences and in-person meetings of the writing panel (as needed/if required)
- Reviews the draft CPU and provides feedback

SELECTING THE WRITING PANEL

Who makes up the writing panel?

The co-chairs are responsible for forming and ensuring balance of the writing panel. The Guidelines Committee may make recommendations for representation or for individuals who should be considered as panel members.

We suggest about 5 to 7 panel members (excluding the co-chairs) as the optimal number of individuals on a writing panel, but this number may vary with the complexity of the topic and breadth of expertise needed. The majority of the writing panel must be CCS members. Consider clinical expertise, specialty/subspecialty/affiliate representation, gender, geographic and generational representation as well as conflict of interest, professional writing ability and willingness to participate actively in the content development process when evaluating potential members. Committee members must commit to responsiveness to ensure timely materials development.

We encourage multidisciplinary panels, and panel members with specific expertise may be sought from other specialty societies as appropriate.

A note about authorship

The minimum level of participation required for authorship recognition should be decided and disclosed to writing panel members at the time of invitation. Members of the Guidelines Committee are not authors of the CPU.

CCS staff support

CCS staff will do the following to support the co-chairs and writing panel:

- send invitations to and track responses from potential panel members;
- coordinate booking of conference calls and writing committee meetings;
- provide co-chairs with dial-in coordinates for panel teleconferences; and
- set up an online community for document sharing and collaboration, if requested.

How do you ensure the panel is balanced and objective?

We strongly suggest 50% + 1 of writing panel members to have no conflict of interest (COI). It is important that any relevant relationships with industry (RWI) are disclosed and any conflicts are identified early in the process to achieve the necessary panel composition.

Co-chairs are responsible for assessing RWI to determine any potential or perceived COI; adjustments to the panel composition may be necessary to achieve the 50% + 1 target. If the 50% + 1 goal cannot be achieved, the co-chairs will bring the issue forward to the Guidelines Committee to determine if the RWI is relevant.

Any questions or concerns about RWI or COI should be discussed with the liaison who may bring the issue forward to the Guidelines Committee, who may bring the issue to the CCS Executive if required. Exceptions for panel membership where COI may exist may be made in the case where specific or unique expertise is required. Any exceptions can only be approved by the liaison, the Guidelines Committee or the CCS Executive or Council.

CCS staff support

CCS staff will circulate a COI form to all chairs and panel members to be completed and returned at the outset of the process.

What about confidentiality?

The co-chairs, members of the writing panel and of the Guidelines Committee may be exposed to confidential and/or proprietary information during the CPU development process. This information must be kept confidential and not disclosed prior to publication.

CCS staff support

CCS staff will ask co-chairs and panel members to sign and return a Confidentiality and Nondisclosure Agreement at the outset of the process.

CONTENT & FORMAT

What does a CPU cover?

Each CPU will be titled in a similar way to promote a readily identifiable brand: "CCS/{AFFILIATE(S)} Clinical Practice Update: The Approach to...". The document must outline the scope of the problem and provide a practical and relatable approach without making formal evidence-based recommendations (i.e., GRADE). The guidelines Committee will advise on and is responsible for ensuring that appropriate strategies and methods for rigor and transparency are followed during development.

The content of CPUs is based on current literature and the combined knowledge and experience of the cochairs and writing panel, who are considered experts on the subject, and conversant with relevant, current evidence. Authors should suggest algorithms or practical tips to guide clinical practice, but DO NOT use the GRADE framework or make formal recommendations as used in Guidelines. If there are disparate opinions that are equally appropriate, these alternatives should also be included. Sufficient referencing should be provided to indicate the evidence base for suggested practice. Display material (Tables and/or Figures) is crucial to effectively conveying the clinical guidance messages the writing panel wants to transmit and should be carefully planned, not an afterthought.

Although the writing panel does <u>not</u> vote on recommendations, which must be made explicitly clear in the manuscript, all members of the writing panel are required to sign off on the draft statement before it is submitted for review. Sign-off ensures that there is consensus among the panel members regarding all content.

What is the format for a CPU?

The recommended length of a CPU will depend on its complexity and breadth. Depending on the scope of the approved topic, there are three possible formats for publication (see CJC Instructions for Authors for full details):

Full CPUs: cover a broad topic area and are analogous to the prior Position statement format (CJC article type Full Clinical Practice Update). Word count limit of 8,000 words including all elements (title page, abstract, text, references, tables, and figure legends).

- 2. Focused CPUs: deal with more focused or better circumscribed areas, (CJC article type Focused Clinical Practice Update). Word count limit of 6,000 words including all elements (title page, abstract, text, references, tables, and figure legends).
- 3. Practical CPUs: provide expert guidance for how to approach a specific clinical problem or issue (CJC article type Contemporary Issues in Cardiology Practice). Word count limit of 4,000 words including text (which should be under 1,500 words from the beginning of the Introduction to the end of the Discussion), tables, figures and references strictly limited in the main paper to 5 references and 2 display items; unlimited additional materials can be provided in a linked Online Supplement.

REVIEW & APPROVAL

Who reviews and approves the draft document?

Before it's submitted to the Guidelines Committee, the draft statement must be well written, consistently formatted, concise and free of errors. The Guidelines Committee will review the draft and provide the cochairs with feedback, which may include requests for clarifications and/or revisions. Once these are addressed, the draft goes back to the Guidelines Committee for final approval. Additionally, each CCS Affiliate or group of Affiliates may have their own internal approval process, which is expected to take place at the same time as the Guidelines Committee review.

If there is significant contention between the feedback provided by the Guidelines Committee and the affiliate, the Guidelines Committee shall be consulted.

Once the Guidelines Committee and the contributing affiliates approve the draft, a formal motion is put forward to CCS Council for approval of the final CPU.

CCS staff support

CCS staff will prepare and disseminate as part of the meeting package a briefing note that outlines the motions for approving each CPU.

CJC PUBLICATION AND DISSEMINATION

How are the CPUs disseminated?

All CPUs will be published exclusively via the *Canadian Journal of Cardiology (CJC)*. All CPUs will be subject to peer review and must be considered up to the high standards required for publication in CJC prior to acceptance. CPU co-chairs are welcome to contact the CJC Editor-in-Chief at any point in the process of CPU preparation. Consultation early in the process is encouraged to make sure that the writing panel and the CJC Editorial Board are aware of mutual expectations and any adjustments to the wiring plan or document are made earlier rather than later in the process. CPUs must be reviewed and approved by the Guidelines Committee and the relevant affiliates prior to submission to the *CJC*.

Once the CPU has been approved, the co-chairs are responsible for submitting the final manuscript to the CJC, where it will be subject to the standard, objective CJC peer review process. Peer review by definition means there is potential for major revision and rejection, which is paramount to maintaining the rigour and standards of CJC.

Who "owns" the CPU?

The copyright of the CPUs will be held by the CCS. As the administering body, any and all copyright requests will be responded to and adjudicated by CCS.

Can CPUs be presented at the Canadian Cardiovascular Congress?

If there is interest in presenting at CCC, co-chairs can develop and submit a workshop proposal through the annual CCC Call for Workshops. Workshop acceptance is not guaranteed — workshop submissions are reviewed and selected by the CCC Scientific Program Committee.

TIMELINES

What is the recommended timeline for developing a CPU?

Given the desire for a platform that facilitates rapid knowledge translation, the timelines for developing Clinical Practice Updates should be short. We estimate that initiation to publication can be completed in as little as six months.

Topic review and approval* 2 to 4 weeks
Content development 12 to 24 weeks
CCS and affiliate review and approval 2 to 4 weeks
Initial CJC peer review 4 to 6 weeks

Final acceptance in CJC 4 to 6 weeks (depending on extent of revisions)

Translation, layout 4 to 6 weeks

Total 24 to 44 weeks

*topic approval occurs quarterly for affiliate requests and annually (during the CCS Call for Topics) for all other requests