



**ENDORSEMENT OF GUIDELINES BY
THE NATIONAL ADVISORY COMMITTEE OF BLOOD AND BLOOD PRODUCTS (NAC)**



NAC ENDORSEMENT OF GUIDELINES WORKING GROUP

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LIST OF ABBREVIATIONS

NAC	National Advisory Committee for Blood and Blood Products
COI	Conflict of Interest
SC	Sub-Committee
RWG	Review Working Group



SUMMARY OF REVISIONS

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SECTION 1.0: NAC FRAMEWORK FOR GUIDELINE ENDORSEMENT

The NAC will consider endorsement of published evidence-based guidelines that meet its mandate and principles pertaining to blood medicine practice and based on a systematic review of the literature. Criteria for guidelines to have endorsement by NAC are adapted from the 2013 National Guideline Clearinghouse Inclusion criteria:

1.1 NAC Framework for Guideline Endorsement Criteria

1.1.1 Aimed at Optimizing Patient Care – contains systematically developed statements to assist health care providers and/or patients to make appropriate decisions focused on a population that may benefit from recommendations pertaining to blood transfusion practice.

1.1.2 Derived from a Reputable Source – produced with the support or auspices of a nationally or internationally recognized organization, such as a medical specialty association, relevant professional society, government agency, and/or organization dedicated to improving patient outcomes.

1.1.3 Systematic – developed according to a recognized and appropriate methodology, where recommendations are based on a systematic review of evidence.

1.1.4 Balance Risks and Benefits – the guideline or supporting documents contain assessments of both benefits and harms of recommended care and/or alternative care options

1.1.5 Available to the Public –the full text is available in English to the public either for free or for a fee. Free access is preferred, but does not preclude NAC consideration of guideline review.

1.1.6 Applicable to modern practice – the guideline must have been developed, reviewed, or revised in the last 3 years, be progressive in the science and practice of transfusion medicine with an overall benefit to patient care, and the guideline available through the NAC website must be the most recent version published

Guidelines that are submitted for consideration of endorsement must be within the scope of transfusion medicine and/or blood or blood product utilization appropriateness, as determined at the discretion of the NAC Endorsement SC Chair prior to review by the NAC Endorsement SC.

Published guidelines may be brought forth to NAC membership via the NAC Endorsement Request Form (Section 4). NAC members, or external organizations / individuals must submit a completed Request Form for a guideline to be considered for endorsement.

SECTION 2.0: DEFINITIONS

- **Endorsement:** Public expression of by NAC after completion of a detailed review and member approval.
- **Non-Endorsement:** Not supported and/or approved by NAC after review.
- **Endorsement with Caveats:** Public expression of by NAC after completion of a detailed review and member approval, with additional statements to note important exceptions or differences in Canadian practice, preferences, and/or product availability.



- **Position Statement:** A written expression by NAC of how the guideline fulfills the NAC mandate of optimizing patient care through recommendations in utilization management of blood and blood products and transfusion medicine practice.
- **RWG:** A voluntary group comprised of 3-6 NAC members with interest and/or expertise in the guideline topic, led by the NAC Endorsement SC Chair that evaluates the guideline submitted for endorsement. The Chair may invite non-NAC members (up to two) with relevant content expertise to participate on an ad hoc basis to enhance the guideline review process.

SECTION 3.0: NAC CLINICAL PRACTICE GUIDELINES ENDORSEMENT POLICY / PROCESS

3.1 Guideline Eligibility for NAC Endorsement

NAC shall consider for endorsement clinical practice guidelines that relate to transfusion medicine practice and meet the NAC Framework for Guideline Endorsement criteria (see Section 1).

3.2 COI Management

NAC members who have a direct COI and/or are also authors of the practice guideline under review shall not participate in the endorsement evaluation (see Section 5 for further details).

3.3 Endorsement Evaluation Process

The NAC Guidelines Endorsement Process is outlined in Appendix A.

3.3.1 Requests for Endorsement

The NAC Endorsement SC shall receive requests to review published clinical practice guidelines. Guidelines must be submitted by the authors, NAC members, or any other interested party using the NAC Endorsement Request Form (see Section 4).

The NAC Endorsement SC shall determine whether the guideline meets eligibility criteria. If the SC determines that eligibility criteria are met, a briefing note outlining the general scope of the guideline will be sent to the CBS-PTBLC for information before proceeding with forming a Review SC for the guideline (please see Section 1).

Following a full review, guidelines not meeting criteria for Endorsement will not be listed publicly. All submissions and final decisions filed for reference, and the submitter of the Request Form will be informed of the decision via the Template Letter for Non-Endorsement (Appendix B). The decision may be appealed when the guideline is updated or after a 3 year period from the decision.

3.3.2 Formation of RWG for Requested Guideline Endorsement

Upon determination of guideline eligibility for review, the NAC Endorsement SC will request participation from NAC membership to form a voluntary RWG comprised of 3-6 NAC members with interest/expertise in the guideline topic. The RWG will be led by the NAC Endorsement SC Chair. If the NAC Endorsement Subcommittee Chair has a Conflict of Interest that precludes their participation in the Review Working Group (see Section 5), an ad hoc Chair for the Review Working Group may be chosen at the discretion of the Endorsement Subcommittee.

The Chair may invite non-NAC members (up to two) with relevant content expertise to participate on an ad hoc basis to enhance the guideline review process.



At least one member of the NAC Endorsement SC and one other member of NAC should be involved in the RWG for each guideline proposed for endorsement.

The RWG members are required to fill out a Disclosure of Potential of COI Form and meet the criteria for participation outlined in Section 5.

3.3.3 RWG Evaluative Process

The RWG shall review the guideline individually using the AGREEII tool, and determine whether the guideline put forth for endorsement is: Endorsed (with or without caveats) or Not Endorsed. Individual assessments with the AGREEII tool should be done within a month of RWG formation and distribution of the tool and sent to the Endorsement SC Chair to collate.

After results are collated, the RWG shall convene to discuss as a group to determine guideline approval.

For guideline endorsement, the guideline shall achieve scores of at least 50% in all Domains, with the exception of Domain 3, which shall require a minimum score of 70%.

A guideline which is Endorsed with caveats entails approval of the document with additional statements to note important exceptions or differences; for example, if the guideline refers to a particular brand of product available only in another country, the caveat may note that the brand name of the Canadian equivalent. The NAC RWG will list these caveats alongside a Position Statement summarizing comments and other affirmations of value.

Guidelines that are Not Endorsed by the NAC Endorsement SC will not be listed, filed, and the submitter of the Request Form will be informed of the decision (see Appendix B for Template Letter for Non-Endorsement). The decision may be appealed when the guideline is updated or after a three year period from the decision.

3.3.4 Post-Evaluation Process

The results of the RWG review of the guideline shall be shared with the NAC, and NAC members shall have the opportunity to provide feedback on the review.

The RWG shall review the feedback from NAC members, and make any changes necessary.

Minutes of the meetings and AGREEII tool documents related to the review of the guideline will be maintained by the NAC Coordinator.

3.4 Dissemination

The RWG will notify the submitter who requested the review whether or not the guideline was endorsed.

For guidelines that are Endorsed, the submitter will be asked to provide a free copy of the guidelines to be publicly available on the NAC website. If the guideline is not publicly available by means of open access, a link to the PubMed article abstract will be provided. The NAC cannot provide funds to grant an article open access.



A Position Statement shall be posted, with guidelines that are Endorsed (with or without caveats) to the NAC website in a specific section of guidelines.

Dissemination of the guideline endorsement is the responsibility of the NAC membership to the provinces they represent, including through provincial and hospital/health authority transfusion committees. Any other avenues of dissemination will be determined by the NAC Endorsement SC.

If NAC assigns a document a Not Endorsed status, it will not be listed on the website. If the submitter of the Request Form for guideline review has questions as to why a guideline was Not Endorsed, a statement will be generated by the RWG and the NAC Endorsement SC Chair will then provide this to the submitter of the Request Form.

All future submitters of Request Forms for the same guideline before the Periodic Review period (see Section 3.4 below) and/or persons inquiring to why that guideline has not been endorsed will be provided the statement generated by the RWG by the NAC Endorsement SC Chair.

3.5 Periodic Review

Endorsed guidelines will be reviewed, at a minimum, once every 3 years by the NAC Endorsement SC. Websites of organizations producing the guideline, the original contact for submission, and/or other contacts of the organization producing the guideline will be contacted for guidelines up for review in January/February annually. At a minimum, this review will consist of ensuring that the Endorsed guideline is the most recent version of the guideline.

If the Endorsed guideline has been updated, the NAC Endorsement SC will determine, in conjunction with NAC, whether it is necessary to review the new document for endorsement.

For guidelines up for review, if possible, at least 2 members of the RWG for the guideline or other ad-hoc members at the discretion of the Endorsement SC will be asked to review the guideline to make a recommendation as to whether or not the guideline is still applicable to be endorsed by NAC.

At the NAC meeting after the Periodic Review, polling of the NAC membership will occur to determine whether the majority feel that the guideline is applicable/appropriate. If the guideline endorsement remains relevant, the Endorsed status will be updated with the most recent review date.

If NAC feels the guideline is no longer applicable/appropriate, the endorsement will be removed from the NAC website and filed.

If a majority consensus cannot be reached to whether the guideline is applicable/appropriate, as adjudicated by the NAC Endorsement SC Chair, a RWG will be formed to reassess the guideline using an abbreviated tool (such as the AGREE-GRS tool)



Section 4.0: NAC CLINICAL PRACTICE GUIDELINE ENDORSEMENT REQUEST FORM

Thank you for your interest in submitting a clinical practice guideline for potential endorsement by NAC. NAC will consider endorsement of published evidence-based guidelines that meet its mandate and principles pertaining to transfusion medicine practice and based on a systematic review of the literature. Before submission, review of the “Endorsement of Guidelines by NAC” Policy document is recommended.

1. Contact (Your name, organization, and email address):
2. Have you any affiliation to the organization responsible for publishing this guideline? Yes No
If ‘Yes’, please specify the nature of your affiliation and any role you have with the organization
3. Title of the Guideline:
4. Journal/Website where the guideline has been/will be published:
5. Date of Publication/Estimated Date of Publication:
6. Is this guideline based on a systematic review; and is there a method of assessing the quality of the evidence base for which guideline recommendations are derived?
7. In a sentence or two, please describe how you believe this guideline will positively improve patient care.
8. Are there any recent guidelines that cover the same subject material as the submitted guideline? If so, please outline if those guidelines are complementary or if the submitted guideline is preferable.
9. Additional Comments:



A review SC will be formed to assess the guideline for endorsement, to use the AGREEII tool independently to guide the SC's recommendation for endorsement. Outlining sections helps reviewers in finding reporting criteria ensures appropriate identification of how the guidelines submitted fulfill all the domains of the AGREEII tool. Please fill out the table below:

Domain Checklist Item	Section(s) of manuscript (ie Background, Methods)	Page #s, paragraph #s of manuscript section
<u>Domain 1: Scope and Purpose</u>		
Objectives of the guideline		
Target population		
<u>Domain 2: Stakeholder Involvement</u>		
Individuals involved in guideline development		
Target population preferences and views		
Target users		
<u>Domain 3: Rigor of Development</u>		
Evidence selection criteria		
Strengths/limitations of evidence		
Methods to formulate recommendations		
Considerations of harms/risks		
External review methodology (if applicable)		
Statement regarding guideline updates		



<u>Domain 4: Clarity of Presentation</u>		
Summary of recommendations section		
<u>Domain 5: Applicability</u>		
Description of facilitators and barriers to implementation		
Implementation advice/tools outlined		
Discussion of resource implications		
Monitoring /auditing criteria for application		
<u>Domain 6: Editorial Independence</u>		
Explicit statement of no influence from a funding body (or no source of funding)		

Please email to coordinator@nacblood.ca:

- A completed copy of this Endorsement Request Form
- A copy of the guideline
- A copy of the COI Policy that was followed during guideline development
- Any other pertinent supporting documents.

Please note if the guideline is endorsed by NAC, the submitter is responsible for ensuring a free copy of the guidelines are available publicly on the NAC website for posting before the endorsement is posted on the website.



Section 5: DISCLOSURE OF POTENTIAL COI FORM

Disclosure of Potential COI for Participants in the NAC Endorsement SC RWG

Organizations may seek NAC endorsement of published clinical guidelines by submitting a request to NAC. In accordance with the guidance document developed by the NAC Endorsement SC, a request for guideline review will lead to a request for volunteers from NAC membership to form a RWG to complete a review of the submitted guideline. To maintain a transparent and consistent process, it is important that potential members of the RWG identify and disclose all relationships or interests that could influence or bias their opinion during guideline review. The reviewer has an important responsibility to disclose of real and potential COI.

Significant COI that would preclude NAC member participation in the RWG:

- Named authorship to the proposed guideline for review.
- Submitted the request form for endorsement of the guideline for review.
- Financial holdings or intellectual property rights (including spouse and/or children) with the organization producing or submitting the work under review.

Potential COI requiring NAC member disclosure prior to participation in the RWG:

- Co-authoring publications with at least one of the authors in the past 3 years.
- Being members of the society or association that created the guidelines.
- Being colleagues within the same section/department or similar organizational unit in the past 3 years.
- Receiving professional or personal benefit resulting from the review.
- Having a personal relationship (e.g. family, close friend) with the author(s).
- Research grants/support from the organization who applied for guideline endorsement.
- Research grants/support from any organization who fund the organization who applied for guideline endorsement.
- Position on advisory board or board of directors or other type of management relationships with the organization applying for guideline endorsement.

Please complete, sign and email the attached form (even if you have no competing interests) to the NAC Coordinator at coordinator@nacblood.ca.



Disclosure of Potential COI for Participants in the National Advisory Committee on Blood and Blood Products Endorsement SC

I have read, understand and agree to the NAC Endorsement SC terms of reference

Name of Author (please print): _____

Signature: _____ Date: _____

Please complete either part A or part B. Please print.

A. _____ I do not have / have not had any financial interest/arrangement or affiliation **within the past 3 years** with one or more organizations that could be perceived as a real or apparent COI of NAC Endorsement SC RWG

Signature: _____ Date: _____

OR

B. _____ I have/had financial interest/arrangement or affiliation **within the past 3 years** with one or more organizations that could be perceived as a real or apparent COI of NAC Endorsement SC RWG.

Please specify below:

AFFILIATION/FINANCIAL INTEREST	NAME OF ORGANIZATION(S)
Grant / Research (PI or co-investigator)	
Consultant / Honoraria	
Stock Shareholder	
Other Financial / Material Support	
Other	

Signature: _____ Date: _____



SECTION 6.0: TERMS OF REFERENCE

6.1 Mandate

The NAC Endorsement SC will receive requests for NAC endorsement of guidelines and evaluate these to determine whether they meet the minimum criteria for consideration. If these are met, the NAC Endorsement SC will form a RWG to perform the evaluation of the guideline.

6.2 Membership

The Chair of the NAC Endorsement SC shall also chair the RWG. The Chair may designate a member of the RWG to serve as Chair in his/her place. The NAC Endorsement SC shall be comprised of 4-8 current NAC members, including the Chair. The RWG shall be comprised of 3-6 NAC members, and may include ad hoc members (generally up to 2) from outside NAC as deemed appropriate by the Chair.

6.3 Meetings

Meetings will be convened at the request of the Chair as required. The NAC Coordinator will arrange teleconferences/meetings and record and distribute minutes of the meetings/record of decisions and maintain the membership list of the NAC Endorsement SC and all RWG.

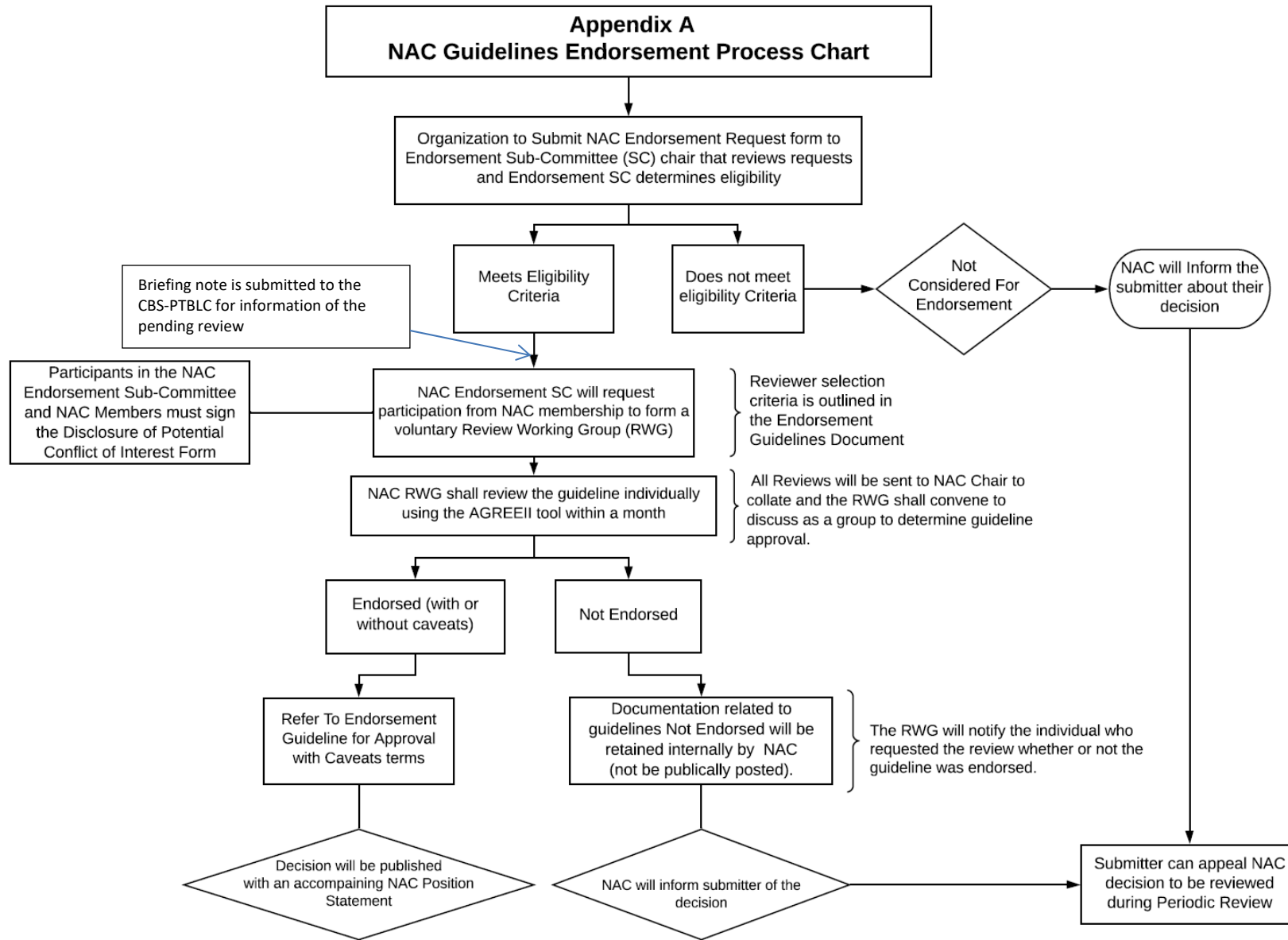


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Agency for Healthcare Research and Quality. NGC and NQMC Inclusion Criteria. <https://www.ahrq.gov/gam/summaries/inclusion-criteria/index.html>, accessed September 20, 2019

Appraisal of Guidelines for Research and Evaluation Enterprise. AGREE Tools. <https://www.agreetrust.org/resource-centre/>, accessed October 25, 2019

Merriam-Webster. Definition of endorse [adapted for this document], <https://www.merriam-webster.com/dictionary/endorsing>, accessed October 25, 2019





APPENDIX B TEMPLATE LETTER FOR NON-ENDORSEMENT



Dear XX:

Re: Submission of "XX" Clinical Practice Guideline to NAC for Endorsement

Thank you for your interest in submitting a clinical practice guideline for potential endorsement by NAC. It has been assessed by transfusion medicine and content experts as part of a working group under the NAC Endorsement Subcommittee.

I regret to inform you that the submitted guideline has not been accepted for endorsement by NAC. Given NAC is a national advisory body for transfusion medicine practice and the high number of guidelines submitted for review, a stringent and validated process to endorse only the highest quality guidelines that are applicable to Canadian practice is employed, as outlined by the *Endorsement of Guidelines by NAC Policy*.

NAC will not list guidelines submitted that have not be endorsed and the record of submission will be filed. If you have questions as to why a guideline was not approved, a statement from the reviewers and myself can be provided upon request at coordinator@nacblood.ca.

The decision may be appealed when the guideline is updated or after a 3 year period from the decision as part of the routine periodic review of endorsed guidelines.

We very much regret the negative decision on this guideline, but appreciate the submission to NAC for consideration to advance the practice of transfusion medicine to optimize patient care. I hope the outcome of this specific submission does not deter you or the organization you represent from the submission of future guidelines.

Sincerely on behalf of the NAC Endorsement Subcommittee,

Chair, NAC Endorsement Subcommittee