Ontario Health
Cancer Care Ontario

Program in Evidence-based Care

Document Assessment and Review Protocol

Version 1.3: May 31, 2023

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1. Overview

The Program in Evidence Based Care (PEBC) is funded by Ontario Health (Cancer Care Ontario) (OH-CCO) to produce clinical practice guidelines and other guidance documents that inform health care decisions aimed to improve the quality of care provided to cancer patients in Ontario. The PEBC bases the guidelines on the best evidence available at the time of writing, but new scientific evidence is being published on a continual basis. The users of the PEBC documents have the expectation that the recommendations are trustworthy and updated regularly to reflect current evidence. The PEBC Document Assessment and Review process has been designed to maximize the efficient use of our resources and to ensure that PEBC documents remain relevant, current, and evidence-based. This protocol provides details of the process and provides instructions for its implementation.

Document Assessment and Review is a two-stage process, an assessment of all the PEBC documents on a regular basis and a subsequent review of new evidence as indicated by that assessment. This process is summarized in the flowchart found in Appendix C and described in the next two sections of this protocol.

2. Assessment

The assessment enables the PEBC to distinguish among documents that are current and relevant, documents that are no longer relevant and those that require an updated literature search and review. The assessment is conducted in the fall of each year for all PEBC documents that are one year old or older. The process is designed to:

- identify documents that contain recommendations or conclusions that may have been invalidated by new evidence
- identify documents that are no longer relevant and therefore do not need to be maintained
- prioritize documents for a full review, if required.

Some documents may not be assessed annually. For example, for a document that consists of system-level guidance developed primarily through consensus, an assessment every two, three, or even more years may be appropriate. The assessment schedule for such documents will be determined through consultation with the group that sponsored the document and will be stated in the document that is publicly available on the OH-CCO website.

Each PEBC document has a designated “owner”; an OH-CCO program, an OH-CCO specialized committee, a Disease Site Group (DSG) or a similar group or organization. The PEBC Assessment and Review Coordinator works with the representatives of the owner of the document (i.e. program lead, chair of committee or DSG) to answer each of the six

Assessment Tool questions (see Appendix A) for each document. Following the consultation, one of the following Assessment Outcomes is assigned to each document by the PEBC . The logic for assigning the outcome is summarized in the flowchart found in Appendix D.

2.1 Archive

Criteria for Outcome: The document may no longer be relevant (Q1 = No), or there are other reasons, based on the assessment, for the document not to be maintained by the PEBC. For example, the clinical area(s) covered by the topic have changed to the extent that a new document is required to provide trustworthy recommendations. This outcome may also be assigned to documents for which the owner(s) acknowledges that the staff resources of the PEBC would be more usefully applied to topics of higher priority.

Result: The document status on the OH-CCO website is listed as ARCHIVED (previously these were listed as EDUCATION AND INFORMATION). ARCHIVED documents are no longer subject to the annual assessment. See Section 4.1.2.

2.2 Defer

Criteria for Outcome: If the document is less than three years old, it can be DEFERRED, provided no credible reason to believe the recommendations are not trustworthy. If the document is older than three years, a more thorough justification for deferral may be needed. Very few documents older than five years will be deferred.

Result: The document status on the OH-CCO website is listed as CURRENT (see Section 4.1.1), and it will be assessed again next year. The document's "Report Date" remains unchanged.

2.3 Review

Criteria for Outcome: The document is still relevant (Q1 = Yes) and suitable for review (Q2 = Yes).

Result: The document requires a review as described in Section 4 and its status is listed as IN REVIEW on the OH-CCO web site. The document is assigned a priority for review according to the Assessment Tool and following the Prioritization Scheme found in Appendix D. Clinical expert(s) are selected by the owner, to be responsible for the review.

2.4 Update

Criteria for Outcome: The document is still relevant (Q1 = Yes) but it is deemed not suitable for Review as there is known evidence that would change the recommendations (Q2 = No), and there is no reason for it to be deferred or to be archived. There is a strong rationale for the document to remain available on the OH-CCO website.

Result: The document status is listed as IN REVIEW on the OH-CCO web site. The owner/sponsoring program must submit a new guideline intake form through the Disease Pathway Management Program (DPM) in order for a new PEBC guideline project to be undertaken.

2.5 Endorse

Criteria for Outcome: The document is still relevant (Q1 = Yes), no known new evidence is available that would change the recommendations (Q5 = No), or there is very strong justification for concluding that, in the absence of a search for new evidence, the recommendations are still valid.

Result: The document is endorsed, and its status is listed as CURRENT on the OH-CCO website. The document is given a new version number, the "Report Date" is changed to the date of that endorsement, and it is subject to annual assessment the next year.

An endorsed document has been reviewed for currency and relevance by the owner and deemed to be useful and trustworthy guidance for clinical decision-making. Endorsement means the document is again current, as if a full update had taken place.

At assessment, this outcome will be rare, because in the absence of a new literature search, it is only justified in a few, narrow circumstances such as:

- The evidence base of the document is complete and fully answers the questions asked by the guideline. The expectation is that there will never be additional evidence.
- The target population of the guideline is very small, making high-quality studies very difficult to design and conduct, and therefore the evidence available in the initial document is liable to be the best evidence ever available on the topic.

3. Review

As noted above, the assessment may conclude that a document requires an updated literature review. The aim of the review is to ensure that any evidence published since the document was completed or last reviewed is incorporated into the existing guideline and that the impact of that evidence on the document recommendations is considered. The status of a document undergoing review is listed as IN REVIEW (see Section 4.1.3) on the OH(CCO) web site.

Documents are reviewed in order of their priority as determined by the assessment process (see Appendix D). Documents of lower priority may not be reviewed within a year of the assessment, depending on resource allocations for staff for this purpose. In this case, they are subject to the next annual assessment.

Using the Document Review Tool (see Appendix B), a full review is conducted, including: an updated literature search; interpretation of the new evidence by the clinical expert(s); and reconsideration of the guideline and its recommendations in response to that new evidence. The clinical expert(s) are selected by the document owner and must complete a Conflict of Interest declaration in accordance with the PEBC Conflict of Interest Policy. The clinical expert should have no financial interests per that policy, although the Scientific Director of the PEBC may waive this requirement as necessary. Any such interests will be reported in the Document Review Tool.

The Review process includes the following three steps.

3.1 Updated Literature Search, Selection, and Data Extraction (Step 1)

The PEBC methodologist assigned to review the document conducts a comprehensive search of electronic databases using the search strategy and study selection criteria found in the original document. Newly identified studies, systematic reviews, and meta-analyses are reported in the Document Review Tool, and the most important outcomes from those articles are extracted and reported. An informal quality assessment is conducted to identify any serious flaws or potential for bias in the newly identified studies.

3.2 Clinical Expert Review (Step 2)

The clinical expert (see Section 3.3) reviews the new evidence, and with the assistance of the PEBC methodologist responds to the questions in the Document Review Tool. The methodologist guides the clinical expert through this process, providing assistance in understanding the meaning of the questions and the possible outcomes. During this step, the document may be removed from the OH-CCO web site if the clinical expert believes the current recommendations could lead to harm based on the newly available evidence (Q6 of the tool). Based on this review, the clinical expert and the PEBC methodologist tentatively assign the document one of four possible review outcomes:

3.2.1 Endorse

Criteria for Outcome: The newly identified evidence supports the current recommendations, and with only minor changes or new qualifying statements.

Result: The document is endorsed (as described in Section 2.5) and the document status is listed as CURRENT on the OH-CCO website. The document is given a new version number, the "Report Date" is changed to the date of the endorsement, and it is subject to assessment again next year.

3.2.2 Update

Criteria for Outcome: The new evidence indicates that changes need to be made the existing recommendations, and that the PEBC and the owner are able to commit the resources to begin a complete update of the document within the next year.

Result: The document status is listed as IN REVIEW on the OH-CCO web site, with details regarding the planned update. If a full update has not been started by the time of the next assessment, it will be reassessed. (see Section 4.1.2).

3.2.3 Delay

Criteria for Outcome: There is reason to believe that new, important evidence will be released within the next year that should be considered before taking further action.

Result: The document status is listed as IN REVIEW on the OH-CCO web site, with details in the report about the awaited new evidence. If the new evidence becomes available within the next year, its consideration will result in the review outcome changing to endorse, update, or education/information. If no new evidence becomes available, the document will undergo assessment in the next year.

3.2.4 Archive (formerly Education and Information)

Criteria for Outcome: The document cannot be endorsed or deferred, and a full update is either not feasible or not desired.

Result: The document status on the OH-CCO website is listed as ARCHIVED (previously these were listed as EDUCATION AND INFORMATION). ARCHIVED documents are no longer subject to the annual assessment. See Section 4.1.2.

3.3 Expert Panel Approval (Step 3):

Once a tentative outcome has been assigned, the PEBC methodologist will draft a new version of the document, with a report overview section (see Section 5.2.1) describing the results of the review and incorporating the completed Document Review Tool. This draft version of the document with the tentative outcomes must be approved by a relevant expert panel.

Where possible, the expert panel that reviews and approves the outcome of the review and the draft version of the document should be the panel that approved the original version (e.g., a Disease Site Group). However, if that expert panel is no longer available, the owner will need to designate another entity as the expert panel or organize a panel for this purpose.

The draft version will be circulated to the expert panel, and they will be asked to provide feedback and approve it. As a guiding principle, 75% of the expert panel members must

approve the tentative outcomes and draft version, but the goal is to achieve full consensus. If the expert panel is unable to reach consensus on the outcome of the review, and less than 75% of its members approve it, the PEBC works with the owner to determine an appropriate next step. This may involve changing the document status to ARCHIVED until such time as a full update of the guideline can be completed.

3.4 Timeframe for Review

The target timeframe for each step above is four weeks.

4. Document Status and Disposition

4.1 Status

Once assessed, and then reviewed if necessary, the document will be assigned one of the three possible statuses on the OH-CCO website, as noted above and defined below.

4.1.1 CURRENT

CURRENT documents are documents that are considered trustworthy by the PEBC and are still being maintained.

4.1.2 ARCHIVED

ARCHIVED documents are documents that will no longer be tracked or updated by the PEBC but may still be useful for academic, historic, or other purposes. They are not considered current guidance for clinical practice. The document status is listed as ARCHIVED on the OH-CCO website, and each document page is watermarked and edited to contain appropriate and explicit information to inform the reader about the document status.

4.1.3 IN REVIEW

IN REVIEW documents are documents that are undergoing further consideration by the PEBC.

4.2 Disposition and Dissemination

If the assessment outcome was to defer, and the document is three years old or less, no change is made to the document on the OH-CCO web site.

In all other cases, once an assessment, and if necessary a review, has been completed, the PEBC document will be altered to include a Guideline Review Summary. The Guideline Review Summary explains the process the document has been through, how the assessment and review outcomes were reached, and the status accorded the document.

All PEBC documents are posted on the OH-CCO web site, except in the following cases:

- During the assessment and review, it was determined that patients may possibly come to harm if the recommendations are followed.
- The document has been entirely replaced by a new document.

4.3 Full Updates

When a document is undergoing a full update, either as a result of a review or for some other reason, the document will be listed as IN REVIEW on the OH-CCO web site.

Appendix A: Document Assessment Tool

Document Assessment Tool

Number and title of document	
Current Report Date	
Literature Search Date	
Date Assessed	
Name and DSG/Expert Panel	
Research coordinator	
Outcome	

1. Is the document still relevant (clinically or to the cancer care system as a whole in some way)?	
2. Should assessment and review of this document be deferred until next year? ***Consider YES if:*** ➢ *The document is less than three years old, and there is no reason to doubt the recommendations* ➢ *The document is between three and five years old, and a justification can be provided as to why the recommendations can be considered trustworthy for another year* ➢ *The document's recommendations are primarily consensus-based (e.g. organizational guidance, recommendations for very rare conditions), and there is little likelihood that the evidence base or the consensus has changed.*	
3. **Do the questions and search criteria as they are in the document address current needs, such that an updated literature search would be useful and identify relevant evidence?** ***Consider NO if:*** ➢ *The standard of care has shifted significantly since the last version of the document, such that the questions only address the topic in part*	

➢ *There are new, significant options (for treatment, diagnosis, etc.) available that are not covered by the current questions, such that new questions would need to be added to the document* ➢ *In general, if you believe that for the document to still be useful it will have to substantially be rewritten* ➢ *The document has been repeatedly deferred, and is now older than five years*	
4. Does the document have an impact on access to care (that is, are decisions about access or payment for care made by the Ministry, OH-CCO, or other organizations based on the recommendations in this document)? ***Consider YES if:*** ➢ *Ministry funding decisions have been, are, or will be made on the basis of this document* ➢ *An indication for a chemotherapy regimen was funded, or rejected, based on the document* ➢ *Case by case review or out of country requests are known to be decided based on the document* ➢ *Funding for some screening, diagnostic, staging or treatment procedure was or is determined*	
5. Is there known evidence that has been published since this document's last literature search (see above) that would result in significant changes to the recommendations?	
6. Should this document be taken off the web site while it awaits full review, or can it be left there with an "IN REVIEW" watermark? ***Consider YES if:*** ➢ *If followed, even in error, the recommendations have the potential to cause harm to patients.*	
Please list any additional factors that should be considered in prioritizing this document for review:	

Appendix B: Document Review Tool

Document Review Tool

Number and title of document under review	
Current Report Date	
Clinical Expert	
Research Coordinator	
Date Assessed	
Approval Date and Review Outcome (once completed)	

Original Question(s):

Target Population:

Study Section Criteria:

Search Details:

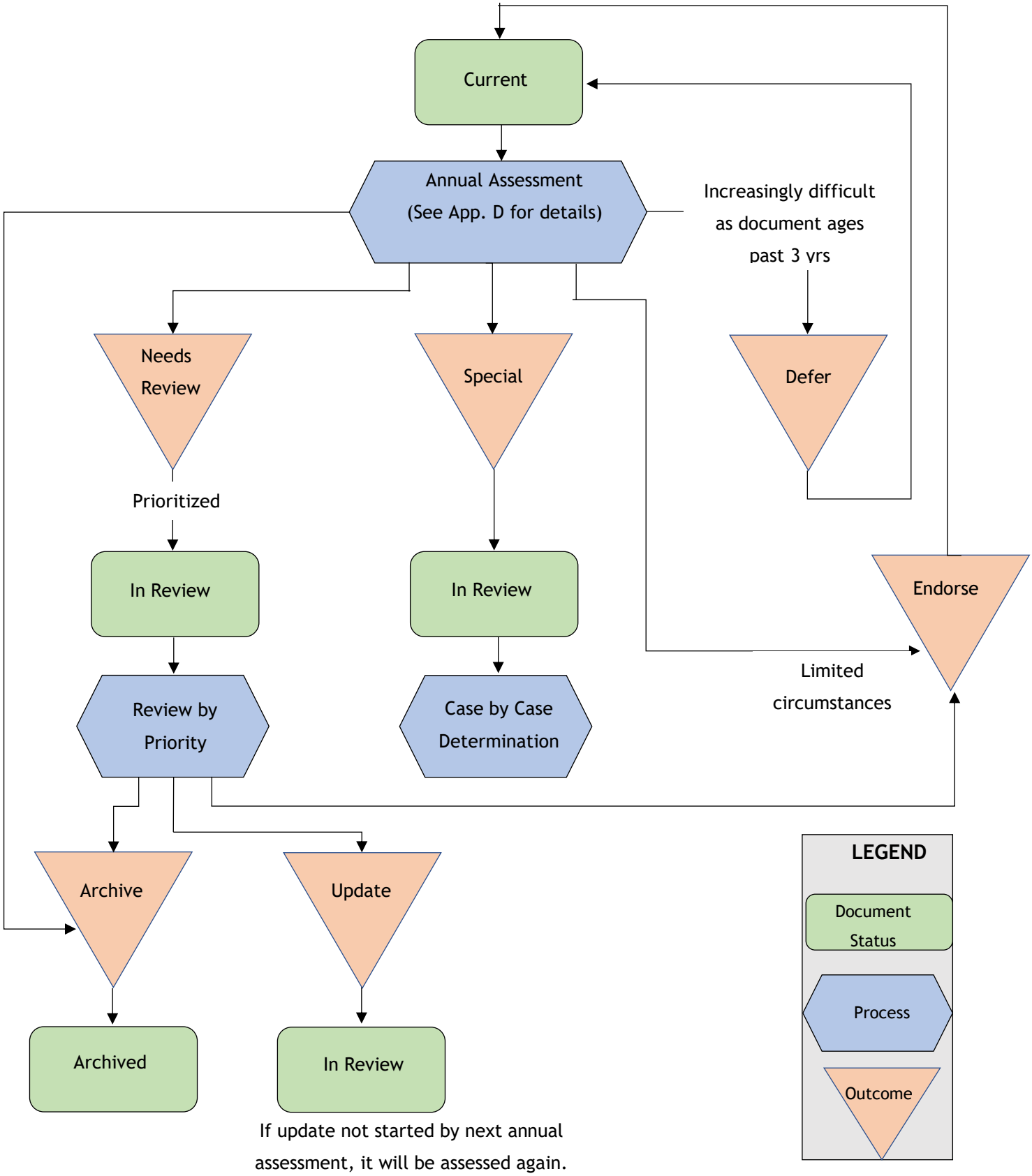
Brief Summary/Discussion of New Evidence:

Clinical Expert Interest Declaration:

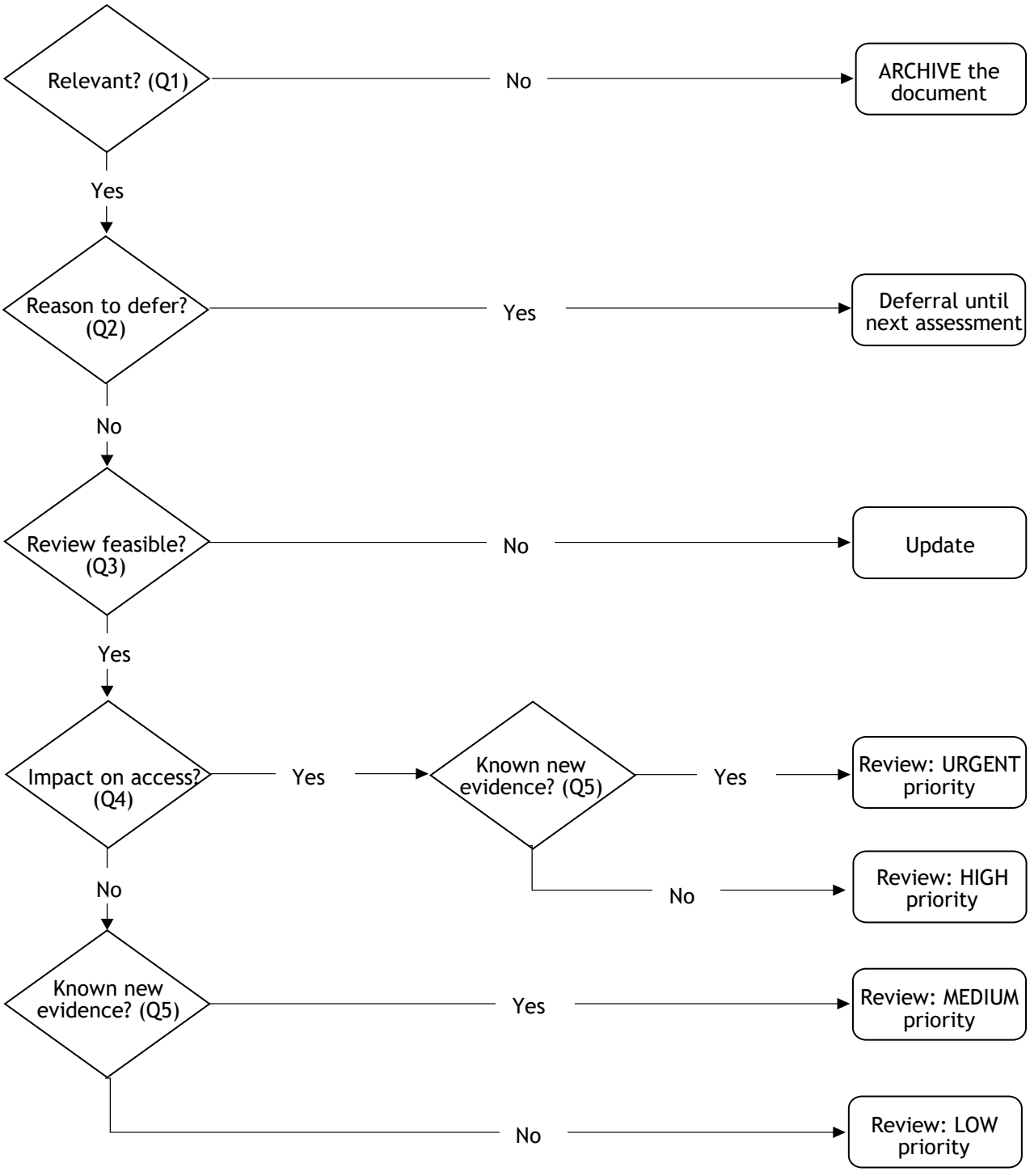
1. Does any of the newly identified evidence, on initial review, contradict the current recommendations, such that the current recommendations may cause harm or lead to unnecessary or improper treatment if followed?	
2. On initial review, a. Does the newly identified evidence support the existing recommendations? b. Do the current recommendations cover all relevant subjects addressed by the evidence, such that no new recommendations are necessary?	
3. Is there a good reason (e.g., new stronger evidence will be published soon, changes to current recommendations are trivial or address very limited situations) to postpone updating the guideline? Answer Yes or No, and explain if necessary:	
4. Do the PEBC and the DSG/GDG responsible for this document have the resources available to write a full update of this document within the next year?	
DSG/GDG Approval Date	
DSG/GDG Commentary	

APPENDIX C: Assessment and Review Process Flow Chart

PEBC Document Assessment and Review Process



Appendix D: Assessment Outcomes and Review Prioritization Scheme



Endorsement may be possible in some cases where the document is still relevant (Q1-Yes) and there is no known new evidence (Q5-No). See section 3.5 for details.