Updating, reaffirmation and sunsetting clinical practice guidelines: Methods from the Canadian Task Force on Preventive Health Care

Abstract

Background: The Canadian Task Force on Preventive Health Care has developed >20 unique guidelines since 2011. With this increasing topic volume, conducting full systematic reviews every five years to update guidelines may not be necessary or feasible. We sought a methodologically robust, transparent and efficient method to enable reaffirmation, or sunsetting (archival), of guidelines that were likely to remain unchanged.

Methods: The 5-year review of guidelines includes analysis of evidence from: 1) ongoing surveillance, 2) targeted search updates, 3) clinical trial registry searches and 4) feedback from clinical experts and previous work group chairs/members. To inform and develop reaffirmation and sunsetting methods, we performed an environmental scan of current literature. Once developed, we piloted our methods on the 2015 “screening for cognitive impairment in older adults” guideline.

Results: We developed methods based on a modified version of the NICE process. These include a summary of the previous guidelines, analysis of new evidence collected during the 5-year review, considerations for reaffirmation or sunsetting and a dissemination plan. Pilot testing resulted in reaffirmation of the aforementioned 2015 guideline. As a result, the reaffirmation process is typically completed in months compared with years for a full update.

Interpretation: These new methods allow the task force to efficiently, systematically, and transparently assess whether guidelines can be reaffirmed, sunsetted or require a full update. We successfully piloted the reaffirmation process using the 2015 “screening for cognitive impairment in older adults” guideline and will use these methods for future guidelines that reach 5 years post-publication.

Introduction

Since 2011, the Canadian Task Force on Preventive Health Care (task force) has produced >20 clinical practice guidelines that support primary care providers in delivering preventive health care (1). In keeping with good practice (2), task force methods state that all guidelines be scheduled for update five years post-publication (3). Full updates involve standard guideline development methods including publishing a new protocol and systematic review (SR) (3). However, full updates may not be necessary when there is little to no new evidence, if new evidence is consistent with the direction and strength of previous guidelines, or if the topic is no longer relevant. Additionally, if we use most of the available resources to update prior guidelines, this will limit the capacity to undertake new guidelines. Given the resource demands of conducting updates using comprehensive standard guideline development methods, we sought an efficient process that would allow us to “reaffirm” or “sunset” guidelines.

We describe here a methodologically robust and efficient process developed by the task force to determine if existing guidelines, deemed to have no meaningful new evidence requiring a full update, could be reaffirmed or sunset.

Methods

Part A: Five-year review

The task force's approach to the five-year review has four components – ongoing surveillance, rapid reviews, upcoming evidence and expert consultation.

Ongoing surveillance

The task force routinely performs ongoing surveillance of published guidelines via Prevention Plus article alerts (https://plus.mcmaster.ca/PreventionPlus/), which provide critical appraisal of relevant high quality evidence (4). These are compiled into monthly and annual reports to flag high impact new evidence that could trigger an early update.

Rapid reviews

When a guideline reaches 5 years, the task force commissions the Canadian Agency for Drug and Technologies in Health (CADTH) (5) to produce a rapid report, focusing on title and abstract searches for all randomized controlled trials (RCTs), SRs and evidence-based guidelines published since the previous guideline. Search updates focus on the key questions most relevant to the strength and direction of the guideline recommendation (e.g., effectiveness of the intervention), but can be expanded to identify other relevant elements of the existing guideline. Observational studies may be included if used in the original guideline. Where necessary (e.g., if the evidence quality appears poor), CADTH may also perform a critical appraisal.

Upcoming evidence

We perform a search for registered trial protocols to determine if ongoing studies are likely to generate relevant findings that would affect our decision to update.

Expert Consultation

We use a standard form to contact the task force member who chaired, and the external clinical experts who advised the original guideline working group (WG) to determine if they are aware of any new evidence, change in policy, patient management, equity, feasibility, acceptability or cost issues that might impact the guideline and its recommendations (Appendix 1). Other clinical experts may be included should the original participants be unavailable or choose not to respond. Previous WG chairs (or members if the chair is unavailable) are also asked to provide information on parts of the evidence to decision (EtD) framework (e.g., benefits and harms, cost, feasibility, patient values and preferences) that were key to informing the guideline.

Synthesis and Topic Prioritization

During the topic selection process, the results of the ongoing surveillance, rapid review, upcoming evidence, and expert opinions are collated and summarised. The synthesized information is reviewed by the task force after which we vote on whether the topic will follow the update, reaffirmation or sunsetting track (Figure 1). Guidelines prioritized for update are added to the short list of topics sent for Delphi consensus during the annual selection process (3). If an update topic is not chosen that year, then we consider it "pending" and it remains on the short list for the next topic selection process. Guidelines may also be identified as requiring an update but are temporarily placed 'on hold' (e.g., obesity for which the concept and approach to prevention are currently evolving - https://canadiantaskforce.ca/guidelines/published-guidelines/obesity-in-adults/). Methods for guideline topics in the reaffirmation or sunsetting track are discussed below.

Part B. Reaffirmation or sunsetting methods

The task force aimed to develop a reaffirmation and sunsetting approach that would balance comprehensiveness and efficiency. We performed a search of the literature based on guideline

groups with identified high quality update methods (2), supplemented with additional evidence identified via an environmental scan for other reaffirmation and sunsetting methods. We considered reaffirmation or sunsetting methods to be relevant if they included separate methods as compared to full updates. We also considered how eligibility for reaffirmation or sunsetting was defined, time frame used, review methods (e.g., rapid review), assessment of the internal or external validity of the evidence (e.g., quality assessment, GRADE, etc.), use of external consultations and dissemination. Elements of existing methods for reaffirmation and sunsetting were obtained to help inform best practices.

Part C. Review of potential reaffirmation and sunsetting methods

Timeliness and resource use

We examined the candidate methods to determine which would reduce resource use in comparison to a full update. Ideally, reaffirmation or sunsetting would include an evidence review but not a full SR or assessment of internal or external validity of the evidence.

Comprehensiveness

Comprehensive methods would include a review of new (and upcoming) RCT evidence since the previous guideline was published. Additionally, it may consider other factors identified in the EtD that influenced the decisions in the original guideline. These include feasibility, cost, equity, acceptability, patient values and preferences, and health care setting. These factors could be considered through clinical expert feedback, literature review, or task force feedback. Finally, these methods should be broad enough to allow for analysis of all types of recommendations (i.e., strong, conditional, for or against).

Methodological robustness

Reaffirmation and sunsetting would involve an evidence search or similar methods to find all applicable studies since the previous guideline was published. This would be based on the scope and key questions from the original guidance. There would be criteria or considerations to allow the task force to make a decision as to whether a guideline can be reaffirmed, sunsetted or requires a full update. There would also be methods for dissemination of the reafirmed guideline.

Part D. Pilot testing

We piloted the selected methods using the task force's 2015 "screening for cognitive impairment in older adults" guideline (6).

Results

Characteristics of Guideline Reaffirmation Methods

Three guideline group methods (NICE, UKNSC, USPSTF) met the criteria of using separate update and reaffirmation methods (7–14). Specific elements of existing reaffirmation methods from NICE, UKNSC, USPSTF, and the CTFPHC were identified and summarized.

Reaffirmation

The NICE methods were selected as the basis for our guideline reaffirmation approach and were modified to fit our needs (7). The NICE methods include a targeted evidence review without a full SR or new assessment of the internal and external validity of the evidence. These methods allow us to draw on the evidence base collected during the 5-year review. Reaffirmation will use the CADTH rapid reports based on the guideline's key question on effectiveness of the intervention. Additionally, the scope of the CADTH review key question or PICO (population(s), intervention(s), comparator(s), outcome(s)) inclusion criteria may be expanded based on clinical expert and task force feedback. Considerations with respect to cost,

feasibility or patient preferences will be determined via feedback from clinical experts. We will also contact the previous WG chair to ask if there is any new evidence that would require an update.

Modifications to the NICE methods include using a set timeframe for assessment (i.e., 5-year review) instead of proactive (ongoing) surveillance alone (i.e., no set time frame for a voted decision regarding update, reaffirmation or sunsetting). Additionally, we include clinical trial registry search and greater dissemination (e.g., peer-reviewed publication) to highlight the updated evidence base used for reaffirmation. Guidelines reaffirmed by the task force will continue to undergo surveillance and key stakeholders will be alerted to the reaffirmation. Consistent with NICE, our reaffirmation methods do not re-assess the internal or external validity of new evidence.

Once the reaffirmation evidence is collected (via 5-year review and additional consultation and feedback), the task force will compare it against considerations for reaffirmation. These considerations were developed based on the USPSTF, NICE and UKNSC reaffirmation methods (7–9) and task force member feedback. They include:
1) (a) Is there new evidence on this guideline?
(b) Is the new evidence consistent with the direction and strength of the previous recommendation?
2) Does feedback from clinical experts or working group chairs or members indicate key advances in evidence or practice in this area since the guideline was published. This may include changes to healthcare models, patient management, regulatory changes, equity, feasibility, patient values and preferences, acceptability or costs.
3) Are there relevant clinical trials are expected to be completed within the next few years?
4) Are there any unaddressed gaps or limitations in the previous guideline that could be improved with additional key questions or changes to the scope (e.g., populations(s), intervention(s), comparator(s), outcome(s), timing, setting(s), study design(s))?

Characteristics of Guideline Sunsetting Methods
Three guideline group methods (USPSTF, NICE, and UKNSC) (7–9) were analyzed and were summarized.

Sunsetting
We modelled the task force sunsetting methods to be consistent with the above reaffirmation approach. As with reaffirmation, sunsetting will not be limited by whether the guideline was for or against an intervention. Evidence from the 5-year review will be used as a basis for determining if a guideline should be sunsetted. Unlike reaffirmed guidelines, those that are sunsetted will not continue to be monitored via ongoing surveillance. Sunsetted guidelines may be re-examined as new topics if re-submitted and selected.

The considerations for sunsetting were developed based on the USPSTF, UKNSC and NICE methods (7–9) and task force feedback. These include an assessment of:

1. Is the guideline no longer relevant to primary care in Canada?
2. Has the guideline topic (e.g., concept, current landscape) evolved and no longer fits with TF mandate?
3. Does feedback from clinical experts or working group chairs or members indicates that the topic is no longer necessary or useful?

4. Does feedback from clinical experts or working group chairs or members indicate any new or predicted changes to healthcare models, patient management, regulatory changes, equity, feasibility, patient values and preferences, acceptability or costs?
5. Is the guideline no longer of sufficient priority to be maintained via ongoing surveillance?
6. Do other current Canadian guidelines align with task force guidelines (i.e., sunsetting would not cause confusion or result in the use of inappropriate guidance)?

Interpretation

Topic pathway

The task force determined that the targeted search updates outlined in the NICE methods (7) best fit with our needs by balancing comprehensiveness with efficiency. In comparison, the UKNSC (8) and USPSTF methods for reaffirmation (full SR with meta-analysis and internal and external validity assessment of the evidence) (7–9) would require time and resources similar to a full update.

For guidelines in the reaffirmation or sunsetting track, the results of the 5-year review are collated and summarised and presented to the full task force along with the previous evidence base and rationale (Figure 1). This evidence is then compared against the respective considerations for reaffirmation or sunsetting and voted on by the full task force. Those that fail to meet the criteria will be re-examined as potential update or sunset/reaffirmation topics.

Pilot testing

We piloted the methods using the task force's 2015 guideline on "screening for cognitive impairment in older adults" (6). Following review and deliberation by the task force, the guideline was approved for reaffirmation, taking approximately 18 months. We are currently seeking re-endorsement by key stakeholders and publication on the Task Force website. This process now allows us to systematically review evidence in a more efficient timeframe (i.e., currently 6 months) compared to the usual 4-5 years needed for a full update.

Limitations

Limitations of the reaffirmation and sunsetting methods include a lack of analysis of the internal and external validity of the evidence. Therefore, reaffirmation statements will not comment on the certainty of the evidence beyond what was found in the original guideline. Given the robustness of the method, (e.g., no new evidence or new evidence is consistent with the previous guideline), it is likely that the task force would have sufficient information to reaffirm the previous recommendation's strength.

The rapid reports produced for the 5-year review are often limited to RCTs, SRs and evidence-based guidelines. Therefore, relevant observational studies may be missed. However, clinical experts or previous WG members would likely identify larger observational studies that could influence the guideline.

These methods also do not routinely include a review on patient values and preferences, equity or feasibility. Instead, feedback from clinical experts and previous WG members is used to identify if there were issues in these domains that would require a full update or if these can be addressed in the implementation section of the reaffirmed guideline.

While unlikely, it is possible that the task force may reaffirm a guideline that is best served by undergoing a full update. To mitigate this risk, reaffirmed guidelines continue to undergo

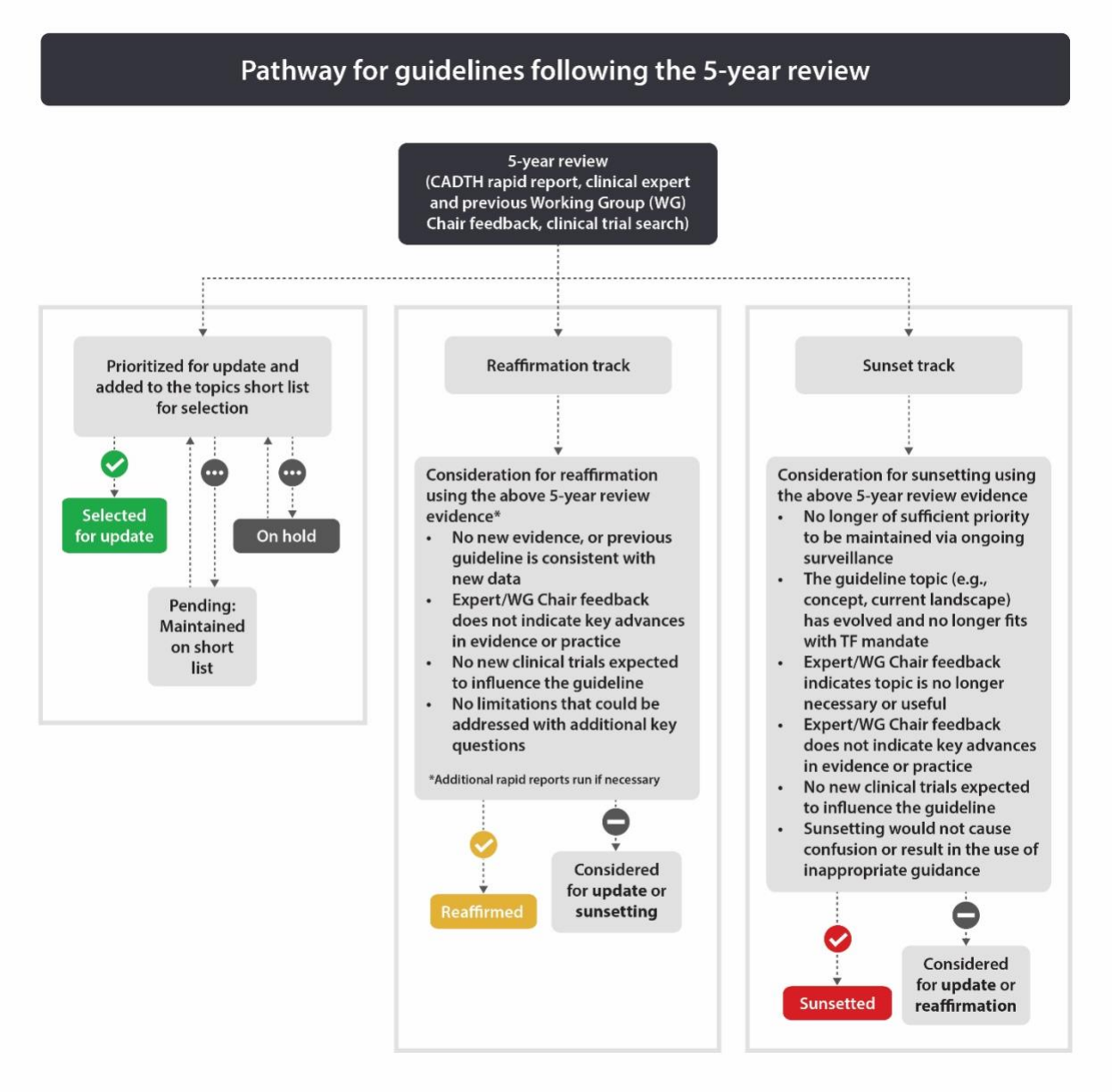
ongoing surveillance for new evidence as well as feedback from clinical experts and stakeholders via an open call and website invitation to submit new topics or updates.

Reaffirmation does not include a meta-analysis, or updating knowledge translation tools (e.g., 1,000 person diagrams); the impact of this will be addressed in the considerations for implementation section of the reaffirmation in a narrative summary describing the impact of any new studies. However, knowledge translation tools should remain relevant as any significant change to the underlying data for figures or tables would result in a full update of the guideline.

Conclusion

The task force concluded that the reaffirmation and sunsetting methods provide a robust and efficient process to reaffirm previous guidelines where change is unlikely. Input from clinical experts and previous WG members allow for consideration of key advances in evidence or practice that could lead to a change in the current guideline. The reaffirmation or sunsetting methods will be used by the task force where a full update is not required.

Figure 1:



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