DIABETES CANADA

Diabetes Canada Clinical Practice Guidelines: Processes Manual

September 2021

1.0 Overview of the Diabetes Canada Clinical Practice Guidelines

1.1 Mandate

The Diabetes Canada Clinical Practice Guidelines (CPG) are comprehensive, evidence-based guidelines intended to guide practice; inform general patterns of care; enhance diabetes prevention efforts in Canada; and reduce the burden of diabetes complications.

The intended users are health-care professionals involved in the management of people with diabetes and those at risk of developing diabetes, with a particular focus on primary care or "usual care" providers.

1.2 Core Values and Principles of Diabetes Canada CPG Development

The CPG are based on values that respect the individuality of people living with diabetes and their clinical and social context. Specifically, we recognize the following:

- Diabetes is a heterogeneous group of syndromes resulting from the complex interplay of biological, social and psychological factors.
- We acknowledge the impact of the social determinants of health and our role in raising awareness and building support for those who need it. The burden of diabetes and its complications is disproportionately experienced by the most vulnerable.
- Optimal care for the population (by addressing social determinants of health and inequities in access to care) is as important as defining optimal care for individuals.
- Diabetes is an important chronic condition which, if inadequately managed, can have negative consequences for affected individuals, their families, communities, society and the economy.
- The impact of diabetes on quality and quantity of life is widely variable.
- We respect and welcome patient autonomy.

As such, our guideline development and dissemination and implementation processes will focus on the following:

- Topics and issues which align with Diabetes Canada's strategic objectives for setting best practice and population impact.
- Recommendations will be based on a rigorous assessment of the best available, and the totality of, evidence:
    - Outcomes important to individuals living with diabetes and clinically significant outcomes will be prioritized over surrogate outcomes.
    - Evidence will take precedence over labelled indications.

    - Thresholds for recommending initiation/uptitration, as well as choice of pharmacotherapy, will be based on available evidence (benefits>risks). Risks and benefits will be weighed.
    - Opportunity costs and individual burden (of disease, comorbidities and therapies) wil be considered.
    - The safety of individuals living with diabetes will be prioritized.

- The development of dissemination and implementation materials and tools will be based on current CPGs and/or best practice in collaboration with DC staff and professional and lived experience partners.

- CPG recommendations and implementation tools:

    - Will be directed towards the benefit of people with (or affected by) diabetes.
    - Should be actionable by health-care professionals.
    - Will avoid promoting marketing advantage of a device or product.

1.3 Structure

The CPG is developed by a multidisciplinary panel of volunteer health-care experts and informed individuals living with diabetes and is based on a rigorous systematic review that rates the quality of evidence and strength of recommendations to support application by persons with lived experience and health-care providers as per framework for evidence-based medicine (Sackett).

The work of these volunteer health-care professional experts and partners with lived experience will be directed by a Steering Committee which will oversee recruitment and composition of working groups and subcommittees, such that for any topic being considered there will be the following input*:

- Clinical expertise
- Lived experience
- Methods expertise
- End-user perspective ± knowledge translation

1.4 Function

The CPG recommendations are intended to improve the quality of care and health-care outcomes of Canadians living with diabetes. The CPG summarize key research findings and make clinical recommendations more transparent. They are meant to reduce inappropriate variation in practice, promote efficient use of health-care resources, empower people living with diabetes, identify gaps in knowledge, prioritize research activities, inform policies affecting people with diabetes, and support quality control activities, including audits of practice.

1.5 Governance

Diabetes Canada has decision-making authority over all aspects of the CPG (revision; dissemination and implementation processes/activities), including the following:

- Final decisions about topics to be covered
- Setting of standards and expectations for review and synthesis of the evidence
- Development of clinical recommendations
- Dissemination and implementation, including development of CPG-based tools/educational materials for both health-care providers and people living with diabetes

The reporting order of the CPG committees is as follows:

1. Diabetes Canada
2. Professional Section Executive
3. CPG Chair/CPG Vice Chair
4. CPG Steering Committee
5. CPG/ D&I Topic Working Groups and Sub-committees

1.6 Disclaimer

The CPG are intended to guide practice and are not intended to serve as a comprehensive text of diabetes management, nor are they intended to set criteria for research protocols. These guidelines are intended to inform general patterns of care. These guidelines are also intended to enhance diabetes prevention efforts in Canada and to reduce the burden of diabetes complications in people living with this disease.

As per the Canadian Medical Association Handbook on Clinical Practice Guidelines (Davis D, et al. Ottawa, ON: Canadian Medical Association; 2007), guidelines should not be used as a legal resource in malpractice cases as “their more general nature renders them insensitive to the particular circumstances of the individual cases.” Health-care professionals must consider the needs, values and preferences of individuals living with diabetes, use clinical judgement and work with available human and health-care service resources in their settings. These guidelines were developed using the best available evidence. It is incumbent upon health-care professionals to stay current in this rapidly changing field.

Unless otherwise specified, these guidelines pertain to the care of adults with diabetes. Where the focus is for other populations it will be stated in the title.

1.7 Confidentiality

The guidelines revision process is a confidential one and no information regarding revisions/updates, including authorship, inclusion of evidence or details concerning preamble and recommendations will be shared externally.

All revisions/updates will remain embargoed until publication in the *Canadian Journal of Diabetes*.

1.7.1 Confidentiality Agreement

Each CPG participant (i.e. Chair, Vice Chair, committee member, person with lived experience, etc.) must sign a confidentiality agreement acknowledging that all CPG materials and processes are strictly confidential and may not be disclosed to any third party without the written consent of Diabetes Canada.

The confidentiality agreement must be signed upon joining the CPG committee and has no expiry. All completed forms will be saved and archived at the National Office of Diabetes Canada.

1.8 Citation

To cite as a whole:
Diabetes Canada Clinical Practice Guidelines Expert Committee. Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes. 2018;42(Suppl 1):S1-S325.

To cite a specific chapter:
Last, First M. "Chapter Title." Journal Year;Vol(Number):XX-XX.

Example: Lipsombe L, Booth G, Butalia S, Dasgupta K, et al. Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada: Pharmacologic Glycemic Management of Type 2 Diabetes in Adults. Can J Diabetes 2018;42(Suppl 1):S88-S103.

1.9 Overview of Roles/Committees

The quality, integrity and lens through which the CPG recommendations are made are influenced by the experts evaluating and interpreting the literature, as well as translating the recommendations into practice tools. As such, care will be taken when striking CPG committees to ensure sufficient experience and expertise, including content expertise, training in critical appraisal/systematic review and knowledge translation/users.

Efforts will be made to ensure that all CPG committees will be comprised of members from diverse perspectives, including:

- Sex and gender
- Knowledge experts vs. knowledge users
- With and without relationships with commercial organizations
- Previous guideline experience vs. novice members
- Disciplines (RN/RD/Pharm, MD, PhD, etc.)
- Geography

- Age
- Persons with lived experience of diabetes

Note: Employees of industry partners are not eligible to be CPG committee members.

1.9.1 CPG Chair/Vice Chair

- Reports to the Diabetes Canada Professional Section Executive
- Leads CPG Steering Committee
- Works in partnership with VP, Science and Policy
- Sets tone and direction
- Oversees the development and revision processes, as well as all D&I and other post-guideline activities
- Leads all meetings/teleconferences for the CPG process, including D&I
- Conflict resolution

Note: Length of terms for the Chair and Vice Chair are three years. In exceptional circumstances, these terms may be renewed for an additional two years, for a total of five years.

1.9.2 Steering Committee

- Comprises the CPG Chair, Vice-Chair, and Past-Chair, Methods Chair, D&I Chair/s, Methods expert, and informed partner/s with lived experience.
- Provides strategic leadership for the CPG
- Selects and Topic Working Group Leads Prioritizes topics for evaluation / revision
- Establishes and oversees the work of sub-committees
- Reviews, discusses and approves all recommendations (100% consensus on all recommendations).
- Determines the need for harmonization with other guidelines (both national and international) as well as other DC policies and/or position statements

Note: Length of terms for members of the Steering Committee are three years. In exceptional circumstances, these terms may be renewed for an additional two years, for a total of five years.

1.9.3 Evidence Review Team

An external stakeholder group engaged by Diabetes Canada will systematically search, review and perform a critical appraisal of the literature, after which all full-text citations and supporting documents will be made available to the topic working group authors.

1.9.4 Topic Working Group Leads

- Review current chapters and suggest need for updates/revisions annually.

- Assemble/Propose members for topic working group which will reflect content expertise, and an ability to generate tools for D&I.
- In collaboration with the Steering Committee, determine the need for harmonization with other national and international guidelines.
- Chair working group calls, appropriately delegate to and oversee work of topic working group members.
- Report to the Steering Committee directly or via CPG council meetings
- Work collaboratively with D&I subcommittee

1.9.4.1 Topic Working Groups

- Comprised of Diabetes Canada Professional Section volunteers, reflecting diverse skills and perspectives as described above (1.9).
- Responsible for developing PICO questions in preparation for the literature search.
- Responsible for completing worksheets documenting their assessment of evidence and summarizing the rationale for their recommendations.
- Responsible for developing/revising recommendations and, if necessary, draft or review text of guideline updates and/or revisions.
- Regularly attend topic working group meetings/teleconferences.
- Complete tasks delegated by working group lead.
- Seek support and/or training from other working group members.
- Responsible for contributing to the development and dissemination of D&I materials (i.e. generate content, provide critical review of educational tools and materials).

1.9.5 Methods Sub-Committee

- Under the direction of the Methods lead (Steering Committee), these members are a selected group of health-care professionals with advanced training in research methods.
- Responsible for ensuring consistency and rigor in the recommendation development process.
- Responsible for providing methodological expertise throughout the revision/recommendation development process.
- Provides operational support to the topic working groups.

1.9.6 D&I Sub-Committee

- Chair will be a member of (or work closely with) the knowledge dissemination pillar of the Professional Section Executive (and/or members of the CPG Steering Committee).
- Will propose members for the D&I subcommittee.
- Chairs regular meetings of the D&I subcommittee.
- Responsibilities include the following:
    - Help the Steering Committee direct the CPG D&I strategy, including review and recommendation of partners.
    - Prioritise topics within the CPG requiring development of tools and resources.

- Partner with the knowledge dissemination pillar of the Professional Section Executive to direct and facilitate guideline dissemination to all Diabetes Canada professional members for the duration of the strategy.
- Provide guidance and comment for the development of innovative and effective evidence-based tools and programs for health-care providers and people living with diabetes.
- Direct and conduct final reviews, plus approval of all content and programs, for clinical and practice accuracy, plus relevance for people with diabetes to make recommendations to the CPG Steering Committee.
- Evaluate the overall strategy and its individual components.
- Leverage committee member expertise and networks to develop collaborative relationships with relevant stakeholder groups.
- Participate in active dissemination activities as per interest and expertise.
- Identify an evaluation plan to measure:

    - Needs of health-care providers and people living with diabetes
    - Results of the strategy objectives (knowledge change, intent to change practice)
    - Impact of practice change and outcomes of people living with diabetes
    - Impact of strategy (analytics, media, etc.)

- D&I subcommittee will work with the topic working group leads to identify working group members who can develop D&I materials.
- Matters of disagreement that arise will be elevated to the CPG Chair and Steering Committee for review, discussion and resolution.

1.9.7 Partnership with Persons with Lived Experience

The involvement of persons with lived experience is a vital element of all aspects of the CPG revision and D&I processes. To achieve this, a person with lived experience will be a full member of the Steering Committee.

Involvement and participation of persons with lived experience will be sought at all stages of the development and D&I processes:

- Call for topics/clinical questions (plan to crowd-source PICO questions from persons with lived experience and providers)
- Development of recommendations
- Development of D&I tools/materials
- Delivery of D&I tools/materials

1.9.7.1 Recruitment of Persons with Lived Experience

- Interested persons with lived experience can apply to be a CPG committee member through the Diabetes Canada website (diabetes.ca).
- Persons with lived experience may be invited by clinicians who are CPG committee members.

- Persons with lived experience may be recruited through Diabetes Canada's local patient-based chapters, many of which are culturally based.
- Persons with lived experience may be recruited through key Diabetes Canada partner organizations (e.g. DAC patient circle representatives).

1.10 Quorum & Voting

A quorum for official votes is 80% of the committee members, including the Chair and Vice Chair. Decisions regarding methods, recommendations and the selection of new members require a non-secret vote.

Members with a potential conflict of interest related to the topic of a particular vote must recuse themselves and are not eligible to vote.

1.11 Conflict of Interest Disclosure Policy/Process

CPG Steering Committee members will be asked to abstain from interactions with industry partners from which they derive a personal financial benefit. Interactions which are necessary as part of their employment or professional practice are permitted, but will be disclosed.

Conflict of interest (COI) disclosure must be submitted by all individuals invited or volunteering to participate in both the CPG revision and D&I processes, including the following:

- Chair and Vice Chair
- Members of the Steering Committee
- Members of the Methods Committee
- Members of the D&I Committee and sub-committees
- All authors (chapter updates, position statements, etc.)
- All external reviewers

All CPG committee members/participants will:

- Disclose conflict for the prior three years (longer, if relevant)
- Update their disclosure forms annually

All COI disclosure forms will be reviewed by the Steering Committee and the Chair and Vice Chair. In cases of uncertainty, further consideration will be sought from the CPG Chair or external advisory committee.

The CPG Chair will highlight COIs and ask for any new COIs to be disclosed at the start of all CPG committee meetings and teleconferences.

Note: All conflicts will be published in the *Canadian Journal of Diabetes* (CJD) with each update (i.e. chapter update, position statement, interim update, etc.). Also, all conflicts will be publicly available on the guidelines website or equivalent.

See Appendix 1 for example of COI disclosure and questionnaire.

1.12. Ethics/Conflict Advisors

The CPG Chair and Diabetes Canada VP, Science and Policy will provide oversight of COI disclosures to ensure compliance with CPG and DC policies.* For potential COI affecting the CPG Chair, the issue will be discussed with the VP, Science and Policy with unresolved issues being forwarded to an ad hoc group of advisors from the Diabetes Canada executive leadership team/Diabetes Canada Board which will be convened as required.

*This ad hoc advisory group is available to provide informal advice to the CPG Chair and VP Science and Policy, as required.

2.0 Overview of the CPG Development Process

The steps in the CPG development/revision process are shown below:

1. Scoping
2. Topic Selection
3. Development of PICO Questions
4. Literature Review
5. Critical Appraisal of Evidence
6. Development/Revision of Chapter & Recommendations
7. Independent Methods Review
8. Revision of Recommendations/Grading
9. External Peer Review
10. Authors Address Feedback
11. Authors Finalize Chapters & Recommendations
12. Final Approval of Recommendations
13. Submission to CJD for Publication
14. D&I Strategy

Important note: Diabetes Canada welcomes input from the diabetes community to improve the CPG in terms of integrity, relevance and applicability. All members of the diabetes community (i.e. individuals living with diabetes, academic experts, clinicians, industry representatives, government agencies, non-profit organizations, etc.) who wish to comment or propose topics to be included in the guidelines, are invited to contact Diabetes Canada, in writing, detailing the intended subject and supporting evidence, if any, for consideration by the Steering Committee.

Such requests must be sent to guidelines@diabetes.ca.

2.1 Chapter Review Process

Chapters and their corresponding recommendations are reviewed annually by the Steering Committee to determine their eligibility for update/revision and whether, based on the evidence, new recommendations need to be developed.

The following set of criteria are put forward to review the relevance and appropriateness of current recommendations:

- Continues to be an Important topic for people living with diabetes?
- Specific guideline is required for people living with diabetes?
- Focus on important outcomes for people living with diabetes?
- Relevant to the needs of PCPs
- Actionable by primary care providers and allied health-care professionals, where relevant
- Length?
- Clarity?
- Are there redundant sections?
- Does any information in the chapter contradict anything from other chapters (i.e. hypoglycemia treatment recommendations)?
- Inaccurate or outdated sections?
- Missing areas?

The Steering Committee, upon consultation with the chapter authors, will approve either a:

    - Full revision of the chapter
    - Update literature review; then consider for revision
        - Major revision
        - Minor revision
- Redesign; refocus
- Archive; retire chapter
- Delete chapter

As members of the Expert Committee, authors, too, will review their respective chapter(s) annually with the following criteria and make recommendations to the Steering Committee:

- Is there important new information?
- Is a new literature review required?
- Is revision anticipated?
    - Major revision
    - Minor revision
- Are additional section(s) required?
- Will revision improve the lives of people living with diabetes?
- Will revision make practice easier for primary care physicians?

2.2 Criteria for New CPG Chapters and Updates

The purpose of a chapter update is to provide guidance to clinicians on important prevention interventions or clinical management of diabetes due to emerging evidence. Topics and chapters will be reviewed at least every 5 years.

Additional chapters or updates will occur if any of these criteria have been met:

- New information has emerged which is important, including a new topic, new significance of an intervention relating to its impact, strength of data or importance to individuals living with diabetes.
- Significant new evidence arises on existing interventions which may change clinical practice and outcomes for people with diabetes.

Guidelines will not be updated if:

- Primary benefit will be to facilitate commercial interest
- Adding an additional similar agent/intervention to an existing recommendation
- Needs of people with diabetes are adequately addressed by other guidelines

2.3 Criteria for Diabetes Canada Clinical Practice Position Statements

Clinical position statements include clinical statements, policy statements influencing clinical practice relevant to people living with diabetes.

- A Diabetes Canada position statement must address an important issue:
    - For DC policy.
    - For people living with diabetes.
    - For clinicians.
- A position statement can be developed:
    - Where there is insufficient data to perform a systematic review.
    - Where no recommendations of Level 1 or 2 exist.
    - Where only Grade D Consensus recommendations are made.
    - As a response to an issue created by other guidelines.

Note: Requests to add a chapter, interim update or develop a position statement may be made by Professional Section members, the public or Diabetes Canada staff. The decision to proceed will be made by Diabetes Canada and based on the listed criteria. See note in section 2.1.

2.4 Assembling Authors for Chapter Updates

- Chapter authors will be selected/approved by the Steering Committee based on their relevant fields of expertise.

- Each chapter will have one lead author, 1 or 2 “evidence resource” persons trained or experienced in clinical epidemiology or clinical research methodology, and up to 6 additional authors, as needed (exceptions to be approved by the Steering Committee).
- Authors will identify clinically important questions related to diagnosis, prognosis, prevention and treatment of diabetes and its complications, which will then be used as a basis for the literature search strategy.
- All authors will review the relevant studies that pertain to each potential recommendation, assign levels of evidence to studies, complete the evidence checklists and provide input on the direction of the chapter, and the wording and grading of recommendations.
- Individual contributors will be listed with an explicit description of their contributions.
- Individuals can cite their contributions as authors (meeting ICMJE criteria) on their CV/institutional annual reports.
- A clear description of all contributors and their contributions will help:
    - Transparency
    - Avoid bias that could compromise the trustworthiness of the CPG
    - Ensure appropriate recognition of all contributions

Please note: Diabetes Canada reserves the right to remove contributors who have not been able to meet the required level of contribution/participation.

2.4.1 Order of Authorship

All published articles will be attributed to the Diabetes Canada Clinical Practice Guidelines. For example:

Title: Monitoring Blood Glucose Levels - Diabetes Canada Clinical Practice Guidelines Update
Author: Diabetes Canada Contributors:

- Expert working group: Chair(s) then random order. a, b, c, d
- Independent Methods Review panel: a, b
- Steering Committee: chair(s) then random order. a, b, c, d, e, f
- Individuals with learned experience panel: chair(s) then random order. a, b, c

2.5 Identifying and Appraising the Evidence

Authors will explicitly define: a) the population to which the question would apply; b) the test, risk factor or intervention being addressed; c) an appropriate reference standard or control population to which the test, intervention or exposure was to be compared; and d) the clinically relevant outcomes being targeted. This information will be used to develop specific, clinically relevant questions that will be the focus of the literature searches. For each question, strategies will be developed combining diabetes terms with methodological terms. Two health sciences librarians with expertise in evidence-based practice will construct and peer-review comprehensive searches of the relevant English-language, published, peer-reviewed literature using validated search strategies of electronic databases (MEDLINE, EMBASE, CINAHL, the Cochrane Central Register of Trials, and PsycINFO [where appropriate]). The literature searches will focus on new evidence published since the previous guidelines/update. If necessary,

updated literature searches will be performed at other intervals throughout the development process.

Once citation duplicates are removed, all references and full-text documents will be loaded into DistillerSR. Using a priori defined criteria of inclusion and exclusion, all citations will be screened at the title and abstract level in duplicate by MERST team members; full-text screening will be completed by a diabetes clinician and methodologist for relevance. All full-text citations and supporting documents will then be made available to the chapter authors for review. Authors will review all remaining citations and systematically determine whether the citation could be used for background material, discarded (with justification) or used to support a new or existing recommendation. Each citation used to formulate, update or revise a recommendation will be critically appraised. The level of evidence will then be determined by the cited paper's objectives, methodological rigour, susceptibility to bias and generalizability.

Citation flow diagrams depicting the search, review and selection of citations for each chapter, specifically, the number of citations reviewed, removed and requiring new or revised recommendations, will be included at the end of each chapter.

Higher levels will be assigned if: a) people with diabetes comprise a predefined subgroup; b) the results in the diabetes subgroup is unlikely to have occurred by chance; and c) the evidence is generated in response to questions that were formulated prior to the analysis of the results. Lower levels will be assigned to evidence that do not meet these criteria.

2.6 Grading the Evidence

- Authors will use worksheets to assign levels of evidence to key articles.
- Each citation used to formulate or revise a recommendation will be assigned a level of evidence according to pre-specified criteria (see Appendix 5), reflecting the methodological quality of the paper.
- Level of evidence will be determined by the cited paper’s objectives, methodological rigor, susceptibility to bias and generalizability.
- If an article of interest is not exclusive to diabetes, then higher levels will be assigned if a) people with diabetes comprised a predefined subgroup; b) the results in the diabetes subgroup were unlikely to have occurred by chance; and c) the evidence was generated in response to questions that were formulated prior to the analysis of the results.

2.7 Revision/Writing of Recommendations

- Existing recommendations will generally not be revised in the absence of new scientific evidence.
- Recommendations have to be clinically directive actions (i.e. a “should” statement).
- Each recommendation has to address a clinically important question related to one or more of the following: detection, prognosis, prevention, or management of diabetes. Health benefits, risks and side effects of interventions should be considered in formulating the recommendations. The preferences and values of persons with lived experience were sought from expert panel members living with diabetes and the literature (where available).

- Where evidence was not available, consensus recommendations will only be made if it meets a clinical need.
- Negative recommendations will not be included.
- Drugs can only be included in recommendations if they have received approval.
- If the evidence supports a class effect, the recommendation will be written as such with specification as to the studied therapeutic agents and/or cited references.
- Whenever possible, each recommendation has to be justified by the strongest clinically relevant, empirical evidence that can be identified; the citation(s) reporting this evidence have to be noted adjacent to the relevant guideline.
- The strength of this evidence, based on prespecified criteria from the epidemiologic literature and other guidelines processes, has to be noted.
- Each recommendation has to be assigned a grade based on the available evidence, its methodological strength and its applicability to the Canadian population.
- Each recommendation will be reviewed by a member of the Independent Methods Review Committee and has to be approved by the Steering Committee, with 100% consensus.
- Guidelines based on biological or mechanistic reasoning, expert opinion or consensus have to be explicitly identified and graded as such; Wherever possible, recommendations will be harmonized with other related guidelines (i.e. the Canadian Cardiovascular Society [CCS], Hypertension Canada and the Canadian Cardiovascular Harmonization of National Guidelines Endeavour [C-CHANGE]).

2.8 Grading the Recommendations

- After formulating new recommendations or modifying existing ones based on new evidence, each recommendation is assigned a grade from A through D (See Appendix 5). The highest possible grade that a recommendation can have is based on the strength of evidence that supports the recommendation (i.e. the highest level of evidence assigned to studies on which the recommendation was based).
- In some situations, the grading might be lowered for subgroups that are not well represented in the study, or in whom the beneficial effect of an intervention is less clear. Grading also may be lowered if the findings from relevant (and equally rigorous) studies on the topic are conflicting. Thus, a recommendation based on Level 1 evidence, deemed to be very applicable to Canadians and supported by strong consensus, will be assigned a grade of A. A recommendation not deemed to be applicable to Canadians, or judged to require further supporting evidence, will be assigned a lower grade.
- The final grading is dependent on the overall evidence available, including the relative strengths of the studies from a methodological perspective and the studies' findings and applicability to the Canadian population.
- Varying grades of recommendations reflect varying degrees of certainty regarding the strength of inference that can be drawn from the evidence in support of the recommendation.
- Consideration should be given to the benefit vs. harm in each chapter when making recommendations.
- In the absence of Level 1, 2 or 3 supporting evidence, or if the recommendation is based on the consensus of the Steering and Executive Committees, the highest grade that may be assigned is Level D.

- Where available, the number of individuals who would need to be treated in order to prevent one clinical event (number needed to treat [NNT]) or to cause an adverse event (number needed to harm [NNH]) will be considered in assessing the impact of a particular intervention. The degree to which evidence derived from other populations is felt to be relevant to diabetes will also be reflected in the wording and grading of the recommendation.

2.9 Interpreting the Assigned Grade of a Recommendation

The grade assigned to each recommendation is closely linked to the methodological rigour and robustness of the relevant clinical research. Therefore, a high grade reflects a high degree of confidence that following the recommendation will lead to the desired outcome. Similarly, a lower grade reflects weaker evidence, and a greater possibility that the recommendation will change when more evidence is generated in the future. Of note, the assigned grade contains no subjective information regarding the importance of the recommendation or how strongly members of the committee feel about it; it contains information regarding only the evidence upon which the recommendation is based. As such, many Grade D recommendations will be those deemed to be very important to the contemporary management of diabetes, based on clinical experience, case series, physiological evidence and current concepts of disease pathophysiology. However, the paucity of clinical evidence addressing the areas of therapy, prevention, diagnosis or prognosis will preclude the assignment of a higher grade.

Varying grades of recommendations reflect varying degrees of certainty regarding the strength of inference that can be drawn from the evidence in support of the recommendation. The CPG and their graded recommendations are designed to satisfy two important needs:

1. The explicit identification of the best research upon which the recommendation is based, and an assessment of its scientific relevance and quality (captured by the assignment of a level of evidence to each citation).

2. The explicit assignment of strength of the recommendation based on this evidence (captured by the grade).

It is important to note that the system chosen for grading recommendations differs from the approach used in some other guideline documents in which a treatment or procedure that is not useful/effective and, in some cases may be harmful, are assigned a grade or class. In the CPG, recommendations to avoid any harmful practices will be graded in the same manner as all other recommendations.

2.10 Independent Methods Review

An Independent Methods Review (IMR) committee is established to ensure consistency and rigour in the recommendation development process. The IMR consists of university-based clinician faculty with advanced training in research methods. The IMR provides methodological

expertise and is a resource available to the recommendation authors throughout the development process.

All drafted recommendations and their supporting evidence are appraised and graded by the recommendation authors. The IMR will then provide a secondary critical review of the recommendation and the evidence to:

- Ensure there is strong fidelity between the wording of the recommendation and the cited clinical evidence

- Provide an independent appraisal and grade for the cited evidence.

Where appropriate, the IMR will suggest rephrasing of recommendations to ensure the recommendation accurately reflects the underpinning evidence. In the event that there is discordance between the author-assigned grade and the IMR-assigned grade, the recommendation will be arbitrated by one of the IMR co-chairs.

All IMR review activities will be systematically performed and recorded to ensure procedural quality and transparency.

Notes:

- Only those recommendations with a grade A to C will be reviewed (Grade D recommendations will not).
- Only new or revised recommendations will be reviewed.
- Wording changes made to existing recommendations that do not result in a change in the meaning of the recommendation do not need to go to IMR. These should be flagged for the Steering Committee to approve.
- Presentation of IMR results to the Steering Committee:
    - If there are any changes to wording/grading, these must be approved by the Steering Committee, with 100% consensus.
    - If the Steering Committee proposes further wording changes, these need to be approved by the IMR committee to ensure that the grading is not affected.

2.11 Process of Approval

- Every Steering Committee meeting must have quorum (80% with Chair/Vice Chair).
- The Expert Committee does not formally vote on the recommendations. Feedback will be taken into consideration, but the Steering Committee has final approval.
- If someone is absent from a Steering Committee meeting, decisions will be sent via email with a fixed timeline to respond (within five days). If no response is received within five days (business days), this will be considered as de facto approval. If the member disagrees with the consensus, a conference call will be scheduled to address the specific issue.

2.12 External Peer Review

External peer review is a critical step to ensure accuracy, credibility and publicity. The draft CPG chapter(s) will be circulated nationally and internationally for content review by numerous stakeholders and experts in relevant fields, including specialists, community primary care providers, academic departments of family medicine across Canada, and specialty and disease support organizations.

This input will then be considered by the Expert and Steering Committees and revisions made accordingly. Revised recommendations will be reviewed and approved by the Steering Committee, with 100% consensus.

External reviewers will be acknowledged by name in the published CPG.

3.0 D&I and Knowledge Translation

The role of the D&I subcommittee is to:

- Translate knowledge from the CPG to be used in the development of educational tools, resources and programs for both health-care providers and people living with diabetes (i.e. webinars, case studies, slide decks, quick reference guide, videos, etc.).
- Develop a comprehensive strategy to disseminate and implement Guidelines to primary care providers, diabetes educators, other allied health-care providers and people living with diabetes.
- Adhere to a systematic approach to ensure that interventions and investment inform best practice in Canada.
- Identify and help coordinate local D&I opportunities for the strategy.
- Stakeholder engagement.
- Monitor and evaluate knowledge translation activities related to D&I tools, resources and programs.

Note: See sections 1.9.6 and 1.9.7 for more detailed information regarding the role and responsibilities of the D&I subcommittee.

Appendix 1: COI Disclosure Framework/Questionnaire

1. Employer(s)

Name	Type of Organization

2. Commercial

Personal Fees

Drug/Device Company	Therapeutic Area/Class	Consulting Fees/Advisory Boards	Speaker Fees	Research (personal fees)	Other	Amount per year ($)
						<$1,000 <$5,000 <$10,000 <$25,000 >$25,000*
Medical Communication Company	Ownership/ Shareholder	Therapeutic Area/Class	Consulting Fees (program development)	Speaker Fees (program delivery)	Other	Amount per year ($)
						<$1,000 <$5,000 <$10,000 <$25,000 >$25,000*

***Note:** Assume >$25,000 would limit role.

3. Research Participation / Institutional Support

Drug/Device Company	Therapeutic Area/Class	Sponsor (company/ investigator)	Research (institutional support)	In kind	Role	Author of Publication

4. Academic

Tenure track?	
Participation influence promotion / merit	
Research focus	

5. Professional

Clinical practice	
Participation will enhance professional reputation	

6. Government Roles

Committees /Advisory Groups

Organization	Role	Therapeutic Area/Topic

7. Personal

		Description
Person with or affected by diabetes	Y/N	
Relative with or affected by diabetes	Y/N	
First degree relative employed/stock holder industry partner	Y/N	
First degree relative employed/ stock holder medical communications company	Y/N	

8. DC Member: Y/N

9. Industry Perspective: Positive / Neutral / Negative

Appendix 2: Confidentiality Agreement

Confidentiality Statement
Diabetes Canada Clinical Practice Guidelines

I _____, certify that all documents and discussions concerning the development and implementation of the Diabetes Canada Clinical Practice Guidelines in which I participate as an XX Committee member, shall be held in the strictest confidence and shall not be disclosed or discussed outside the review meetings.

_____
Name

_____
Date

Appendix 3: Criteria for Assigning Levels of Evidence

Criteria for assigning levels of evidence to the published studies

Level	*Criteria*
Studies of diagnosis	
Level 1	a. Independent interpretation of test results (without knowledge of the result of the diagnostic or gold standard) b. Independent interpretation of the diagnostic standard (without knowledge of the test result) c. Selection of people suspected (but not known) to have the disorder d. Reproducible description of both the test and diagnostic standard e. At least 50 patients with and 50 patients without the disorder
Level 2	Meets 4 of the Level 1 criteria
Level 3	Meets 3 of the Level 1 criteria
Level 4	Meets 1 or 2 of the Level 1 criteria
Studies of treatment and prevention	
Level 1A	Systematic overview or meta-analysis of high-quality RCTs a. Comprehensive search for evidence b. Authors avoided bias in selecting articles for inclusion c. Authors assessed each article for validity d. Reports clear conclusions that are supported by the data and appropriate analyses OR Appropriately designed RCT with adequate power to answer the question posed by the investigators a. Patients were randomly allocated to treatment groups b. Follow up at least 80% complete c. Patients and investigators were blinded to the treatment d. Patients were analyzed in the treatment groups to which they were assigned e. The sample size was large enough to detect the outcome of interest
Level 1B	Non-randomized clinical trial or cohort study with indisputable results
Level 2	RCT or systematic overview that does not meet Level 1 criteria
Level 3	Non-randomized clinical trial or cohort study; systematic overview or meta-analysis of level 3 studies
Level 4	Other
Studies of prognosis	
Level 1	a. Inception cohort of patients with the condition of interest, but free of the outcome of interest

b. Reproducible inclusion/exclusion criteria
c. Follow up of at least 80% of subjects
d. Statistical adjustment for extraneous prognostic factors (confounders)
e. Reproducible description of outcome measures

Level 2	Meets criterion a) above, plus 3 of the other 4 criteria
Level 3	Meets criterion a) above, plus 2 of the other criteria
Level 4	Meets criterion a) above, plus 1 of the other criteria

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* In cases where such blinding was not possible or was impractical (e.g. inten- sive vs. conventional insulin therapy), the blinding of individuals who assessed and adjudicated study outcomes was felt to be sufficient.

RCT, randomized controlled trial.

Appendix 4: Criteria for Assigning Grades of Recommendations

Criteria for assigning grades of recommendations for clinical practice

Grade	Criteria
Grade A	The best evidence was at Level 1
Grade B	The best evidence was at Level 2
Grade C	The best evidence was at Level 3
Grade D	The best evidence was at Level 4 or consensus