

Canadian Optimal Medication Prescribing and Utilization Service

Expert Review Committee (CERC)

Terms of Reference

The Canadian Optimal Medication Prescribing and Utilization Service (COMPUS) Expert Review Committee (CERC) is an independent advisory body, consisting of Core Members and Specialist Experts. CERC makes recommendations and provides advice related to the identification, evaluation and promotion of Optimal Therapy in drug prescribing and use in Canada. The recommendations reflect current medical, scientific, and economic knowledge and clinical practice in the Canadian healthcare system

In these Terms of Reference, unless otherwise provided, the capitalized terms are defined in Appendix 1 and shall apply herein.

1.0 Mandate

The mandate of CERC is advisory in nature and is to provide recommendations and advice to the COMPUS Directorate at CADTH on assigned Topics that relate to the identification, evaluation and promotion of Optimal Therapy in the prescribing and use of drugs across Canada. In making optimal therapy recommendations and providing advice regarding the Topic, CERC:

- a) considers clinical and cost effectiveness evidence within the identified population;
- b) develops recommendations and advice with the aim of contributing to optimal health outcomes and fostering a sustainable health care system for Canadians; and
- c) considers the practical needs of policy makers, health care providers and consumers in implementing and using the recommendations and advice toward the promotion of Optimal Practices.

2.0 Responsibilities

CERC's responsibilities are:

- a) to develop evidence-based Optimal Therapy Recommendations for the Topic identified for review by the COMPUS Advisory Committee based on:
 - i) a review of practices in the identified topic area including:
 - o the strength and quality of evidence supporting them; and
 - o the strength and quality of available cost-effectiveness information;
 - ii) the clinical validity and applicability of the practices to clinical practice; and
 - iii) Stakeholder advice and input.
- b) to identify areas requiring further research;
- c) to identify currently accepted practices that may require updating based on new evidence;
- d) to act as a resource in identifying gaps in practice and drug use related to the Topic under review and in validating key messages to address the gaps;
- e) to act as a resource with respect to Intervention Tools and Strategies that will facilitate the adoption and implementation of the recommended Optimal Therapy;
- f) to identify key Stakeholders and potential partners who can facilitate the adoption and implementation of the recommended Optimal Therapy; and
- g) to provide guidance to the COMPUS Directorate on other issues, as requested.

3.0 Accountability

CERC is an expert advisory committee of CADTH and reports to the CADTH Board of Directors through CERC's Chair.

4.0 CERC Membership

4.1 Composition

CERC consists of Core Members appointed to serve for all Topics under consideration during their term of office, and Specialist Experts appointed to provide their expertise in recommending Optimal Therapy in respect of one or more specific Topics.

(a) Core Members

The membership of CERC shall include eight Core Members.

Two of the Core Members shall be Public Members to bring a lay perspective.

The remaining six Core Members must hold qualifications as physicians, pharmacists, health economists or other relevant qualifications with expertise in one or more areas, such as, but not limited to:

- a) family practice
- b) institutional or community clinical pharmacy
- c) pharmacoconomics
- d) clinical epidemiology
- e) drug utilization expertise
- f) methodology
- g) affecting behaviour change (through health professional and/or patient, and/or policy interventions)
- h) critical appraisal

(b) *Specialist Experts*

The membership of CERC shall also include three or more Specialist Experts with recognized expertise in the prescribing or use of the particular drug or group of drugs or treatment of a condition identified for review by the COMPUS Directorate in relation to a Topic under review. As more than one Topic may be under review in the same period, the number of Specialist Experts serving in a given period will be determined by the number of Topics under review.

4.2 Appointment/Nomination Process

Nominations for appointment of Core Members to CERC shall be made in accordance with the process set out in the attached Appendix 2.

Candidates for Public Members of CERC will be selected with reference to the Profile of Public Members of the CADTH Expert Advisory Committees as set out in the attached Appendix 3.

The Core Members including Public Members shall be appointed by the CADTH Board of Directors.

The Specialist Experts shall be appointed by the CADTH President and CEO after:

- a) providing members of the CAC an opportunity to propose names of experts for consideration; and
- b) consulting on a short list of candidates with the Chairs of CERC and CAC.

4.3 Term of Appointment

Upon creation of CERC, four of the Core Members, (including one Public Member), shall be appointed for a term of three years and the remaining four Core Members shall be appointed for a term of two years. Thereafter, all Core Member appointments shall be for a term of two years.

The terms of any Core Member may be renewed at the discretion of the CADTH Board of Directors.

Notwithstanding anything set out in these Terms of Reference, the CADTH Board of Directors shall have the right to remove and/or replace a Core Member at or before the expiry of his/her term.

Each Specialist Expert shall be appointed for such term as the CADTH President and CEO shall deem appropriate in the circumstances. The President and CEO shall also have the right to remove and/or replace a Specialist Expert at or before the expiry of his/her term.

4.4 Committee Officers

The officers of CERC shall be the Chair and Vice-Chair who shall be appointed by the CADTH Board of Directors from the Core Members.

Regarding the term of appointment of the first Chair and the first Vice-Chair of CERC, the Chair shall be appointed for a term of two years and the Vice-Chair for a term of one year. Thereafter the appointment of the Chair and Vice-Chair shall be for a term of two years, and may be renewed at the discretion of the CADTH Board of Directors.

The Chair shall preside at all meetings of CERC. In addition, the Chair is responsible for reporting on CERC activities to the CADTH Board of Directors and shall act as the key liaison between CERC and CADTH. The Chair shall be the sole spokesperson for CERC.

The Vice-Chair shall, in the absence or disability of the Chair, perform the duties and exercise the powers of the Chair.

4.5 Withdrawal from Committee

A Member may resign from CERC at any time upon written notification to the CADTH secretariat.

Members who are absent for more than two consecutive CERC meetings will automatically forfeit membership on CERC. However, the CERC Chair has the discretion to approve, in advance, an extended absence of any Member.

4.6 Voting Rights

Each Core Member, including each Public Member, shall be entitled to vote on all matters coming before CERC.

Every Specialist Expert shall only be entitled to attend, and to vote, in respect of the Topic(s) for which he/she has been appointed to CERC.

5.0 CERC Meetings

5.1 Frequency of Meetings

CERC shall hold such meetings as may be required to carry out its responsibilities. The number of meetings will be determined by the COMPUS Directorate in consultation with the CERC Chair.

5.2 Notice of Meetings

Meetings of CERC may be held at any time and place in Canada to be determined by the Members, provided that reasonable notice of such meeting shall be given in advance to each Member entitled to vote at such meeting.

5.3 Quorum

The quorum in relation to all CERC matters that do not relate to a Recommendation shall be five (5) of the Core Members.

The quorum in relation to all CERC matters in relation to a Recommendation shall be five (5) of the Core Members plus 50% of the Specialist Experts appointed in relation to the Topic under consideration.

5.4 Attendance

Core Members shall attend all meetings. Specialist Experts shall attend only those meetings where issues, related to their specific Topic, are on the agenda.

A Core Member or Specialist Expert who is unable to attend the in-person meeting may request permission from the Chair to participate in the meeting via other means such as video conference, teleconference or other communications facilities. The Chair shall have sole discretion in deciding whether to grant permission to such Core Member/Specialist Expert request but shall only grant permission in exceptional circumstances.

5.5 Attendees

In addition to CERC Members, only the following persons shall be entitled to attend CERC meetings:

- a) CAC members appointed by participating provincial and territorial health ministries and federal publicly funded drug plans
- b) Experts by invitation (see below)
- c) CADTH staff:
 - i) the CADTH President and CEO
 - ii) the most senior staff person from the COMPUS Directorate
 - iii) COMPUS Directorate staff

CAC members may attend as observers but do not have the right to participate in the discussion and deliberations or to vote.

Experts invited by the CERC Chair may attend in circumstances where CERC has questions or requires clarification regarding issues related to Optimal Therapy within the topic area under review, methodologies related to evaluating currently accepted practices or other matters relevant to CERC's work. Such experts may participate in discussion upon request, but shall not participate in, or be present during, any voting.

The CADTH staff attending the meeting shall serve as a resource to CERC. They will provide administrative and secretariat support and may actively participate in the presentation of information or discussions at the request of the CERC Chair. They shall also assist in obtaining additional information and/or expert advice at CERC's request. CADTH staff shall not have the right to vote.

Other individuals may be invited to attend as observers at the discretion of the Chair and CADTH.

5.6 Agenda

CERC's meeting agendas are developed by the CERC Chair in consultation with the COMPUS Directorate.

5.7 Conflict of Interest Disclosure

At the commencement of each meeting, the Chair shall ask Members if they have any conflicts of interest to disclose. Any Member with a conflict must disclose such conflict and comply with the Conflict of Interest Guidelines and Code of Conduct.

5.8 Decisions

No Decision or Recommendation can be made unless there is a quorum.

Decisions will typically be made by consensus. If a vote is necessary, except as set out below, a simple majority of the quorum of Core Members is required. In the event of an equality of votes on any Decision, the chairperson of the meeting shall have a second and deciding vote.

Every CERC Recommendation shall be decided by a majority of votes. Every voting Member participating in the meeting must vote (i.e., for or against) on the motion for the adoption of a Recommendation; a Member cannot abstain from voting. In the event of an equality of votes on any Recommendation, the chairperson of the meeting shall have a second and deciding vote.

5.9 Records of Meetings

Minutes shall be kept of all CERC meetings and all Recommendations, and shall be signed by the Chair.

A copy of the minutes of every committee meeting shall be sent to voting Members, observers, relevant CADTH staff and the CADTH President and CEO.

6.0 Remuneration/Honoraria

A reasonable remuneration or honoraria for all Core Members, Specialist Experts and invited experts shall be fixed by CADTH.

Committee Members and experts shall be entitled to be paid reasonable expenses incurred by them in the performance of their duties.

7.0 General Provisions

7.1 Indemnity

Every Core Member and Specialist Expert shall be indemnified and saved harmless by CADTH from and against:

- a) all costs, charges, and expenses which such Core Member and Specialist Expert sustains or incurs in or about any action, suit or proceedings, which is brought, commenced or prosecuted against him or her, or in respect of any act, deed, matter or thing whatsoever, made, done or permitted by him or her, in or about the execution of the duties of such Core Member and Specialist Expert or in respect of any such liability;
- b) all such other costs, charges, and expenses which he or she sustains or incurs in or about or in relation to the affairs thereof, except such costs, charges or expenses as are occasioned by his or her own wilful neglect or default.

7.2 Secretariat and Administrative Support

Secretariat and administrative support for CERC is provided by CADTH.

7.3 Amendment to the Terms of Reference

These Terms of Reference may be amended at any time, and from time to time, by the CADTH Board of Directors.

7.4 Code of Conduct

Every person attending CERC meetings must abide by the Code of Conduct.

7.5 Conflict of Interest Guidelines

All CERC Members must undertake in writing to abide by the terms of the Conflict of Interest Guidelines. A summary of the conflict of interest disclosure for each Member will be publicly available on the CADTH web site.

7.6 Sub-committees

CERC may form sub-committees and/or task groups to fulfill its mandate. The reimbursement of any expenses associated with sub-committees will require CADTH approval in advance.

APPENDIX 1

Definitions

In the Terms of Reference of the COMPUS Expert Review Committee (and appendices referred to therein), the following definitions apply, unless otherwise provided.

CADTH: Canadian Agency for Drugs and Technologies in Health, a corporate body duly incorporated under the laws of Canada.

CADTH Board of Directors: The CADTH Board comprises 13 Directors appointed by the Deputy Ministers of Health of the federal government, nine provinces, and three territories. The Board is accountable to its Members, the participating federal, provincial and territorial health ministries, for the delivery of CADTH's programs.

CERC: COMPUS Expert Review Committee.

CERC Nominating Committee: the nominating committee established according to the CERC Terms of Reference for recommending candidates for appointment as Core Members to CERC.

CERC Terms of Reference: the Terms of Reference established for CERC by the CADTH Board of Directors.

Code of Conduct: the code of conduct for CADTH committees approved by CADTH.

COMPUS: Canadian Optimal Medication Prescribing and Utilization Service.

COMPUS Advisory Committee (CAC): the COMPUS Advisory Committee consists of nominees from the participating provincial and territorial health ministries and one representative from the federal publicly funded drug programs. The CAC also has a number of Observers from affiliated organizations. The CAC provides advice to the CADTH Board and the COMPUS Directorate to enable COMPUS to meet its goals and objectives.

COMPUS Directorate: the directorate established within CADTH to deliver the COMPUS program.

Conflict of Interest Guidelines (or COI Guidelines): the conflict of interest guidelines established by CADTH that guide the CADTH expert committee members, reviewers and other external experts.

Core Member: a Member of CERC, including a Public Member, appointed to serve for all Topics under consideration by CERC during such Member's term of office.

Decision: any action/recommendation/advice provided by the Core Members of CERC which does not require the advice of Specialist Experts.

Intervention Tools and Strategies: related COMPUS deliverables that facilitate the optimal prescribing and utilization of drugs, leading to optimal health outcomes and cost-effective use of drugs:

- Intervention tools – deliverables (e.g., didactic presentation, newsletter, decision support aid, quick reference prescribing aid) aimed at influencing behaviour on prescribing and utilizing drugs and designed to assist in the implementation of COMPUS key messages.
- Strategies, activity(ies), program(s) or policy(ies) – that support the adoption of optimal therapy by prescribers, patients, or governments, and advice for jurisdictions and other stakeholders for implementing, monitoring and evaluating the uptake and impact of intervention tools.

Member: a Member of CERC, including a Core Member and a Specialist Expert.

Optimal Therapy (OT): an evidence-based approach to prescribing or using drugs that is clinically effective and cost-effective and that contributes to optimal health outcomes

Optimal Therapy Initiative (OTI): an activity, program, intervention, or policy aimed at encouraging patients, healthcare professionals, and others to adopt Optimal Therapy (e.g., public service messages, patient education materials, physician educational programs).

Optimal Therapy Recommendations: evidence-based recommendations for prescribing and utilizing drug(s) (i.e., optimal therapy)

Public Member: a person selected to be a Core Member of CERC in the capacity of a member of the general public and not as a representative of any specific interest, group, or organization.

Recommendation: an action/recommendation/advice provided by CERC on the basis of its assessment of the supporting evidence.

Specialist Expert: a Member of CERC with expertise in a Topic area, appointed to provide expertise in recommending Optimal Therapy related to the Topic area.

Stakeholders: patients and consumers, manufacturers who make and market medications, physicians and others who prescribe medication, pharmacists who dispense medication and provide pharmaceutical care, other health care providers who may influence medication use, and payers who are responsible for covering the cost of a medication (in essence, an individual or group that may be involved in the use of prescription drugs from manufacturing to consumption).

Topic: prescribing and utilization of drugs, management of conditions or other areas of interest identified by the COMPUS Advisory Committee as the subject for which Optimal Therapy is to be identified, evaluated and promoted by COMPUS.

APPENDIX 2

COMPUS Expert Review Committee (CERC) Nominating Committee Terms of Reference

1.0 CERC Nominating Committee

1.1 Composition

The CERC Nominating Committee shall be composed of the following members who shall each have the right to vote at meetings of the CERC Nominating Committee:

- a) CAC Chair;
- b) Three (3) CAC representatives;
- c) CERC Chair;
- d) One member appointed from and by the CADTH Board of Directors; and
- e) The most senior staff person from the COMPUS Directorate

The CERC Chair shall abstain from participating in any discussion, and from voting, on the nomination of any candidate to fill the vacancy, or anticipated vacancy in the office of Chair of CERC.

1.2 Role and Responsibilities Relating to Nomination of Core Members

The role and responsibilities of the CERC Nominating Committee shall be:

- a) to receive nominations for appointment of Core Members to CERC;
- b) to identify potential candidates for appointment as Core Members to CERC;
- c) to maintain a record of all nominations received;
- d) to recommend to the CADTH Board of Directors, on request, a slate of candidates to fill vacancies of Core Members.

1.3 Meeting Attendees

In addition to the members of the CERC Nominating Committee, only the following persons shall be entitled to attend meetings of the CERC Nominating Committee but without the right to vote:

- a) the CADTH President and CEO;
- b) CADTH staff person acting as recording secretary.

The CADTH staff attending the meeting shall serve as resource to the CERC Nominating Committee. They provide administrative and secretariat support. They shall also assist in obtaining additional information at the CERC Nominating Committee's request.

2.0 Nomination of Candidates for Appointment as Core Members

2.1 The nomination process for candidates for appointment as Core Members of CERC shall be:

- a) CADTH advises the CERC Nominating Committee of all vacancies and anticipated vacancies;
- b) CADTH shall publish a notice of CERC vacancies and anticipated vacancies on the CADTH web site and shall, through electronic means or otherwise, inform subscribers to its subscription service of the notice.
- c) Federal, provincial and territorial jurisdictions, relevant health professional bodies, individual health and other professionals, and the general public may propose to the CERC Nominating Committee, upon being notified of vacancies and anticipated vacancies, nominees that meet the member qualifications set out in the CERC Terms of Reference. The CERC Nominating Committee may also propose nominees.
- d) The name and short *curriculum vitae* of each nominee, together with a short rationale supporting the nomination, must be submitted to the CERC Nominating Committee with each nomination.
- e) The Nominating Committee keeps a record of all nominations received.
- f) From time to time, at CADTH's request, the CERC Nominating Committee recommends to the CADTH Board of Directors a slate to fill vacancies, having regard:
 - a. In the case of a Public Member, to the candidate's qualifications and suitability with reference to the Profile of Public Members of the CADTH Expert Advisory Committees in Appendix 3; and
 - b. In the case of other Core Members, to the candidate's:
 - i) qualifications;
 - ii) expertise/credentials in disciplines related to the prescribing or dispensing and use of drugs within the Canadian context and/or evaluation or critical appraisal and/or experience in developing guidelines;
 - iii) experience on a drug advisory or other expert committee. (This will be considered an asset but is not a requirement.);
 - iv) ability to comply with the COI Guidelines;
 - v) availability/commitment of time to participate fully in CERC.
- g) The Nominating Committee's recommended slate of candidates shall:
 - i) in the case of CERC's Chair, propose one candidate only;

- ii) in the case of CERC's Vice-Chair, propose one candidate only; and
- iii) in the case of CERC's other Core Members, propose a number of candidates equal to the number of vacancies to be filled, plus three.

2.2 The recommended slate shall be accompanied by the *curriculum vitae* and written rationale in support of each proposed candidate.

2.3 After due consideration, the CADTH Board of Directors may appoint as Core Members those candidates selected from the slate recommended by the CERC Nominating Committee.

3.0 General Provisions

3.1 Agenda

Nominating Committee meeting agendas shall be developed by the committee Chair in conjunction with the COMPUS Directorate.

3.2 Conflict of Interest Disclosure

At the commencement of each meeting, the Chair shall ask members if they have any conflicts of interest to disclose. Any member with a conflict must disclose such conflict and comply with the Conflict of Interest Guidelines and Code of Conduct.

3.3 Quorum

A majority of the members appointed to the Nominating Committee shall constitute a quorum at meetings of the committee

3.4 Decisions

No decision can be made unless there is a quorum. Decisions will typically be made by consensus. If a vote is necessary, a simple majority of the quorum is required.

3.5 Records of Meetings

Minutes shall be kept of all Nominating Committee meetings and shall be signed by the Chair.

A copy of the minutes of every committee meeting shall be sent to members of the committee, relevant CADTH staff and the CADTH President and CEO.

3.6 Remuneration and Honoraria

A reasonable remuneration or honoraria for all non-jurisdictional Nominating Committee members shall be fixed by CADTH.

Committee members shall be entitled to be paid reasonable expenses incurred by them in the performance of their duties.

3.7 Indemnity

Every Nominating Committee member shall be indemnified and saved harmless by CADTH from and against:

- a) all costs, charges, and expenses which such members sustains or incurs in or about any action, suit or proceedings, which is brought, commenced or prosecuted against him or her, or in respect of any act, deed, matter or thing whatsoever, made, done or permitted by him or her, in or about the execution of the duties of such member or in respect of any such liability;
- b) all such other costs, charges, and expenses which he or she sustains or incurs in or about or in relation to the affairs thereof, except such costs, charges or expenses as are occasioned by his or her own wilful neglect or default.

3.8 Secretariat and Administrative Support

Secretariat and administrative support for the Nominating Committee is provided by CADTH.

3.9 Amendment to the Terms of Reference

These Terms of Reference may be amended at any time, and from time to time, by the CADTH Board of Directors.

3.10 Code of Conduct

Every person attending the Nominating Committee meetings must abide by the Code of Conduct.

3.11 Conflict of Interest Guidelines

All Nominating Committee members must undertake in writing to abide by the terms of the Conflict of Interest Guidelines.

APPENDIX 3

Profile of Public Members of the CADTH Expert Advisory Committees

Definition

For purposes of the CADTH Expert Advisory Committees, a Public Member is a person selected to be a member of a committee in the capacity of a member of the general public and not as a representative of any specific interest, group, or organization.

General

All members are expected to comply with the Terms of Reference of the committee, including the provisions governing conflict of interest.

Time Commitment

Members of the Expert Advisory Committees will be advised at the commencement of the nomination process, the estimated number of meetings per year they should expect to prepare for and attend.

Knowledge, Experience and Abilities

- Knowledge of, or interest in, issues related to the health care system
- Knowledge of, or interest in, issues relevant to CADTH's mandate and the mandate of the committee
- Experience in committee and/or community work
- Demonstrated awareness of, and interest in, the perspectives of members of the general public on issues related to health care services and medicines
- Ability to act with integrity and independence of specific interests
- Ability to relate to and respect a diverse range of values and beliefs
- Ability to gain respect and credibility within a diverse range of stakeholders and the wider public
- Ability to work constructively as a member of a team
- Ability to form constructive working relationships
- Ability to communicate effectively
- Ability to review and synthesize considerable amounts of information