Canada's Drug Agency
L'Agence des médicaments du Canada
Drugs. Health Technologies and Systems. Médicaments, technologies de la santé et systèmes.

Deliberative Framework for Expert Committees at Canada's Drug Agency

As part of ongoing quality improvement work by Canada's Drug Agency (CDA-AMC) on its deliberative processes for expert committees, CDA-AMC has developed a new deliberative framework. The deliberative framework is intended for use across all of the expert committees at CDA-AMC, and it explicitly outlines the domains of value that should be considered by the committees.

The use of an explicit deliberative framework ensures consistent, transparent reasoning, and supports legitimate, impartial, and inclusive deliberations.[1] It also aligns deliberations with decision-makers' needs and strengthens public confidence in the legitimacy of the deliberation and the subsequent recommendations and/or guidance.

In evaluating health technologies with the deliberative framework, expert committees at CDA-AMC are asked to consider 5 domains of value: Clinical Value, Unmet Clinical Need, Distinct Social and Ethical Considerations, Economic Considerations, and Impacts on Health Systems.

Clinical Value

Description

Clinical value is the value that patients derive from a health technology in terms of its effect on their health and health-related quality of life. The determination of the clinical value of a health technology requires the measurement of its clinical benefits and harms and an assessment of the impact of these effects on patients. Clinical benefits and harms are assessed against relevant comparators.

Considerations

- Whether the technology under review demonstrates at least comparable clinical value (if expected to be substitutive treatment) or added clinical value (if expected to be additive treatment)
- Whether the technology under review demonstrates acceptable clinical value for the full patient population under review or for a subpopulation
- Magnitude of differences in clinical effectiveness and harms between the health technology under review and relevant comparators, and their importance to patients
- Alignment of comparators with clinical practice in Canada
- Importance of outcomes to patients
- Certainty of the clinical evidence
- Assessment of unmet clinical need and whether there should be greater allowance for uncertainty in the clinical evidence

Unmet Clinical Need

Description

Unmet clinical need is the morbidity and/or mortality arising from a condition or symptom that is not addressed effectively by available treatments.

Considerations

- Availability (i.e., public funding status), effectiveness, and harms of alternative treatments
- Severity of the condition
- Challenges with evidence generation due to rarity of the condition or ethical issues (e.g., the patient population includes a vulnerable population, such as pediatric patients)

In addition, the committee is asked to consider the following equity considerations: Are there existing inequities in the availability of alternative treatments across patient populations or jurisdictions that would be addressed by the technology under review?

Distinct Social and Ethical Considerations

Description

This domain addresses the social and ethical implications of health technologies not already assessed in the other domains, and how they affect patients, caregivers, populations, and the organization of health systems.

It includes nonclinical needs, which are the social, psychological, and logistical factors that influence the appropriateness, accessibility, and acceptability of a health technology beyond its direct clinical outcomes.

It also examines the broader social and ethical considerations related to the design, evaluation, and implementation of health technologies.

Considerations

- Patient, caregiver, and provider perspectives and experiences of the condition, as well as expectations of the technology under review, including:
  - accessibility and acceptability of the health technology and relevant comparators
  - care setting (e.g., tertiary, inpatient, ambulatory, community, home care)
  - geographic distribution of health services
  - treatment burden on patients (e.g., psychological, financial, physical, relational)
  - treatment burden on family and caregivers
  - mode of administration
  - referral and/or prescriber requirements
- Respect for persons and communities (e.g., implications for informed consent, stigma associated with the use or implementation of the technology)

- Autonomy and dignity
- Confidentiality and patient privacy (e.g., considerations related to data ownership, retention, and transfer, including biological specimens, or legal or regulatory aspects)
- Implications of uncertainty in the clinical evidence and associated uncertainty in economic evaluations (e.g., distribution of the benefits, risks, and burdens across patients, caregivers, clinicians, or health systems)
- Environmental impacts of the production, use, or disposal of the health technology

In addition, the committee is asked to consider the following equity considerations: Does the patient population include historically disadvantaged or equity-deserving groups? Are there equity considerations for subgroups within the disease or condition addressed by the health technology, and what are the implications for patients who are not eligible for treatment?

Economic Considerations

Description

This domain addresses economic evidence to inform the financial, human, or other resource implications associated with the technology under review, and whether it is worthwhile to allocate resources to the technology under review given its expected clinical benefits. Considerations may include the potential resource or cost impacts of the technology under review versus relevant comparator(s).

Considerations

- Whether all health impacts and costs have been considered and robustly measured
- The magnitude of difference in clinical effectiveness and harms between the health technology under consideration and relevant comparators
- The magnitude of difference in total costs associated with the health technology under consideration and relevant comparators
- Whether there are resource or cost considerations that fall outside the health care system
- Certainty of the clinical and economic evidence

Impacts on Health Systems

Description

This domain comprises 2 distinct but interrelated components: *organizational feasibility of adoption* is the ease with which the health technology can be implemented in the health system while realizing its clinical value, and *economic feasibility of adoption* examines how the adoption of a health technology will economically impact the payer or budget holder.

Considerations

- Expected utilization of the health technology under consideration
- Implications of implementing the health technology for the health system relating to:
  - infrastructure requirements (e.g., treatment with the technology under review requires that all patients access another technology or infrastructure that may not be in place)
  - expected impacts on the use of other technologies or resources (including health human resources)
  - training and competency requirements
- Expected budget impact of implementing the health technology (i.e., expected increase in budget, expected decrease in budget, no change, uncertain or unable to determine)

In addition, the committee is asked to consider the following equity consideration: Are there any factors that need to be addressed to support the equitable implementation of the technology under review?

References

1. Oortwijn W, Husereau D, Abelson J, et al. Designing and Implementing Deliberative Processes for Health Technology Assessment: A Good Practices Report of a Joint HTAi/ISPOR Task Force. *Value Health.* 2022;25(6):869-886.