



Position statement:

Confidentiality of clinical evidence informing health technology assessment decision making

Who are we?

1. CADTH is Canada's drug and health technology agency. It is a not-for-profit organization funded by Canada's federal, provincial and territorial governments to provide independent information and advice about the drugs, devices and services used in Canada's publicly funded healthcare systems.
2. Founded in 2006 and non-profit incorporated in 2013, the Institute for Clinical and Economic Review (ICER) is a non-partisan, independent, go-to-resource for objective evidence about the value of healthcare in the US.
3. The National Institute for Health and Care Excellence (NICE) balances the best care with value for money across the NHS and social care in England, to deliver for both individuals and society as a whole.

What do we do?

4. CADTH, ICER and NICE conduct independent assessments of drugs and other health technologies. Health policy and practice decision makers use our assessments to inform decisions about access to, funding for and appropriate use of drugs, devices, medical, dental and surgical devices and procedures. Our assessments are publicly available.
5. Our agencies operate in different healthcare systems and have our own methods and procedures. However, we have broadly similar aims, and our work is underpinned by common values of health technology assessment (see the [new definition of health technology assessment](#)).

We seek to maximise transparency in our effort to put evidence at the heart of decision making. We owe it to patients, their families, clinicians and all our stakeholders to be clear about the evidence considered when we make, and inform, choices about the allocation of scarce healthcare resources.

6. Given these similarities, we want to work together to identify solutions to shared issues affecting our agencies. This position statement on confidentiality of clinical evidence is the first of these collaborations.

What changes are we making?

7. We are being asked to inform and make decisions ever earlier in the lifecycle of health technologies, when evidence is still maturing and is often unpublished. Recognising this, we have accepted data in confidence and redacted it from public documents. We believe it is now time to change the way we think about confidential information.
8. For evaluations starting after April 2023, NICE technology appraisals and CADTH will no longer routinely redact clinical data that is awaiting publication when we publish our guidance. ICER will allow redaction of data that is formally planned for public release for 12 months, as academic in confidence.
9. For other clinical data, we have defined a list of categories for which we expect the data to be made available in the public domain where it informs the development of our guidance (see appendix A). We will review and update the list as new challenges arise.
10. Respecting the different contexts in which our agencies operate we will have our own policies for managing clinical data for which there is no plan to publish.

11. We will continue to accept redaction of data that is commercially sensitive, such as information around pricing and terms of reimbursement arrangements.
12. We consider it the responsibility of the evidence holder to ensure they respect the principle of transparency, especially when it concerns clinical data that has been sourced directly from people using healthcare services.

Why are we making these changes?

13. There are 4 main reasons for these changes:
 - a) Transparency is critical to public trust in evidence-based decision making in health and a cornerstone of health technology assessment. Other agencies involved in health technology assessment and regulation are demanding increased levels of transparency (see [the European Medicines Agency's page on clinical data publication](#), [EU regulation 2021/2282 on health technology assessment](#) and [the Canadian government's guidance on public release of clinical information](#)).
 - b) It is no longer appropriate to assume that release of clinical evidence as part of an assessment inhibits publication in a medical journal. In this context, the International Committee of Medical Journal Editors (ICMJE) notes that it 'does not consider results or data contained in assessment reports published by health technology assessment agencies, medical regulators, medical device regulators, or other regulatory agencies to be duplicate publication (see the [ICMJE annotated recommendations for the conduct, reporting, editing, and publication of scholarly work in medical journals](#)).
 - c) We want our health technology assessment processes to be streamlined and efficient so we can use our resources on activities important for our users.

d) We accept that those that work with us, and the public at large, expect us to work differently, and we agree with them (see the BMJ Open's [Audit of data redaction practices in NICE technology appraisals from 1999 to 2019](#)).

Suzanne McGurn,
President and CEO

Dr Steven Pearson,
President

Dr Sam Roberts,
Chief Executive

Canadian Agency for
Drugs and
Technologies in
Health

Institute for Clinical
and Economic
Review

National Institute for
Health and Care
Excellence

Appendix A: redaction status of clinical data

CADTH, ICER and NICE have agreed a shared list of categories of clinical data that can be redacted.

Respecting the different contexts in which the agencies operate, we retain the freedom to individualise implementation of this list in our policies.

- For CADTH, redactable means that the confidential information will be removed in all documents that are publicly posted by CADTH. Redactions do not expire after a set period, but CADTH may elect to update a previously posted review report should the redacted information become available in the public domain.
- For ICER, redactable means that the data are marked as academic-in-confidence and redacted for 12 months or when the data becomes publicly available, whichever is sooner.
- For NICE, redactable means that the confidential information will be removed in all documents that are publicly posted by NICE. Redactions do not expire after a set period.

Table 1: Shared list of categories of clinical data and redaction status

Item	Redactable	Rationale
Methods used to conduct a study or to analyse data from a study	No	Methods information is required to understand how inputs are derived and does not predicate inputs that are considered confidential.
Clinical data that are available in the public domain	No	Information that is publicly available is not considered confidential information.
Clinical data not yet in the public domain but either: <ul style="list-style-type: none"> • awaiting publication in a journal or • will be released into the public domain by regulatory authorities 	NICE and CADTH: no ICER: yes	To avoid unnecessary redaction of information which will subsequently become publicly available. Responding to the ICMJE statement that results or data contained in assessment reports published by health technology assessment

		<p>agencies, medical regulators, medical device regulators, or other regulatory agencies are not considered to be duplicate publication (see ICMJE statement).</p> <p>Some clinical data is subject to mandatory disclosure and placed in the public domain as part of transparency policies implemented by regulatory agencies (see the European Medicines Agency's page on clinical data publication, and the Canadian government's guidance on public release of clinical information).</p> <p>Data awaiting presentation at congress that is not in the public domain and with no further public release will be treated as clinical data without a publication plan.</p>
Clinical data that has not been made publicly available and for which there is no plan for the data to become publicly available	Yes	If the data is not in the public domain, then this information is redactable.
Sponsor's indirect comparison that has not been made publicly available and for which there is no plan for the data to become publicly available	Yes (not applicable for ICER)	If the data is not in the public domain, then this information is redactable.
Data from real-world evidence studies that has not been made publicly available and for which there is no plan for the data to become publicly available	Yes	If the data is not in the public domain, then this information is redactable.
Critical appraisal of clinical studies and indirect comparisons	No	This is not considered to be confidential information and will not be redacted.
Data derived from opinion or assumption	No	This is not considered to be confidential information and will not be redacted.
References	No	Referencing is required to understand from where inputs and assumptions are derived and does not predicate inputs that are considered confidential.

Figure 1 Question flowchart to inform redaction status

