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Bringing us together or pushing us apart

Will JCA, HEMA, and other cross-border collaboration initiatives improve patient access?

ISPOR Educational Symposium

May 14, 2025

Our expert panel

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Disclaimer: The information provided in this presentation does not constitute legal advice. Cencora strongly encourages the audience to review available information related to the topics discussed during the presentation and to rely on their own experience and expertise in making decisions related thereto.

Poll question

Which of the following most closely describes your organization?

- Academia
- Pharmaceutical and/or device manufacturer
- Healthcare consulting
- Government and/or healthcare policy group
- Other

Today's topics

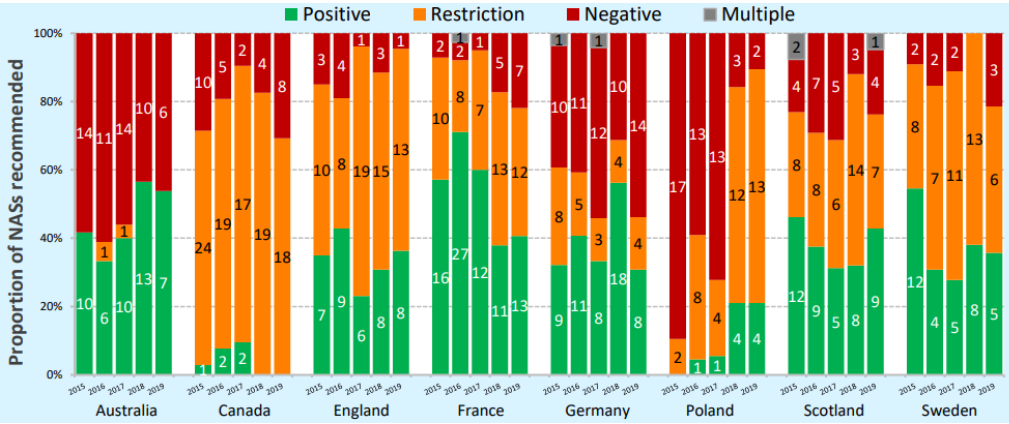
- Introduction to cross-border HTA collaboration
- Collaboration for sharing workload
- Collaboration for sharing methods
- Collaboration for sharing intelligence - the Canadian experience
- Conclusions

Introduction to cross-border HTA collaboration

Why do we need cross-border collaboration in HTA?

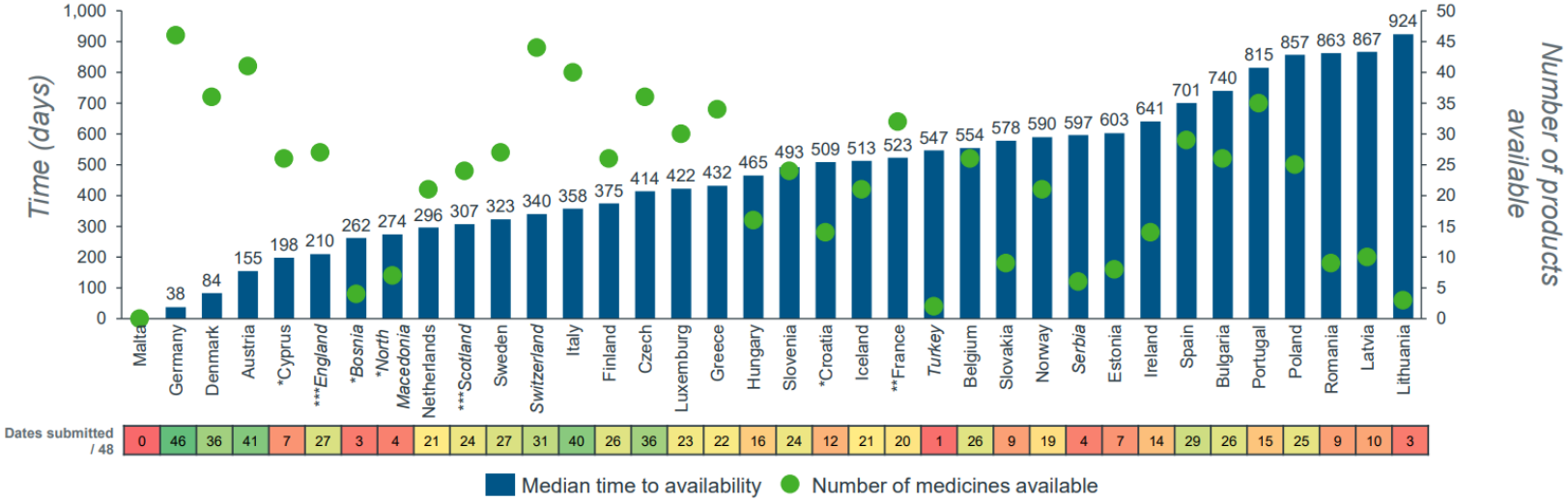
- Health technology assessment (HTA) agencies share the common goal of enabling patient access to new treatments
- However, HTA evaluations of value and benefit vary greatly across markets/countries:
  - Differing evaluation processes
  - Varied methods to determine value/benefit
  - Individual guidelines for how to apply benefits (eg, weighting, thresholds) resulting in highly divergent pricing and reimbursement decisions

HTA recommendation comparison across countries between 2014-2018



How do these approaches to HTA impact patient access?

Differing methodology and appraisal criteria for HTA results in wide variation in availability of treatments across Europe



EFPIA, Patients WAIT indicator survey, 2024

Cross-border collaborations for HTA – broad aims

Sharing workload and coordinated assessment (equitable access across members)

- EC HTAR (JCA): European Commission HTA regulation (Joint Clinical Assessment)
- JNHB: Joint Nordics HTA-Bodies

Sharing methods, innovation, and best practices

- HEMA: Health Economics Methods Advisory initiative

Sharing intelligence and information (alignment of frameworks, horizon scanning)

- Confidentiality of Clinical Evidence Informing HTA Decision-Making position statement
- BeNeLuxAIr: Belgium, Netherlands, Luxembourg, Austria, Ireland

Joint Nordic HTA-Bodies (JNHB)

Successful cross-border HTA collaboration

- Formerly FINOSE, re-launched as the JNHB in June 2024
- Joint assessments include clinical efficacy and relevant economic evaluation components
- **Aim is to accelerate availability of new medicines through collaboration**
- 4 assessments conducted since June 2024
  - Focus on oncology and rare disease
  - Mean assessment time: 82 days

JNHB members include:

- Danish Medicines Council (DMC)
- Finnish Medicines Agency (Fimea)
- National University Hospital of Iceland (Landspitali)
- Norwegian Medicines Products Agency (NOMA)
- Swedish Dental and Pharmaceutical Benefits Agency (TLV)

Nordic collaboration through JNHB – Fimea; Assessments - JNHB

What is the Joint Clinical Assessment (JCA)?

New EU-wide HTA process; a single clinical assessment occurring in parallel with the European Medicines Agency (EMA) marketing authorization process

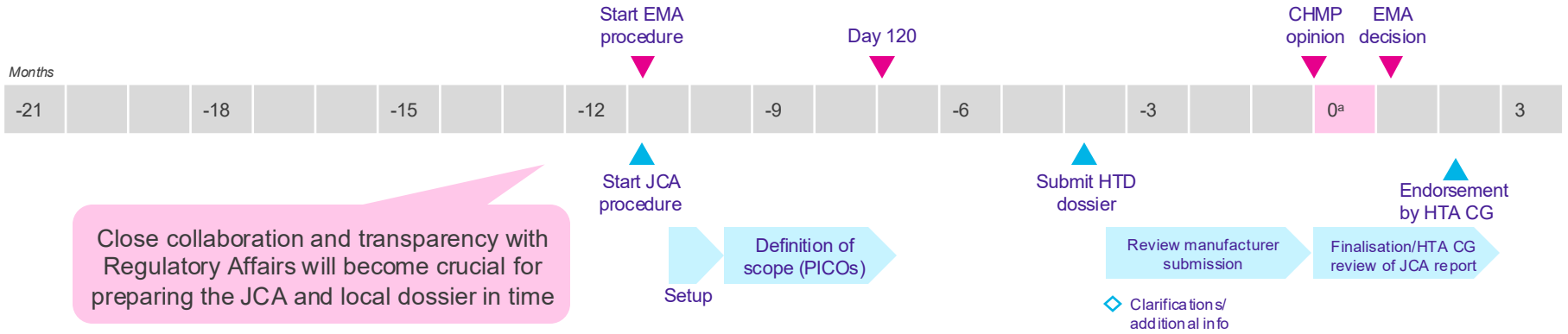
- Integral part of the EU HTA Regulation
- Focus is on relative effectiveness; price & economics are out of scope
- Reliant solely on the review of the manufacturers evidence submission
- High level of transparency expected in final public report
- Legally non-binding, but countries expected to give “due consideration” to its conclusions

Overall aims of the process are to:

- Harmonize processes and evidence requirements
- Avoid duplication of dossier development for manufacturers
- Accelerate patient access across its member states (“solidarity”)

What is the process & submission requirements?

Overall process, from initiation to publication of the JCA, is expected to take 13 months; endorsement of the final report is expected 30 days after EMA approval



Key: CHMP – Committee for Medicinal Products for Human Use; CG – (member states) coordination group; EC – European Commission; EUnetHTA – European Network for Health Technology Assessment; HTA – health technology assessment; JCA – Joint Clinical Assessment; PICO – population, intervention, comparator, outcomes.

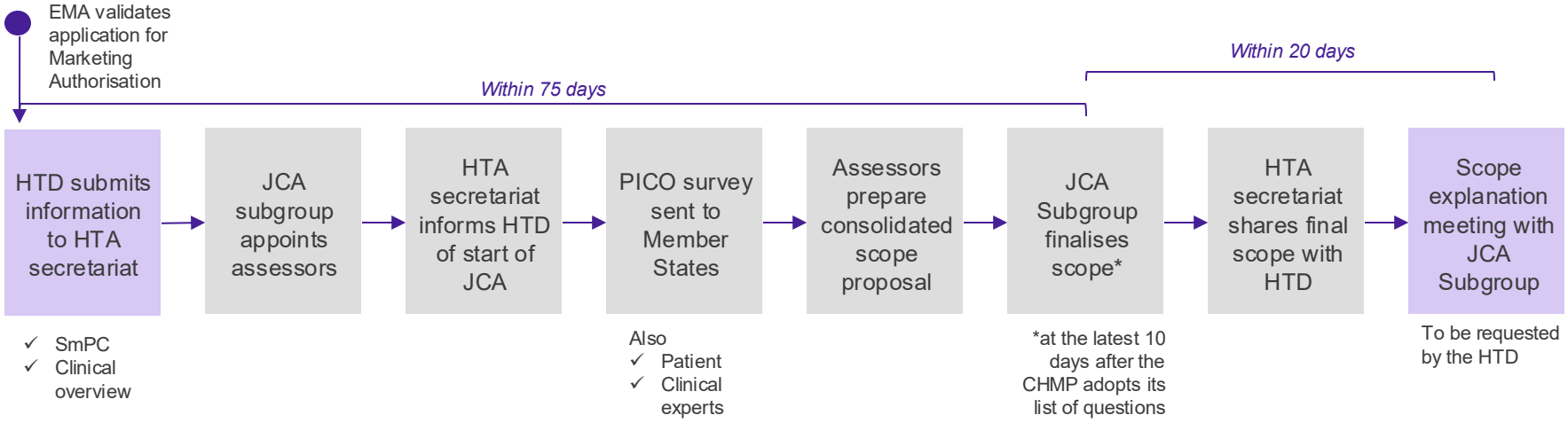
[a] Time zero (T0), months = date of CHMP opinion.

Based on new medical entity, assuming average regulatory timelines. Representative of published timelines by EUnetHTA in July 2023. https://www.eunethta.eu/wp-content/uploads/2023/07/July-13-HTD-meeting-D5.1-and-D5.4.pdf

What is the process & submission requirements?

No industry input

Defining the scope of the JCA entails surveying all 27 member states of the EU on what population, intervention, comparators and outcomes (PICOs) should be addressed by the procedure



HTD – health technology developer; JCA – joint clinical assessment; PICO – population, intervention, comparator, outcome. Source: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401381

What is the health economics methods advisory (HEMA) initiative?

International working group created to foster collaborative, independent research into new health economic methods and processes for HTA

- Canada's Drug Agency (CDA-AMC); US-based Institute for Clinical and Economic Review (ICER); England's National Institute for Health and Care Excellence (NICE)
- Focus is on methods (potential benefits, limitations, and uncertainties, novel methods, suggestions for future research)
- First topic (March 2025): What treatment benefits are appropriate to consider in HTA decision-making?

Overall aims of the process are to:

Examine pressing topics from independent perspective

Provide guidance and recommendations for HTA community

Coordinate the development of publications

ICER, NICE, and Canada's Drug Agency Convene the Health Economics Methods Advisory - ICER

How is HEMA structured?

International collaboration focused on theoretical research and **practical application** of HTA methods

Organized into a Working Group and a Steering Committee

Explicit goal of including diverse perspectives, experience, and geographies to inform HTA decision-making

Includes representation from patient organizations, academic institutions, pharmaceutical and life sciences groups, payers, and policy groups across Canada, UK, and US

9

Member working group

8

Member steering committee

Steering Committee guides the selection and prioritization of research topics

ICER, NICE, and Canada's Drug Agency Convene the Health Economics Methods Advisory - ICER

Poll question

How do you think cross-border collaboration will impact patient access to new therapies?

- Large positive effect
- Small positive effect
- No/very limited effect
- Small negative effect
- Large negative effect
- Unsure/don’t know

Collaboration for Sharing Workload and Facilitating Patient Access

Michael Drummond, DPhil

Professor Emeritus
Centre for Health Economics
University of York, UK

What are the main challenges? (1)

Depending on the diversity of the jurisdictions, the current standard of care may vary

Different decision-makers may have different preferences for various clinical and patient-reported outcomes

Taken together, these considerations may imply a large number of PICOs* to be examined[1]

In the context of JCAs, the EU HTA Coordinating Group (HTA CG) is keen to keep the number of PICOs to a manageable level

* PICO = Population, intervention, comparator, outcome

1. Cencora. *HTA Quarterly* Winter 2024

What are the main challenges? (2)

Decision-makers in different jurisdictions may have different views on the validity or relevance of elements of the analysis

These include, but are not confined to:

- the validity of various types of clinical studies (eg, RCTs vs others)
- the role and use of real-world evidence
- the validation of surrogate outcomes
- evidence synthesis: direct and indirect comparisons
- the relevance of patient reported outcomes

Some of these issues can be handled in joint assessments by using sensitivity analysis

In the context of JCAs, the Member State Coordinating Group of HTA (HTA CG) has issued guidance on many of these topics

What does it mean for the pharmaceutical industry?

- Manufacturers are only required to submit their core clinical evidence once, rather than multiple times to different HTA bodies
- However, manufacturers will still need to engage with the different HTA bodies' local processes and procedures, which can vary considerably and may have to change to make the best use of the joint assessments[1]
- In some cases, the analyses conducted for the joint assessment may be sufficient for the HTA body to make a coverage, or reimbursement, recommendation for a new product, but the likelihood of this is currently unclear in the case of JCAs
- To meet local decision-making needs, HTA bodies in EU member states are allowed to ask the company for additional data
- Those jurisdictions currently requesting economic evaluations may still require companies to submit a dossier containing economic analyses, consistent with their local guidelines

[1]Wang T, McAuslane. Ensuring the efficiency and effectiveness of Joint Clinical Assessment in national HTA decision-making: insights from the 2024 CIRS multi-stakeholder workshop. Journal of Market Access and Health Policy 2025;13:9`doi.org/10.3390/jmahp13010009

What's the potential impact on patient access?

It is likely that JCAs will lead to the clinical component of HTAs being completed faster across the EU as whole, offering the potential of earlier patient access

However, the 'economic' component of HTA, including economic modelling and/or price negotiation, remains the responsibility of individual jurisdictions

Depending on the nature of the product and the manufacturer's price expectations, this can be the most difficult and time-consuming part of the HTA process

In addition, jurisdictions can still request the collection of additional data and/or propose managed entry schemes

Although the EU regulation will increase the availability of clinical assessments for more jurisdictions, in many cases the main barrier to patient access remains the jurisdiction's ability or willingness to pay

Overall, the existence of JCAs is unlikely to reduce patient access, but may not increase it very much

Summary

- Collaboration of HTA bodies to share workload makes sense for the resource-intensive tasks in HTA if the results are generalizable across settings
- Collaboration is likely to be more successful if:
  - the current standard of care is similar across settings
  - there is a convergence of views on the key methodological principles
  - the local HTA processes can be adapted to use the results of the joint work effectively

Collaboration for sharing methods

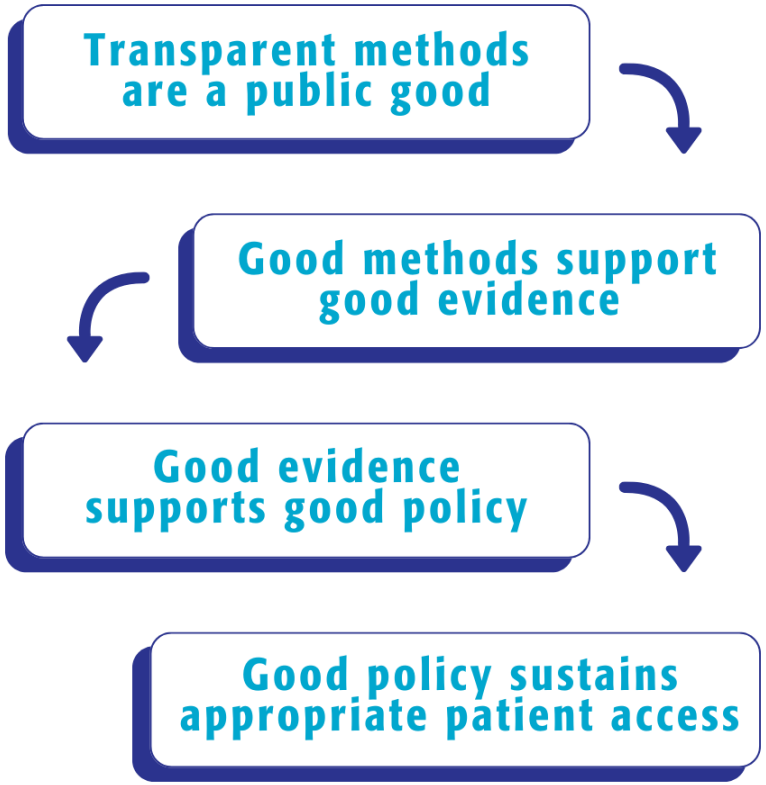
Jon Campbell
NPC Chief Science Officer
ISPOR Montreal, May 2025

National Pharmaceutical Council®

Does Sharing = Caring (As It Relates to HTA Methods and Patient Access)?

National Pharmaceutical Council®

How Are HTA Methods & Patient Access Connected?



What Are Examples of Good Methods?

ISPOR Good Practices & Special Task Force for U.S. Value Assessment

Second Panel on Cost-Effectiveness in Health & Medicine

NPC's Guiding Practices for Patient-Centered Value Assessment

HTA Inputs:
Environmental Context + Science + Judgment
→ Tool, Not Rule

When Are Methods & Patient Access Aligned?

1. Best practices & methods sharing are transparent
2. Environment (e.g. supply chain) misaligned incentives are mitigated/minimized
3. Methods are fit for purpose (priorities vary by jurisdiction)

= Theory vs. Practice: Does Value → Patient Access?

Challenges Aligning Methods & Patient Access: Judgment Can Influence Methods

A health economist serves on HEMA and receives funding from HTA agencies to co-author report

What outcome is predicted if the health economist and HTA agencies share the position that drug prices are "too high"?

The health economist is assigned to co-write a project on assessing treatment benefits

Predicted outcome: a limited set of treatment benefits are best for inclusion within HTA exercises

Challenges Aligning Methods & Patient Access: Environment & Context Matter

Tomorrow's access can be conditioned on today's access

NPC Research at ASCO: Access to initial and subsequent indications of new oncology drugs: A U.S.-Canada comparison

Today's standard of care becomes tomorrow's therapeutic alternative

Industry Insights on JCA & Patient Access

Unscientific Straw Poll of Industry Members

How do you view the JCA to impact patient access (over 5 years in Europe)?

- 7 votes small (or large) negative impact
- 2 votes neutral or small positive impact

How do you view the JCA to impact patient access (over 20 years, globally)?

- 6 votes small (or large) negative impact
- 3 votes neutral or small positive impact

Summary

We all have a role to play in promoting best practices and good methods!

Be aware — applying good methods in theory & practice

- Judgment and its role in scientific research
- Environment and its role in lumping versus splitting regarding collaborative research

Like any evidence, HTA evidence requires judgment and is specific to its environment suggesting that the findings may be useful tools given the appropriate context (not rules)

Collaboration for sharing information and intelligence

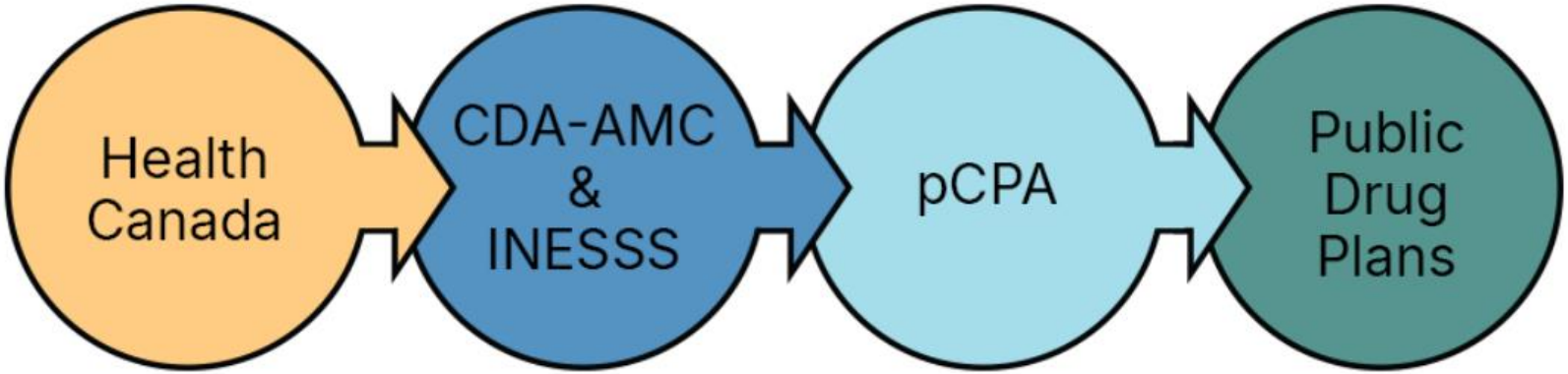
The Canadian experience

Eldon Spackman
Associate Professor
Faculty of Medicine, Department Community Health Sciences

May 14, 2025

The Canadian Experience: Collaboration to a Point

- Canada's healthcare system is publicly funded and administered, with provincial and territorial governments primarily responsible for its delivery.

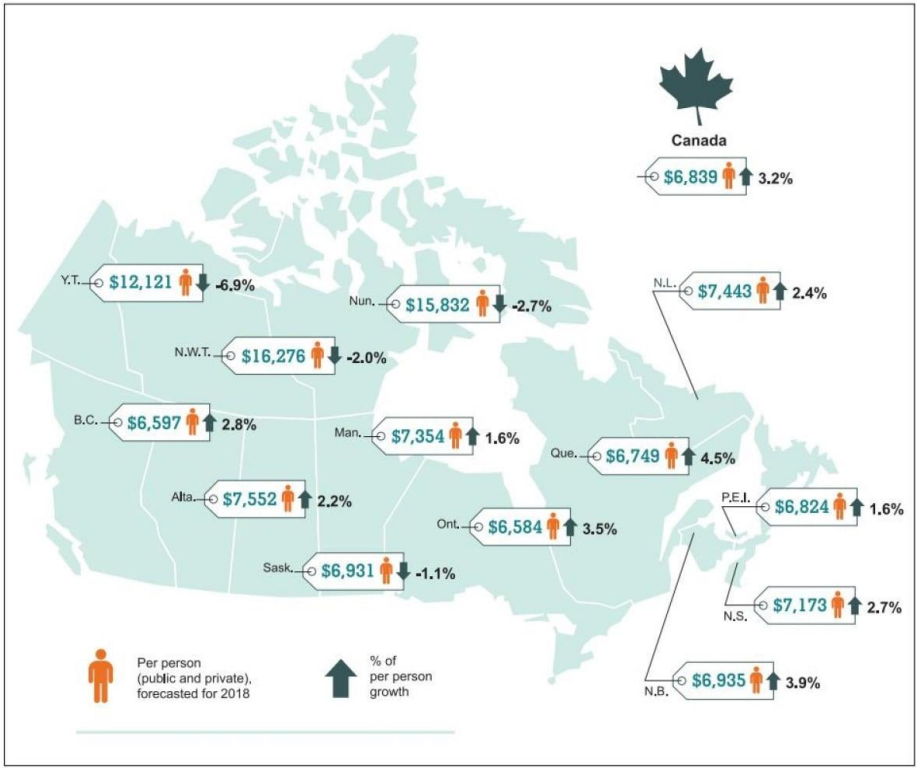


The Good

- Advantages
  - Reduce duplication
  - Optimize resource utilization
  - Consistency in processes
  - Bargaining power?
  - Allows for Differences

… and the Bad

- Challenges
  - Different context
    - Populations
    - Needs
  - Different systems
  - Different costs



REPORT CARD

Health Indicators

	Canada	N.L.	P.E.I.	N.S.	N.B.	Que.	Ont.	Man.	Sask.	Alta.	B.C.	Yukon	N.W.T.	Nunavut
Life expectancy	B	C	C	C	B	B	A	C	D	B	A	D–	D–	D–
Premature mortality	B	B	B	B	B	A	A	D	D	B	A	C	D–	D–
Infant mortality	C	D	B	C	B	C	C	D–	D–	D	B	C	D–	D–
Self-reported health	A	A	A	A	A	A+	A+	A+	A	A+	A	A	A+	A
Self-reported mental health	A	A	B	B	B	A	A	A	A	A	B	B	B	D
Mortality due to cancer	B	D	C	D	C	C	B	C	B	A	A	D–	D–	D–
Mortality due to heart disease and stroke	B	C	C	B	B	A	B	B	B	C	B	B	C	A
Mortality due to respiratory diseases	B	C	C	C	C	B	B	B	B	B	B	D	D	D–
Mortality due to diabetes	C	D–	B	C	C	B	C	D	D	B	C	D–	A	A+
Mortality due to nervous system diseases	B	B	B	B	B	B	B	B	B	B	B	B	A	A
Suicides	B	B	A	B	B	B	A	B	C	B	B	A	C	D–

Note: Data for the most recent year available were used. For details on methodology and data sources, see the "Methodology & Data" section of this website.
Source: The Conference Board of Canada.

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International Collaborations

- Health Economics Methods Advisory [HEMA]
- Position statement: Confidentiality of clinical evidence informing health technology assessment decision making

Example: CDA-AMC Therapeutic Review for COPD drugs

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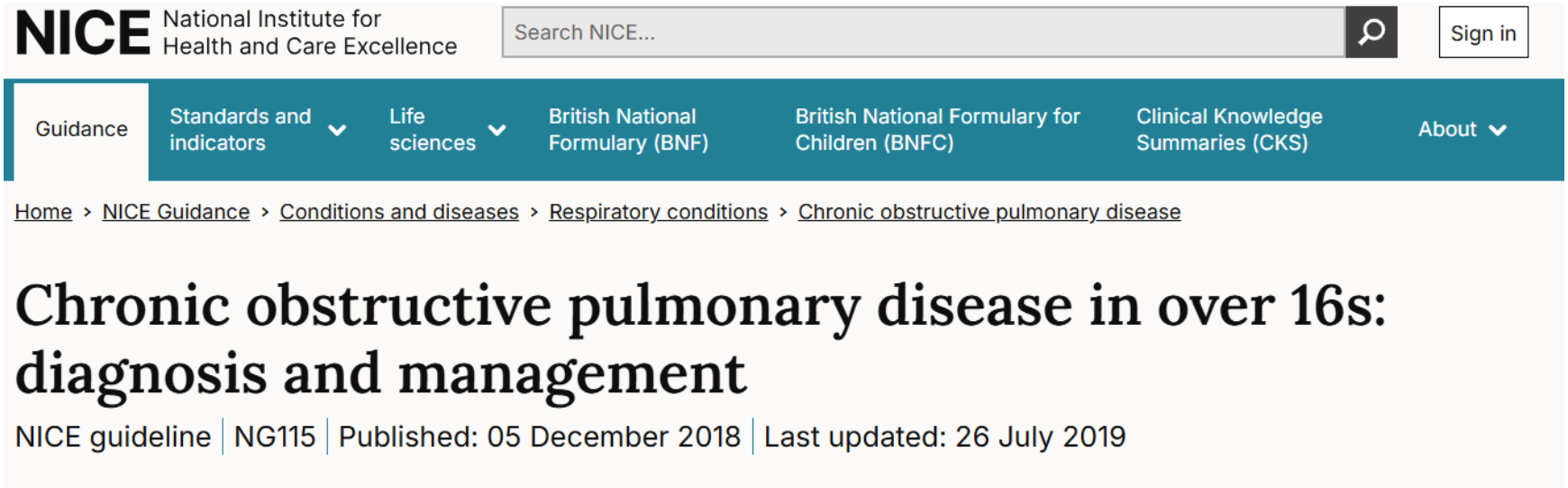

Summary

- Reduce resources for HTA and manufacturers
  - Could reduce the complexity of thought, if not critical
- Lead to faster decisions
- More consistency

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Conclusions

Cross-border collaboration in HTA

Summary and conclusions

Benefits

- ✓ Shared (reduced) workload
- ✓ Increased speed to access
- ✓ Alignment/refinement of methods
- ✓ Increased transparency and consistency of decision-making

Challenges

- ✓ Local context is key
- ✓ Local decisions on:
  - ✓ Reimbursement
  - ✓ Pricing/cost-sharing
  - ✓ Place in therapy/clinical guidelines and standard of care

Will continue to result in variation across jurisdictions in patient access and outcomes

Poll question

How do you think cross-border collaboration will impact patient access to new therapies?

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Q&A


Thank you धन्यवाद Děkujeme Mange
takk Vă mulțumesc Gracias Vielen D
شكراً لك Teşekkürler Dėkojame jum
спасибо Merci 谢谢 Obrigado ありが
ございました cảm ơn bạn Paldies 감사합
Hartelijk dank Thank you धन्यवाद Dě
Mange takk Vă mulțumesc Gracias
Vielen Dank شكراً لك Teşekkürler D