

Why open source?

Good science



Efficiency savings



Improved methods



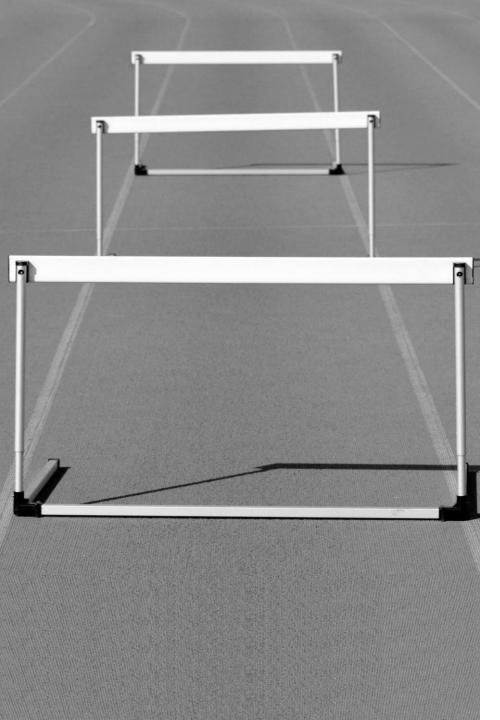
Better decisions



Learning







Transparent modelling initiatives come in different flavours

OPEN DEVELOPMENT (E.G. IVI)

- ✓ Stakeholder buy-in
- ✓ Reporting standards

MODEL SHARING (E.G. PEER MODELS NETWORK)

- ✓ Open access
- ✓ Interoperability

COLLABORATION (E.G. MOUNT HOOD)

- ✓ Experts only
- ✓ Methods development





SIG survey findings

- Use by HTA agencies is a very important signal
- Lack of interest from decision-makers perceived as a key barrier
- Concerns about commercial barriers and difficulties with data sharing

ISPOR Report

Opportunities and Barriers to the Development and Use of Open Source Health Economic Models: A Survey

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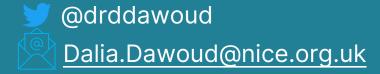
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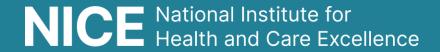
The Industry Professional @regilardino

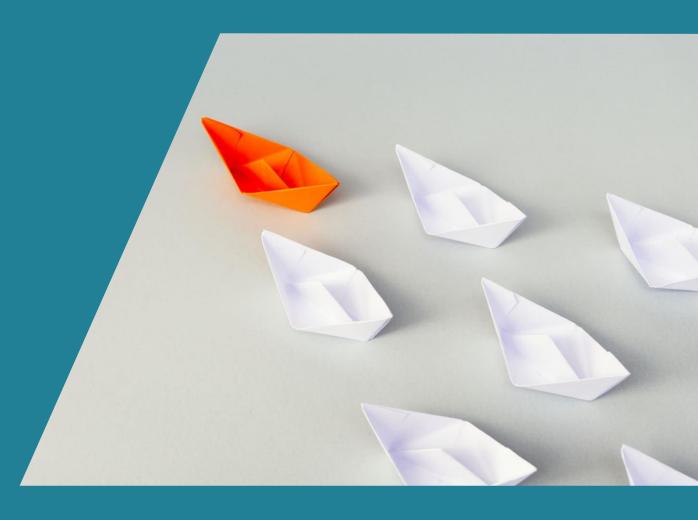
Are open-source models really for HTA and policy?

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Disclaimer

- No conflicts of Interest to Declare
- Views expressed are my own and not those of NICE
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Why not?

- Confidentiality
- Ownership
- Maintenance and updating
- Complexity
- •Experience and skills
- •Resistance to change
- •Industry's resistance



Why?

- Transparency
- Collaboration
- Efficiency
- Peer reviewing
- Functionality
- Innovation

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COVID-19 Best Practice Guidance



Best-practice guidance for the health technology assessment of diagnostics and treatments for COVID-19

Authors

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On behalf of the COVID-19 HTA best-practice guidance development group*

October 2021

Assessing effectiveness

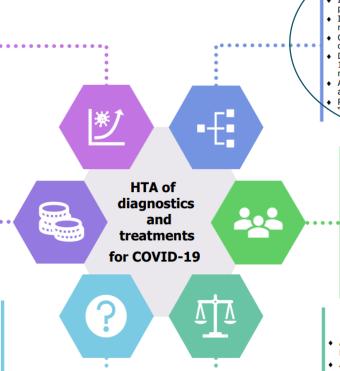
- Adaptive RCTs preferred for efficacy
- Promote high-quality RWE to fill evidence gaps
- Use "living" evidence reviews
- Carefully consider generalisability to the relevant setting
- Prespecify subgroup analyses
- Refer to the list of suggested core outcomes and core outcomes sets

Assessing value for money

- Use cost—utility analysis, if usually preferred, with supportive costeffectiveness and cost-consequence analyses where useful
- Consider both a healthcare and a broad societal perspective
- Use robust data from related conditions where necessary
- Use usual threshold values, but engage in research about preferences during a pandemic

Handling uncertainty

- Transparently report evidence gaps, assumptions made and the pandemic context
- Extensive subgroup, extreme value and threshold analyses
- Use probabilistic analysis
- Consider using value of information analysis to inform research priorities
- Mitigate uncertainty by implementing a "living" HTA approach
- Responsively update decisions (including reinvestment and disinvestment) based on new information



Economic modelling

- Ideally, use simulation models to account for patient heterogeneity
- Include long-term outcomes, disease transmission and system capacity
- Calibrate uncertain inputs to ensure plausible outputs, e.g. using RWE
- Develop a whole-disease model for COVID-19, as an epidemiological (SEIR) model with nested diagnosis and treatment components
- Allow simpler analyses where they may be acceptable for decision-making
- Regularly update the model to support "living" HTA

Stakeholder engagement

- Ensure a broad range of stakeholders can contribute to HTA process
- Including citizens, patients, carers and proxies, and organisations that represent specific groups who are at higher risk or underrepresented
- Prioritise based on a tiered approach
- Consider novel approaches to engagement, such as digital and online tools

Other important factors

- Affordability should be assessed using budget impact analysis
- Affordability concerns should trigger commercial discussions
- A "living" HTA approach would facilitate managed access agreements
- Consider other potentially relevant elements of value, including equity, reduced fear of contagion, and scientific advancement
- Try to capture them quantitatively (e.g. in utility values), otherwise narratively

"Living" HTA

- Mitigate uncertainty by implementing a responsive approach
- Review decisions in response to new information
 - Including disinvestment
 - Health Technology Management
- Develop a COVID-19 whole-disease pathway simulation model
 - Flexible, modular, transparent
 - Responsive & ongoing updates
 - Facilitate rapid decision making & prioritisation

Practical considerations

- Commissioning & ownership
- Data access & transfer
- Ongoing management
- Review & critique
- Barriers to use

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Are open-source models really for health technology assessment and health policy?



Objectives for making models publicly available:

Transparency external verification and validation

Consistency reusing trusted models in specific settings

Efficiency leveraging code from previous work

Innovation disseminating examples for new methodologies



Conceptual / policy considerations:

- (Corporate) transparency and thought leadership
- False sense of transparency and quality:
 - The model does not detail the modelling process
 - Open-source models are not necessarily good models
- Framework for claiming open-source in this context:
 - Value of publishing models vs. data
 - External peer-review process
 - Mandatory use of models



Technical / practical considerations:

- Data sharing and the (potential) role for synthetic data
- Resources and expertise for reviewing OSM outside of HTA process
- Timing / triggers, responsibility and funding for model updating
- Documentation and certification of updated model versions

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Are open-source models really for health technology assessment and health policy?

November 7, 2022

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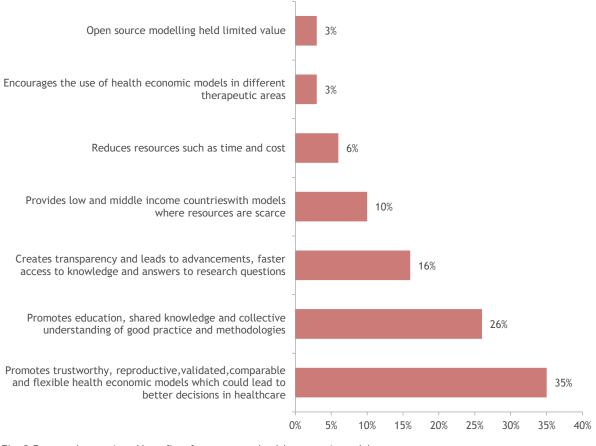


Disclaimer

The view and opinions expressed as part of this presentation are those of the author and do not necessarily reflect the official policy or position of Bristol Myers Squibb.

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What are the stakeholder's consideration about OSMs



How important do you consider each of the following potential uses of OSMs?

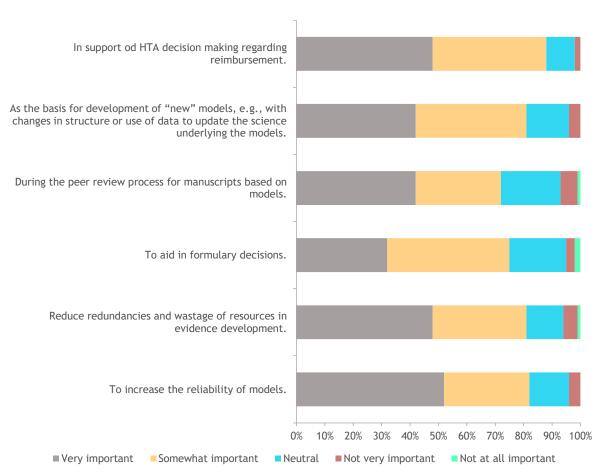


Fig. 2 Frequently mentioned benefits of open-source health economic models



Making health economic models available in an open format was considered beneficial by the different stakeholders independently of their purpose

Dunlop WCN, Mason N, Kenworthy J, Akehurst RL. Pharmacoeconomics. 2017 Jan;35(1):125-128

Pouwels XGLV, Sampson CJ, Arnold RJG. Value Health. 2022 Apr;25(4):473-479



Are open-source models really for health technology assessment and health policy?







Objectives for making models publicly available:

- Efficiency: Reduce redundancy in evidence development
- Innovation: Disseminating examples for new methodologies
- **Consistency:** Reusing *trusted* models in specific settings
- Transparency: External verification and Validation
 - Will decision makers / HTA go open-source as well?

Conceptual/policy considerations:

- Corporate transparency and commercial sensitivity
- Documentation and certification of updated model versions
- Timing/triggers, responsibility and funding for model updating

Technical/practical considerations:

- Languages employed in OSM are not the usually required by HTA
- Internal / External Capabilities
- Fit for purpose

