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Unlocking the Potential of Open Source Models: Strategies to Navigate Barriers in Development and Adoption

ISPOR 2024 – Atlanta, Georgia USA

May 6, 2024 11:45PM – 12:45PM

1

Welcome and Session Objectives

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--Entrepreneur-in-Residence, National Heart, Lung and Blood Institute (NHLBI)/National Institutes of Health, New York, NY, USA
--Adjunct Full Professor, Icahn School of Medicine at Mount Sinai, New York, NY, USA
--President, Arnold Consultancy & Technology, LLC, New York, NY, USA

Today's Panel

Renée JG Arnold

Entrepreneur-in-Residence, National Heart, Lung and Blood Institute (NHLBI)/National Institutes of Health, New York, NY, USA

Daniel Ollendorf

Director of Value Measurement and Global Health Initiatives at the Center for the Evaluation of Value and Risk in Health, CEVR, Tufts Medical Center
Chief Scientific Officer and Director of Health Technology Assessment (HTA) Methods and Engagement at the Institute for Clinical and Economic Review (ICER)
Boston, Massachusetts, USA

Elisabeth Fenwick

OPEN Health HEOR & Market Access,
Oxford, UK

Rob M. Boer

Head of Economic Modeling Team & Senior Research Fellow ACOS Health Economics and Outcomes Research (HEOR)
Abbvie Inc, Irvine, California, USA

Session Objectives

- Explore innovative approaches to surmounting barriers associated with development and use of Open Source Models (OSMs) from 3 viewpoints:
  - Academic/consultant
  - Health technology assessment (HTA) authority
  - Pharmaceutical industry
- Detail straightforward methods to overcome these barriers in the various environments

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Introduction to Barriers to Broad Use of OSMs

Renée JG Arnold, PharmD, RPh

- Entrepreneur-in-Residence, National Heart, Lung and Blood Institute (NHLBI)/National Institutes of Health, New York, NY, USA
- Adjunct Full Professor, Icahn School of Medicine at Mount Sinai, New York, NY, USA
- President, Arnold Consultancy & Technology, New York, NY, USA

What are OSMs?

- Open source models (OSMs) are those for which all data and programming associated with the model are made openly available to enhance transparency and, perhaps, facilitate replication and ongoing modifications of the model.
- They have the potential to enhance the acceptance of model-based cost-effectiveness analyses and allow for faster access to critical knowledge.

ScienceDirect

Contents lists available at sciencedirect.com
Journal homepage: www.elsevier.com/locate/jval

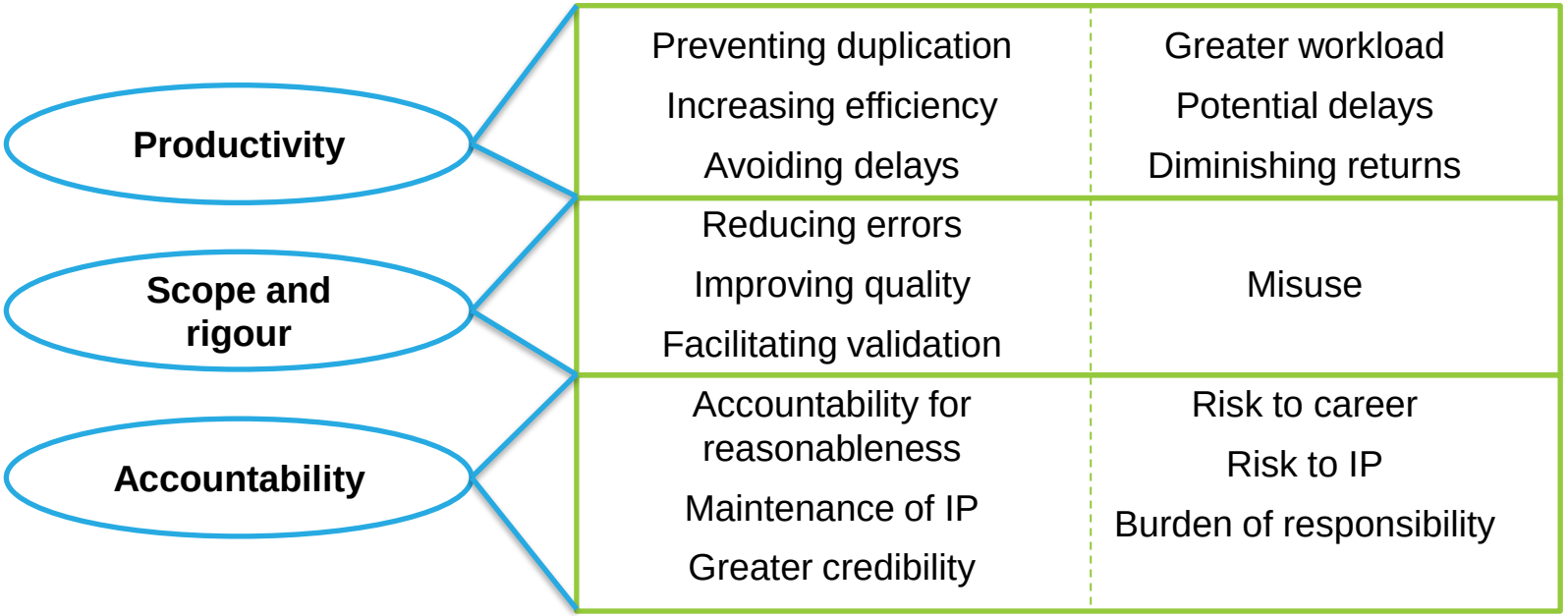
ISPOR Report

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

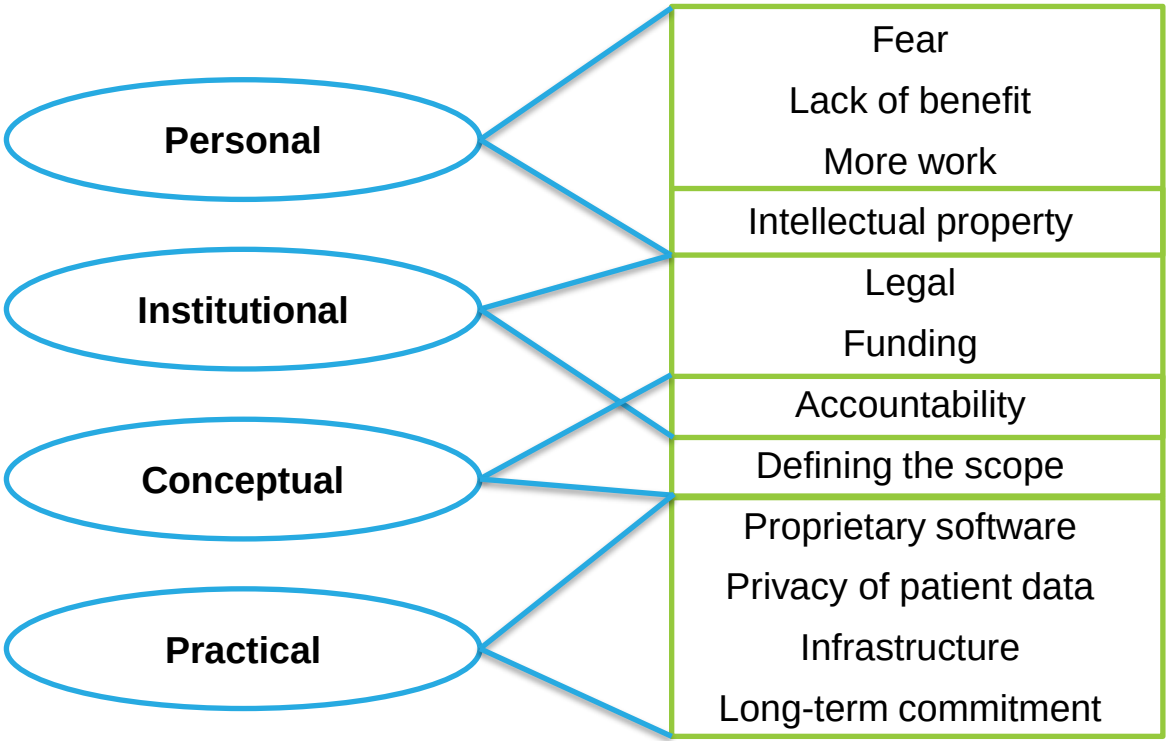
Xavier G.L.V. Pouwels, PhD, Christopher J. Sampson, PhD, Renée J.G. Arnold, PharmD, RPh, On behalf of the Open Source Models Special Interest Group

VALUE HEALTH. 2022; 25(4):473–479

Benefits and risks



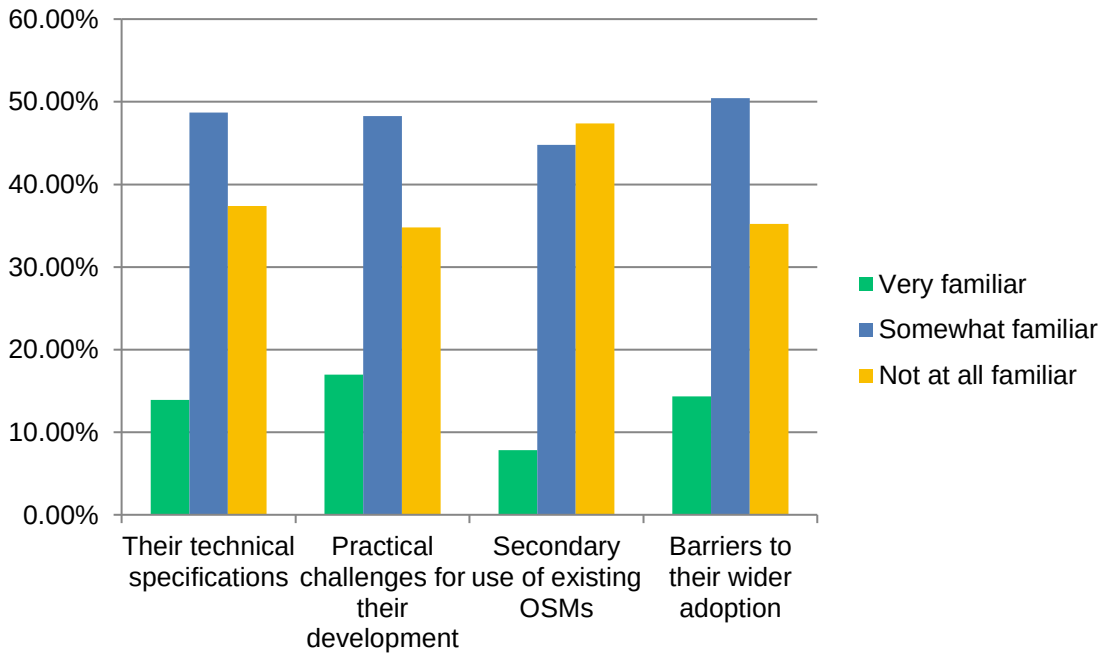
Barriers


Personal
Institutional
Conceptual
Practical
Fear
Lack of benefit
More work
Intellectual property
Legal
Funding
Accountability
Defining the scope
Proprietary software
Privacy of patient data
Infrastructure
Long-term commitment

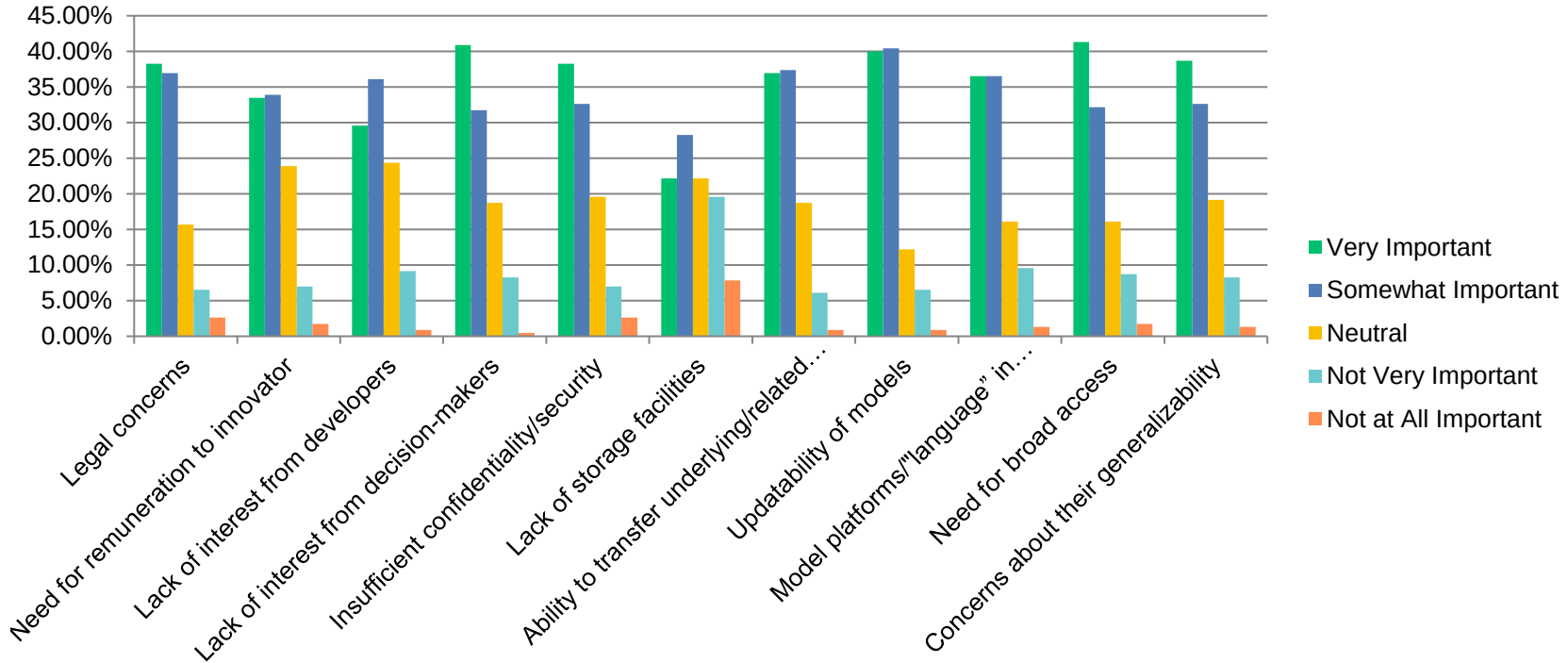
Survey contents

- 8-question survey with matrix statements (very familiar/somewhat familiar; strongly agree / somewhat agree / neither agree nor disagree, etc.)
- 230 respondents; 121 interested in SIG membership

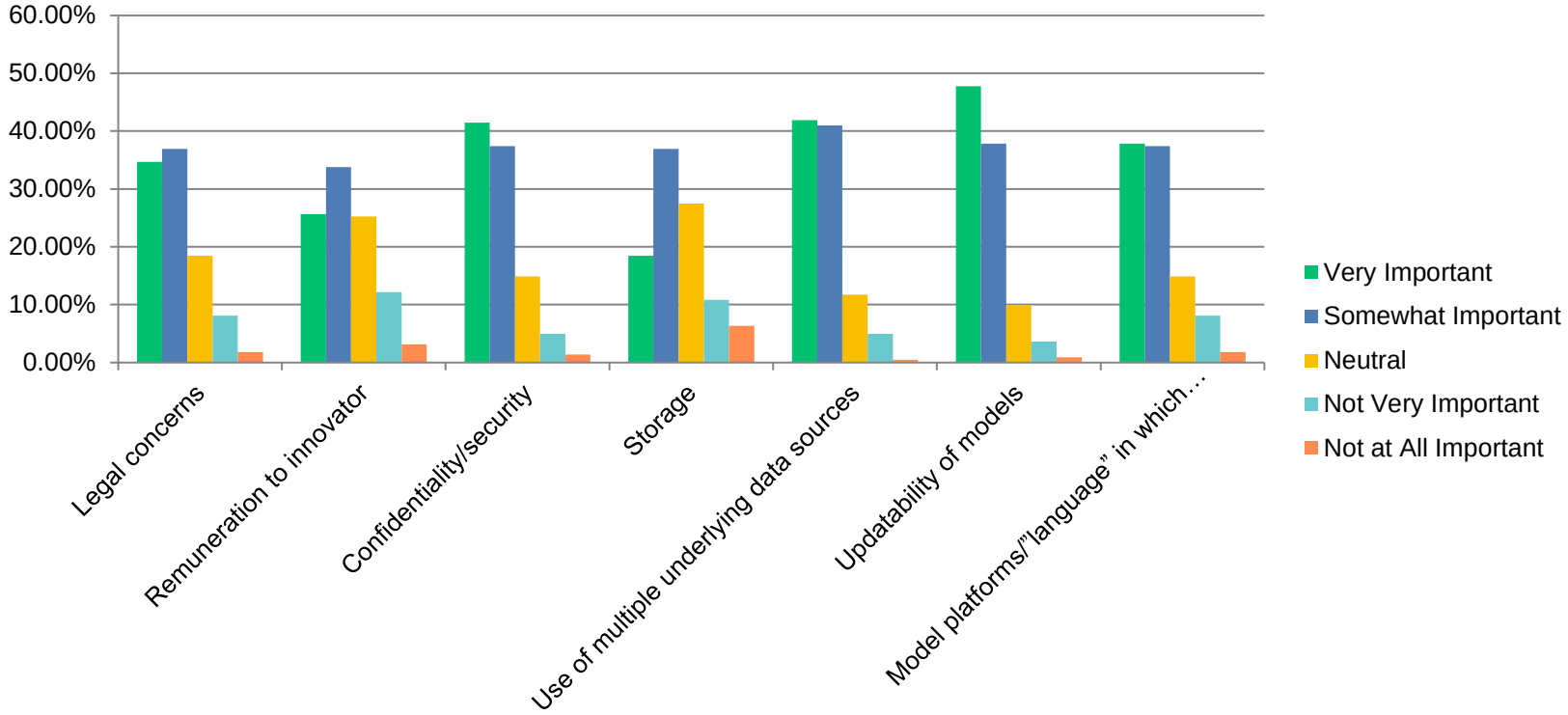
How familiar are you with the following aspects of open source models (OSMs)?



How important do you consider each of the following potential barriers to the development and use of OSMs?



How important do you consider each of the following issues, which could be the subject of a webinar or conference session on the topic of OSMs?



2

Overcoming OSM Barriers: the Academic/Consultant Perspective

Elisabeth Fenwick, PhD
Chief Scientific Officer
OPEN Health HEOR & Market Access,
Oxford, UK

Open Source Models – deconstructing the definition: Part I

- "Open source models (OSMs) are those for which **all data and programming** associated with the model are made openly available to enhance transparency and, perhaps, facilitate replication and ongoing modifications of the model."
- All data – immediately raises concerns regarding the confidentiality of trial data used to populate the model
- Is there an option to allow access to the model programming without the data?

Open Source Models – deconstructing the definition: Part II

- "Open source models (OSMs) are those for which all data and programming associated with the model **are made openly available** to enhance transparency and, perhaps, facilitate replication and ongoing modifications of the model."
- Openly available – suggests no cost to access/utilize the model
- Given model development is not costless who should bear the cost of developing the model? Hosting the model? Maintaining the model?
- Once a model is funded, and developed, what incentive is there to make the model open source?

Open Source Models – deconstructing the definition: Part III

- "Open source models (OSMs) are those for which all data and programming associated with the model are made openly available to **enhance transparency** and, perhaps, facilitate replication and ongoing modifications of the model."
- Access to the data and programming does not necessarily lead to transparency

Open Source Models – deconstructing the definition. Part IV

- "Open source models (OSMs) are those for which all data and programming associated with the model are made openly available to enhance transparency and, perhaps, **facilitate replication and ongoing modifications** of the model."
- Who is allowed to make modifications?
- Who is responsible for validating modifications?
- Who monitors usage of the model?

Revisiting the potential barriers

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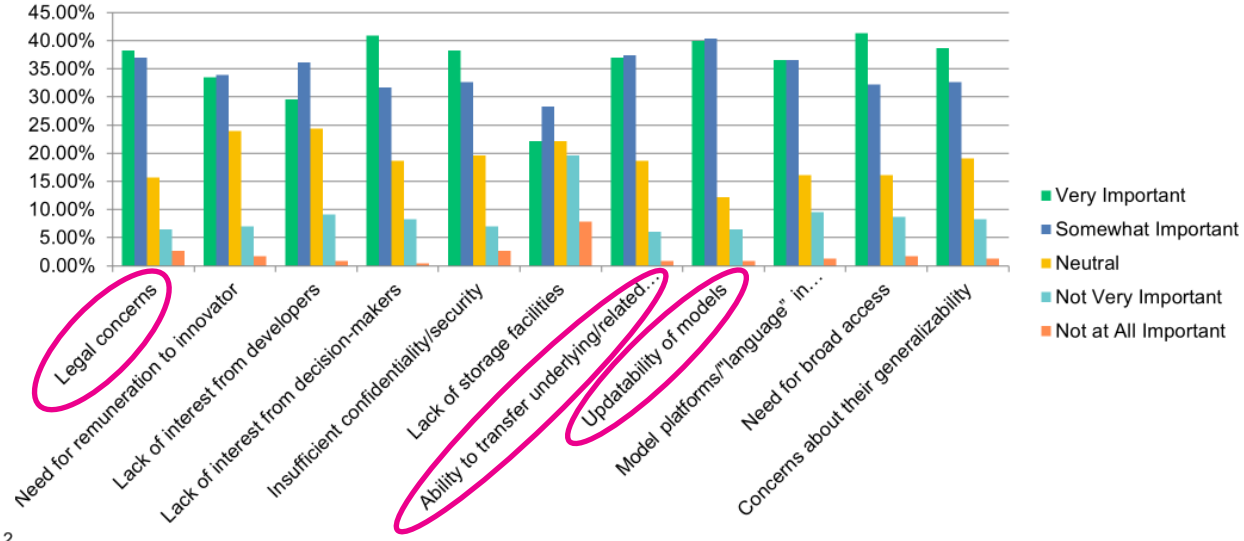
How important do you consider each of the following potential barriers to the development and use of OSMs?



12

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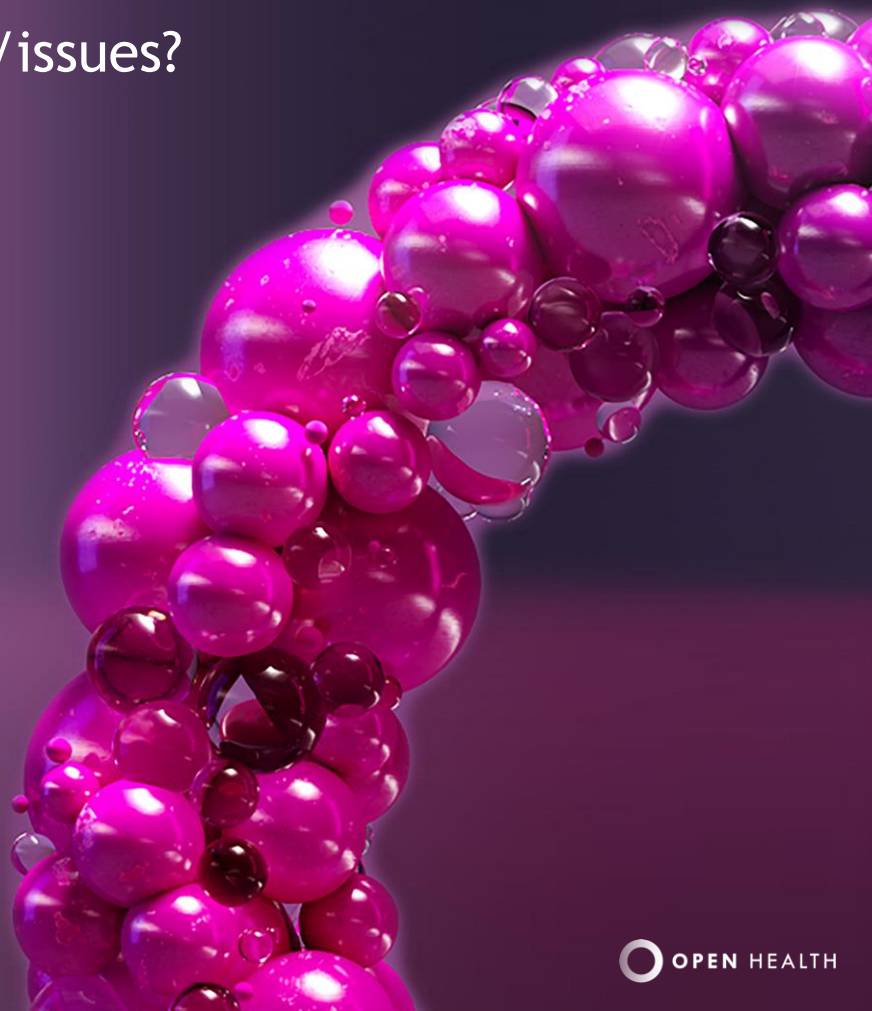
How could we overcome the barriers/issues?

- Data
- Funding
- Transparency
- Maintenance



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3

Overcoming OSM Barriers: the HTA Perspective

Daniel Ollendorf, MPH, PhD
Director of Value Measurement and Global Health Initiatives at the Center for the Evaluation of Value and Risk in Health, CEVR, Tufts Medical Center
Chief Scientific Officer and Director of Health Technology Assessment (HTA) Methods and Engagement at the Institute for Clinical and Economic Review (ICER)
Boston, Massachusetts, USA

Disclosures

- Current employee of the Institute for Clinical and Economic Review

My Once (and Current) Life

ICER and Model Transparency

- Independent, privately-financed HTA organization in USA
- Primary funder: Arnold Ventures (AV)
- AV a major supporter of Center for Open Science
- Grantees typically required to make all data, code, etc. public
- Exception made for ICER economic models
  - Why?

Challenges with ICER Model Transparency

- Models developed by academic collaborators worldwide under contract
- University IP concerns
- Model misinterpretation/misuse
- “Chilling” effect on future grants
- At odds with ICER’s “brisk” timeline

ICER Model Transparency: “Green Shoots”

- Model sharing program
  - Limited access to full model during draft report public comment period
  - Agreements between universities and manufacturers/patient groups
  - No sharing with external parties
  - Access ends after 30 days

ICER Model Transparency: “Green Shoots”

Practical Application | Open Access | Published: 05 September 2019

Achieving Appropriate Model Transparency: Challenges and Potential Solutions for Making Value-Based Decisions in the United States

Josh J. Carlson, Surrey M. Walton, Anirban Basu, Richard H. Chapman, Jonathan D. Campbell, R. Brett McQueen, Steven D. Pearson, Daniel R. Touchette, David Veenstra, Melanie D. Whittington & Daniel A. Ollendorf

PharmacoEconomics **37**, 1321–1327 (2019) | Cite this article

1742 Accesses | **2** Citations | **8** Altmetric | Metrics

Abstract

Transparency in decision modeling remains a topic of rigorous debate among healthcare stakeholders, given tensions between the potential benefits of external access during model development and the need to protect intellectual property and reward research investments. Strategies to increase decision model transparency by allowing direct external access to a model’s structure, source code, and data can take on many forms but are bounded between

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Sections References

Abstract
Introduction
Potential Benefits of Direct Model Access
Challenges to Direct Model Access
Potential Solutions and Way Forward
Real-World Example: Model-Sharing Initiative by t...
Conclusions
References
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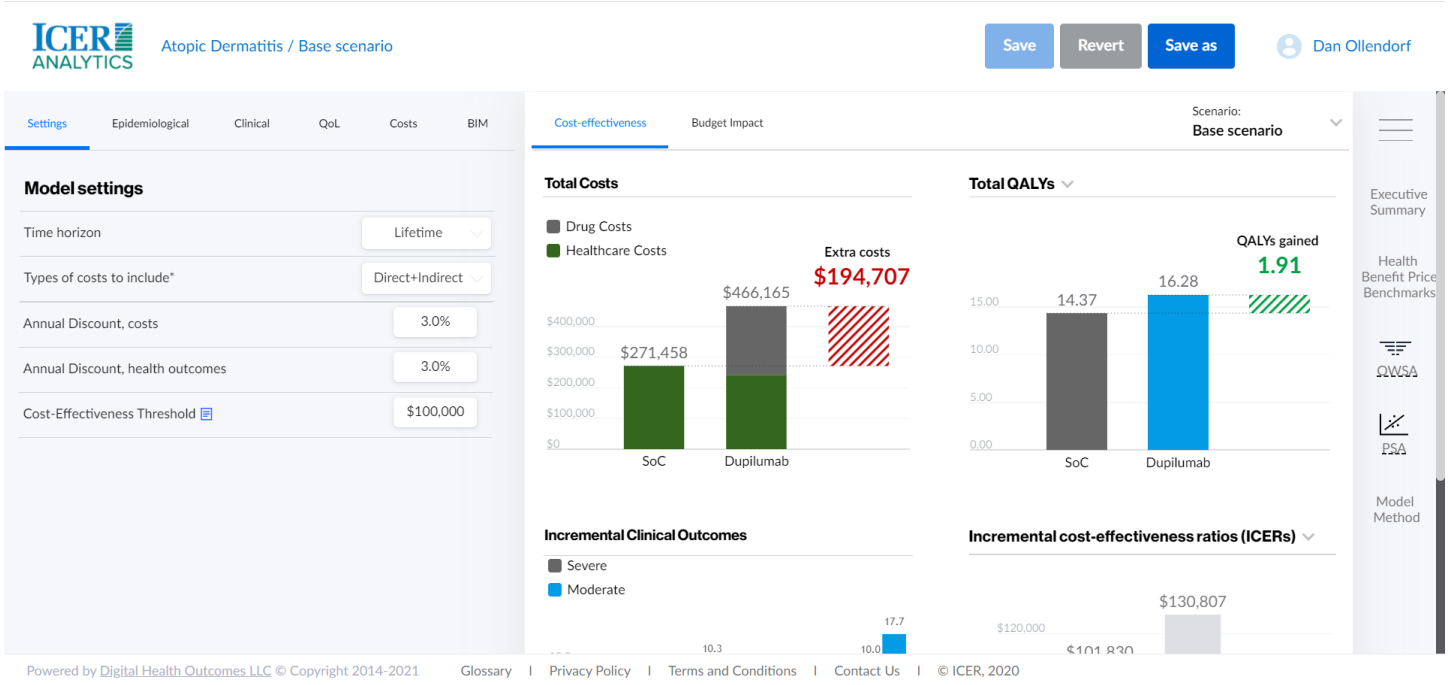
About this article

ICER Model Transparency: “Green Shoots”



My Other Life

CEVR Open-Source Clearinghouse

- Initiated with Gates Foundation grant
- Flexible re: submission of files or link to OSF, GitHub, etc.
- No stringent documentation requirements
- Promoted via webinars, social media, etc.
- and…
- 18 models submitted in 8 years
- Nearly 1/3 from Tufts faculty!!!
  - Why?

Modeler Survey

Research Letter | Open Access | Published: 08 May 2019

Publication of Decision Model Source Code: Attitudes of Health Economics Authors

Joanna Emerson, Rachel Bacon, Alma Kent, Peter J. Neumann & Joshua T. Cohen

PharmacoEconomics **37**, 1409–1410 (2019) | Cite this article

1697 Accesses | **3** Citations | **41** Altmetric | Metrics

A Correction to this article was published on 19 June 2019

This article has been updated

Dear Editor,

Computer decision models serve as the analytic foundation for most health economic evaluations, the prominence of which continues to grow. Cohen et al. [1], Cohen and Wong [2], and Sampson and Wrightson [3] have argued that authors should publish the decision

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Sections | References

Change history
References
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About this article

Survey Results

- Response to survey invitation: 7% (18/248)
- 5 of 18 agreed to post in clearinghouse
  - 4 ultimately did
- Reasons given for not posting:
  - Need to improve and/or fully document code
  - IP concerns
  - Concerns about misuse
- Not stated, but likely: no cultural expectation to do this

Summary

- 2 different experiences, same entrenched reluctance
- Limited model transparency is not true open source
- #1 lesson in pandemic analytics: we NEED open source!
- Possible ways forward:
  - Digital rights / creative commons licensing
  - Governance / peer review
  - Research sponsor *insistence*
  - Journal *requirements*

4

Overcoming OSM Barriers: the Pharmaceutical Industry Perspective

Rob M. Boer, PhD
Head of Economic Modeling Team & Senior Research Fellow ACOS
Health Economics and Outcomes Research (HEOR)
Abbvie Inc, Irvine, California, USA

Open Source Models in Pharma: Barriers and What Next?

Rob Boer

Economic Modeling Team, Evidence & Value, AbbVie

May 6, 2024

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Barriers

- Our products are unique and our models need to reflect unique characteristics => highly tailored
- We do not want to give our expensive models to our competitors for free
- Nobody is asking us for open source models
  - HTA authorities tend to be fine with some level of confidentiality
  - If e.g. NICE makes a model themselves, that is not even open source
- Potential misuse
  - When IVI asked us for feedback on an open source model in development, reaction in our company was:
    How can we prevent wrong use of that model that makes our product look bad?
- Even ICER (which does not have an interest in confidentiality) does not make their model public due to intellectual property
- Making a model open source requires a ***lot*** of extra work => probably not efficient
  - Accessible code
  - Respond to questions
  - Herding cats that work on the code

Science requirement

- Should an economic model be open source to deserve the label ‘scientific’? (publication and reproducibility)
- Randomized trials are obviously considered scientific.
  - Reproducibility trial requires following the published methods of the trial.
  - Reproducibility does not require working with the exact same trial participants.
- Using the same economic model does not constitute reproduction of a scientific effort.
- At best, using the same model provides more opportunities to discover errors, which will never be as good of a test as independent implementation of the model.
- Good enough to publish the model assumptions in enough detail that a competent modeler can make a model that produces the same results if both models would be error free.
- Most publications of models currently do not meet that standard.
- I would very much like that journals will try to maintain that standard.
- Making the whole model public is only one way to meet that standard.

Why would a pharma company be interested in making open source models?

- Multiple uses of same model may save some money/effort.
  - Savings from re-use vs. less uniqueness.
  - Extra effort for producing open source.
- Help persuade stakeholders of the conclusion of the model.
  - So far, they are not asking, and we have not perceived the need.
- HTA authority requiring open source.
  - HTA authorities tend to be fine with some level of confidentiality
  - If e.g. NICE makes a model themselves, that is not even open source

Viable open source requires many uses

- There are a few open source economic modeling packages in R (heemod, hesim).
- Something similar to heRo3 or FieCon Model Builder may be viable as open source project.
- Existing software for economic modeling is not yet good enough for handling uniqueness and for making the best case with an HTA authority
  - I think that it is possible to make that.
  - If someone wants to initiate a generic open source modeling project, I may be able to give some help.
- Potential:
  - Save money/effort by faster/easier implementation of single/unique models.
  - Lower threshold to restructure based on new evidence or insight.
  - Prevent implementation errors.
  - General use would create a model design language that facilitates complete model description.

5

Discussion