OPEN SCIENCE & HEALTH ECONOMIC EVALUATIONS

WHY INTRODUCING OPEN SCIENCE IN THIS COURSE?

- Comenius Teaching Fellow grant
- Discrepancy between how researchers (and practitioners) should produce scientific knowledge and teaching these skills
 - Creating awareness concerning Open Science
 - Providing some tools to become an 'open practitioner'
- More details on the project:
 - Presentation: https://doi.org/10.5281/zenodo.7372278
 - Grant application: https://doi.org/10.3897/rio.8.e97853

LEARNING OBJECTIVES

After this lecture, you should be able to:

- Define what Open Science entails and its importance
- Explain how Open Science principles and practices can be applied to health economic models

OUTLINE

- Why open science?
- What is open science?
- Open Science in HTA
- Why should I care?

1. WHY OPEN SCIENCE?

PUBLISH OR PERISH

"The prevailing pragmatism forced upon the academic group is that one must write something and get it into print. Situational imperatives dictate a 'publish or perish' credo within the ranks"

(Source: Wilson, Logan. The academic man: A study in the sociology of a profession. Transaction Publishers, 1964.)

Academic achievement = #publications, citations, H-index, ...

• Measurable

Pressure to publish

SYSTEM CAN LEAD TO FRAUD

Diederik Stapel: 'Wat ik heb gedaan is volledig fout. Maar zo begon het niet'

Veerle Vroon - 20 februari 2020



Source: <u>https://cmweb.nl/2020/02/diederik-stapel-</u> wat-ik-heb-gedaan-is-volledig-fout-maar-zobegon-het-niet/ "... I think it is important to emphasize that I never informed my colleagues of my inappropriate behavior. I offer my colleagues, my PhD students, and the complete academic community my sincere apologies. I am aware of the suffering and sorrow that I caused to them. I did not withstand the pressure to score, to publish, the pressure to get better in time. I wanted too much, too fast. In a system where there are few checks and balances, where people work alone, I took the wrong turn. I want to emphasize that the mistakes that I made were not born out of selfish ends."

Source: Brabants Dagblad. 31 October 2011. Translated from Dutch

IT'S NOT ONLY ABOUT PSYCHOLOGY...

Los Angeles Times

Key Breast Cancer Study Was a Fraud

BY THOMAS H. MAUGH II AND ROSIE MESTEL

APRIL 27, 2001 12 AM PT

TIMES MEDICAL WRITERS

A key study pointing to the effectiveness of high-dose chemotherapy and bone marrow transplants in treating metastatic breast cancer was based on faked data, cancer experts said Thursday.

The American Society of Clinical Oncology announced that an unscrupulous South African researcher, Dr. Werner Bezwoda, has led thousands of women with breast cancer to undergo expensive, debilitating and often fatal bone marrow transplants. His data were fraudulent, suggesting the controversial procedure was more effective than it actually is, the society concluded.

- Dr. Werner Bezwoda
- Faked data
- Potential population harm!
 - Intervention administered without actual proof of effectiveness

Source: <u>https://www.latimes.com/archives/la-</u> <u>xpm-2001-apr-27-mn-56336-story.html</u>. Consulted on 12-04-2023

HEALTH ECONOMIC EVALUATIONS CAN ALSO BE BIASED



Source: Xie & Zhou. BMJ 2022;377:e069573 License: <u>Creative Commons CC-BY-NC 4.0</u>

THE FILE DRAWER EFFECT

- The file drawer effect
 - Negative results are not submitted
 - Selective/ distorted reporting
- But negative results are as important as positive results!
 - Unnecessary duplication of work
 - Decrease efficiency of research





A REPRODUCIBILITY CRISIS?



Matt Anticole Is there a reproducibility crisis in science? Link: <u>https://www.youtube.com/watch?v=FpCrY7x5nEE</u> License: <u>CC BY-NC-ND</u>

A REPRODUCIBILITY CRISIS?

"More than 70% of researchers have tried and failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments."

Source: Baker, Nature 533, 452–454 (2016) <u>https://doi.org/10.1038/533452a</u>



WHAT ABOUT HEALTH ECONOMIC MODELS? HE MODEL REPLICATION

- Uncommon
- Aim:
 - Important for research integrity & transparency
 - New & update model conceptualisation ('bypass' de novo development)
- Berjemo et al. 2017
 - 5 health economic models using publicly available information
 - 1 replication stopped, 2 replicated, 2 not replicated
- McMannus et al. 2019
 - 5 health economic models using publicly available information
 - Comparison with original outcomes: -4.54% to 108.00% for costs; -3.81% to 0.40% for outcomes

HE MODEL REPLICATION BARRIERS AND FACILITATORS

Barriers

- Incomplete inputs reporting
- Use of ambiguous language (e.g. concerning assumptions)
- Confidentiality of model inputs
- Errors
- Conflicting information concerning model structure and inputs
- No clarification from original author (clear annotations are important!)

Facilitators

- Clear model structure
- Provide example calculations
- Clear reporting of (inputs) tables
 and assumptions
- Journal data sharing policies, word limits, and the use of supplementary materials

Source: McMannus et al. 2019

OTHER THREATS TO THE CREDIBILITY OF SCIENCE?

are you a threat to the credibility of Science?

As an AI language model, I do not have the ability to pose a threat to the credibility of science. However, it is important to use any tool, including AI, responsibly and ensure that any outputs or conclusions drawn from it are rigorously tested and validated using scientific methods. It is also important to recognize the limitations of AI and the potential for bias in its outputs. Ultimately, the credibility of science depends on the rigor and transparency of the scientific method and the community's commitment to upholding those standards.

2. WHAT IS OPEN SCIENCE?

GIVE YOUR OPINION

- Based on the information you've just heard: what is open science to your opinion or what does it entail?
 - Write it on a piece of paper (1 minute)
- Discuss with your neighbour (2 minutes)
- Share! (2 minutes)

OPEN SCIENCE

"[O]pen science is defined as an <u>inclusive</u> construct that combines various movements and practices aiming to make multilingual scientific knowledge <u>openly available</u>, accessible and <u>reusable</u> for everyone, to increase scientific collaborations and <u>sharing of information</u> for the benefits of <u>science and society</u>, and to <u>open the processes</u> of scientific knowledge creation, evaluation and <u>communication</u> to societal actors <u>beyond the traditional scientific community</u>. It comprises all scientific disciplines and aspects of scholarly practices, including basic and applied sciences, natural and social sciences and the humanities, and it builds on the following key pillars: open scientific knowledge, open science infrastructures, science communication, open engagement of societal actors and open dialogue with other knowledge systems."

UNESCO Recommendations on Open Science: https://unesdoc.unesco.org/ark:/48223/pf0000379949.locale=en accessed on 12-04-2023 License: <u>CC BY-SA 3.0 IGO</u>

WHAT IS OPEN SCIENCE?

- Doing science right
- Opening the research process
- Inclusive
- Transparent and accountable
- Reproducible and allowing verification
- Science that is (more) relevant to society



OPEN SCIENCE AFFECTS THE ENTIRE RESEARCH CYCLE



Adapted from: B. Kramer & J. Bosman, Utrecht University Library. Utrecht University Summer School (August 26-30, 2019) Link: <u>https://docs.google.com/presentation/d/1V5iJarksQlzJNBM0T8FrrbgGrEhthScY585JEfx7eCk/edit#slide=id.g3d88e11ed5_3_67</u>

OPEN SCIENCE IS NOT ONLY ABOUT OPEN ACCESS PUBLISHING!

assessment outreach publication writing analysis

adding alternative evaluation, e.g. with altmetrics communicating through social media, e.g. Twitter sharing posters & presentations, e.g. at FigShare using open licenses, e.g. CC0 or CC-BY publishing open access, 'green' or 'gold' using open peer review, e.g. at journals or PubPeer sharing preprints, e.g. at OSF, arXiv or bioRxiv using actionable formats, e.g. with Jupyter or CoCalc open XML-drafting, e.g. at Overleaf or Authorea sharing protocols & workfl., e.g. at Protocols.io sharing notebooks, e.g. at OpenNotebookScience sharing code, e.g. at GitHub with GNU/MIT license sharing data, e.g. at Dryad, Zenodo or Dataverse pre-registering, e.g. at OSF or AsPredicted commenting openly, e.g. with Hypothes.is using shared reference libraries, e.g. with Zotero sharing (grant) proposals, e.g. at RIO



B. Kramer & J. Bosman <u>https://101innovations.wordpress.com</u>

Source: Kramer, Bianca, & Bosman, Jeroen. (2018, January 14). Rainbow of open science practices. Zenodo. https://doi.org/10.5281/zenodo.1147025

TOOLS FOR OPEN SCHOLARLY COMMUNICATION

101 Innovative tools and sites in 6 research workflow phases (< 2000 - 2015)



• 400+ tools for open scholarly communication!

Source: Kramer, Bianca; Bosman, Jeroen (2015): 101 Innovations in Scholarly Communication - the Changing Research Workflow. figshare. Poster. <u>https://doi.org/10.6084/m9.figshare.1286826.v1</u>

PROMISES OF OPEN SCIENCE

- Improve quality of research
 - More transparent and reproducible
- Efficiency of research
 - Secondary data use
 - Reduce costs of research
 - New hypotheses generation
- Knowledge exchange and impact
 - Increased visibility
 - Credits for the entire work you performed (e.g. software code)

BARRIERS TO OPEN SCIENCE

- Paywalls to consult AND share scientific knowledge
- Time requirement
- Lack of awareness
- Lack of institutional motivation
- Funding
- Lack of incentives

RISKS OF OPEN SCIENCE

- Data misuse and misinterpretation
- Loss of privacy
- Ethical concerns:
 - Different legislations address data sharing and confidentiality differently
 - Ethically controversial studies may lead to decreased willingness to participate in research

Source: Lakomý et al. 2019

OPEN SCIENCE IS ABOUT SCIENCE & SOCIETY

- Performing relevant research for and with society
- Public outreach and engagement
- Mitigate misinformation
- Citizen science
 - Citizen as contributors and collaborators in research project
 - Citizens' active participation in different stage of the research cycle
 - ECSA 10 Principles of Citizen Science
 - <u>https://www.ecsa.ngo/ecsa-guidelines-and-policies/</u>

OPEN SCIENCE INITIATIVES

- Open repositories
 - Open Science Framework
 - ZENODO
 - DANS-EASY
 - ...
- Fostering the practical implementation of Open Science (FOSTER)
- Framework for Open and Reproducible Research Training (FORRT)
- Open Science Communities
 - Student Initiative on Open Science
- FAIR data
- European Citizen Science Association
- And many more...

FAIR PRINCIPLES

- Findability
 - Meta-data
 - Easy for both human and machines
 - Unique persistent identifier (e.g. doi)
- Accessibility
 - Clear on how to access the data (authorization?)
- Interoperability
 - With other applications and workflows
- Reusability
 - Ultimate goal of FAIR
 - (meta)data should be clearly described
 - Allow replication and combination with other data

Source: GO FAIR https://www.go-fair.org/fair-principles/ accessed on 12-04-2023



RECOGNITION AND REWARDS ASSESSMENT

- Goal:
 - Broader recognition of academic staff's work (e.g. education, research, impact, leadership and patient care)
 - More diversity in academic career paths
 - Focus on quality, creativity and content instead of quantity of research results
 - Stimulating Open Science
 - Stimulating academic leadership
- It will take some time!
- In NL: https://recognitionrewards.nl/
- @UT: <u>https://www.utwente.nl/en/service-portal/topics/recognise-reward-talent/#recognition-and-rewards-room-for-everybody-s-talent</u>

OPEN SCIENCE @UT

- UT Shaping 2030:
 - Embrace Open Science
 - By 2023: Open Access and FAIR data as the new norm
- Open Science Community Twente
 - Events & Newsletter
- Digital Competence Centre, supports
 - Improving open, reproducible, and transparent research
 - Open Access publication
 - Adhering to FAIR principles
- 4TU FAIR data Fund
- BMS Open Access Fund
- Recognition & Rewards: Shaping Expert Group Individuals and Teams

3. OPEN SCIENCE IN HTA

TO YOUR OPINION

- 1. Why is Open Science relevant in the context of HTA / HE modelling?
- 2. How does the Open Science principles and practices affect HTA/ HE modelling?

WHY OPEN-SOURCE MODELLING?

- HE models inform public health decisions
- HE models are generally not publicly available
 - Lack of transparency
 - Difficult to get insights in how HE models work
- Lack of systematic (reporting of) model validation
 - Risk of errors \rightarrow harmful decisions
- \rightarrow 'Black box' feeling

"an article about computational result is advertising, not scholarship. The actual scholarship is the full software environment, code and data, that produced the result." Source: Donoho DL. An invitation to reproducible computational research. Biostatistics. 2010;11(3):385–8. pmid:20538873

HEALTH ECONOMIC MODEL TRANSPARENCY

What is (health economic) model transparency?

Eddy et al. 2012: transparency = "clearly describing the model structure, equations, parameter values, and assumptions to enable interested parties to understand the model"

> Figure: Own material & logo's are used with permission from Microsoft

TRANSPARENCY IS NOT ONLY ABOUT PROGRAMMING



Source: <u>https://www.quora.com/What-do-you-</u> mean-for-IT-spaghetti-code



Source: Sampson et al. 2019

MODEL TRANSPARENCY – EDDY ET AL. 2012

- 'What does the model do and how?'
- Purpose:
 - Allow review of the model's structure, equations, parameter values and assumptions
 - In order to understand model accuracy, limitations and potential applications
- Documentation is crucial:
 - Non-technical: for any interested reader, to understand the model results
 - Technical: for reviewers and modellers, to be able to review/replicate the model

TRANSPARENCY OF INTENDED METHODS

Methodology

Content of Health Economics Analysis Plans (HEAPs) for Trial-Based Economic Evaluations: Expert Delphi Consensus Survey



Joanna C. Thorn, PhD,* Charlotte F. Davies, PhD,* Sara T. Brookes, PhD, Sian M. Noble, PhD, Melina Dritsaki, PhD, Ewan Gray, PhD, Dyfrig A. Hughes, PhD, Borislava Mihaylova, DPhil, Stavros Petrou, PhD, Colin Ridyard, PhD, Tracey Sach, PhD, Edward C.F. Wilson, PhD, Sarah Wordsworth, PhD, William Hollingworth, PhD

- Why? Lack of consistency!
- 58 items divided in 8 sections (administrative data, method of data collection & analysis, reporting, ...)
- You can still deviate from the plan \rightarrow justify why

TRANSPARENCY THROUGH REGISTRATION



Source: <u>https://osf.io/registries/rwe/discover</u> accessed on 12-04-2023

- Real world evidence registry
 - Improve transparency of reporting of studies using realworld evidence
- 36 registrations since 2021...

TRANSPARENCY THROUGH OPEN-SOURCE MODELS (OSM)

- OSM Clearinghouse (<u>https://cevr.shinyapps.io/Clearinghouse/</u>)
 Repository of OSM
- PeerModels Network (<u>https://www.peermodelsnetwork.com/</u>)
 - Improve model accessibility
 - Stakeholders' involvement
- Innovation and Value Initiative (<u>https://thevalueinitiative.org/</u>)
 - OSM development
 - Stakeholders' involvement and iterative model development
- ISPOR Open Source Models Special Interest Group

WHY OPEN-SOURCE MODELS?



Source: Pouwels et al. 2022

IMPROVING PRACTICE THROUGH OSM

PharmacoEconomics (2019) 37:1329–1339 https://doi.org/10.1007/s40273-019-00837-x

PRACTICAL APPLICATION

A Need for Change! A Coding Framework for Improving Transparency in Decision Modeling

Fernando Alarid-Escudero¹© · Eline M. Krijkamp²© · Petros Pechlivanoglou³© · Hawre Jalal⁴© · Szu-Yu Zoe Kao⁵© · Alan Yang⁶© · Eva A. Enns⁵©

- Framework using open source software R
- Coding recommendations
 - Map structure
 - Variable names
- Why?
- \rightarrow Not all health economists are not software engineers!

OSM IN PRACTICE

PharmacoEconomics (2019) 37:1313–1320 https://doi.org/10.1007/s40273-019-00827-z

PRACTICAL APPLICATION

Developing Open-Source Models for the US Health System: Practical Experiences and Challenges to Date with the Open-Source Value Project

Jeroen P. Jansen^{1,2} · Devin Incerti¹ · Mark T. Linthicum¹

PharmacoEconomics (2019) 37:829–843 https://doi.org/10.1007/s40273-018-00765-2

ORIGINAL RESEARCH ARTICLE

A Flexible Open-Source Decision Model for Value Assessment of Biologic Treatment for Rheumatoid Arthritis

Devin Incerti¹ · Jeffrey R. Curtis² · Jason Shafrin¹ · Darius N. Lakdawalla³ · Jeroen P. Jansen^{1,4}

Accessibility

Check for updates

- Different stakeholders require different (level of) information (e.g. web-interface)
- Requires more resource than traditional HE models
- Iterative development based on stakeholders' feedback
 - Challenging to include clinical expert feedback

OPEN-SOURCE HE MODELS

• Any idea why health economic models are not routinely publicly accessible?

BARRIERS TO OPEN-SOURCE HE MODELS



Source: Pouwels et al. 2022

OVERCOMING BARRIERS – CONFIDENTIALITY LIVING HTA'S



• Avoid sending / sharing data

- Data separated from model
 - Transparency & validation
- Automatic update of results
 - New data
- BUT
 - Not yet 100% safe
 - Running model remotely is still a 'black box'
 - Still complex to set up
 - Working without the underlying data is challenging

OVERCOMING BARRIERS – CONFIDENTIALITY SYNTHETIC DATA



Source: <u>https://synthetichealth.github.io/synthea/#home</u> accessed on 12-04-2023

BROADENING ACCESS MAKING HE MODELS SHINY



ShinyApp function

Figure 1. Diagram depicting how the Sick-Sicker app is structured.

Source: Smith & Schneider. 2020

- Allows non-technical users to interact with HE model
 - Useful for communication and validation
- Requires additional skills
- Shortcut:
 - <u>ShinyQuickStarter</u> (<u>https://cran.r-</u> project.org/web/packages/Shin yQuickStarter/index.html)

BENEFITS & RISKS OF TRANSPARENCY

Benefits	Risks
Productivity	
 Prevent duplication Increase efficiency Avoid delays 	 Greater workload Potential delays Diminishing returns
Scope and rigour	
 Error reduction Improve quality Facilitate validation 	• Misuse
Accountability	
 Accountability for reasonableness Maintenance of IP Greater credibility 	 Risk to career Risk to IP Burden of responsibility

Source: Sampson et al. 2019

HE MODEL VALIDITY (EDDY ET AL. 2012)

Reliability: Are the results reproducible?

More technical issue

Validity: Is the model fit-for-purpose?

Non-technical, requires judgement



Source: https://pixabay.com/vectors/tiro -target-butt-shot-gun-bullet-160574/

HE MODEL VALIDITY (EDDY ET AL. 2012)

- 'How well does the model represent reality?'
 - Purpose: judging the accuracy of a model in making suitable/relevant predictions
 - Can we 'trust' the model and model outcomes?
- Consider
 - Simplifications
 - Assumptions
 - Different sources
 - Extrapolations



TYPES OF VALIDITY (EDDY ET AL. 2012)

- Face validity
 - Corresponding to current science & evidence
- Verification / internal validity
 - Behave as intended / implemented correctly
- Cross validity
 - Comparing the model with others
- External validity
 - Model outcomes compared with real world outcomes
- Predictive validity
 - Model forecasts compared with actual outcomes

ASSESSING THE VALIDITY OF HE MODELS

- AdviSHE (Vemer et al. 2015): Tool to help **describe** validation efforts :
 - Validation of the conceptual model
 - Input data validation
 - Validation of the computerised model
 - Operational validation
 - Other validation techniques
- TECH-VER checklist (Büyükkaramiki et al. 2019): comprehensive checklist for the technical verification of decision analytical models

4. WHY SHOULD I CARE?

Adapted from: Student Initiative for Open Science. SIOS LECTURE "Introduction TO open science" Retrieved from <u>https://osf.io/2qsd6</u> on 30-11-2022

YOUR OPINION IS NEEDED

- Discuss in pairs (3 minutes)
 - Why do you think Open Science is relevant to you?
 - How do you think Open Science may affect your daily working life?
- Share (2 minutes)

FIRST SOURCE: SIOS 2019

• You are the future researcher

- Perform research relevant for society
- Moral 'obligation' to perform open, transparent, and reproducible research
- Adherence to Open Science is gaining attention for academic careers

• You are the future **practitioners**

- Best practices informed by Open research
- You are (future) citizens
 - Be critical, not cynical!
 - Don't believe everything you read

SECOND

- You may benefit from Open Science endeavours:
 - Find and re-use open data and software
 - Efficiency gain!
 - Facilitate collaboration
 - Enhance quality of your work
 - Enhance visibility of your work

WRAP UP

- Open Science is a movement promoting research that is more:
 - Transparent
 - Valid
 - Reproducible
 - Reusable
 - Accessible
 - Inclusive
- Within HTA, Open Science is mostly championed through opensource modelling, public outreach, stakeholder involvement during HE model development
- You may benefit from practicing Open Science!

ANY QUESTION?



Source: Compound of Interest. 2014. A Rough Guide to Spotting Bad Science. <u>https://www.compoundchem.com/wpcontent/uploads/2014/04/A-Rough-Guide-to-Spotting-Bad-Science-20151.pdf</u> accessed on 12-04-2023

ANY QUESTION ON THE HTA-RELATED LITERATURE?



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