

Value of Information (VOI)
Analysis for Research
Decisions: *Emerging Good Practices Task Force*

Final Recommendations

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Moderator:

Rachael Fleurence, PhD, National Evaluation System for Health Technology Coordinating Center (NESTcc), Medical Device Innovation Consortium (MDIC), Arlington, VA, USA

Panel:



James Murray, PhD, Global Health Outcomes, Center of Expertise, Eli Lilly and Company, Carmel, IN, USA

Gillian D Sanders Schmidler, **PhD**, The Robert J. Margolis, MD, Center for Health Policy, Duke University, Washington, DC, USA

Lotte Steuten, PhD, MSc, Fred Hutchinson Cancer Research Center and The Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute, University of Washington, Seattle, WA, USA





Task Force Members:

- Claire Rothery, PhD, Co-Chair, Senior Research Fellow, University of York, York, England, UK
- · Elisabeth Fenwick, PhD, Co-Chair, Senior Principal, Health Economics, ICON plc, Abingdon, UK
- Anirban Basu, PhD, Professor, Department of Pharmacy, University of Washington, Seattle, USA
- Salah Ghabri, MD, PhD, Health Economist, Department of Economic and Public Health Evaluation,
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- Saskia Knies, PhD, Senior Advisor Pharmacoeconomics at National Health Care Institute (Zorginstituut Nederland), Diemen, the Netherlands

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Task Force Members continued...

- Erik Koffijberg, PhD, Associate Professor of Health Economics, University of Twente, Enschede, The Netherlands
- James F. Murray, PhD, Research Fellow, Global Health Outcomes and Real World Evidence, Center of Expertise, Eli Lilly and Company, Indianapolis, USA
- Gillian D. Sanders Schmidler, PhD, Professor of Population Health Sciences and Medicine, Duke Clinical Research Institute, Duke University, Durham, NC, USA
- Lotte M.G. Steuten, PhD, Associate Member/Professor, Fred Hutch HICOR / University of Washington – Department of Pharmacy, Seattle, USA
- · Mark Strong, PhD, Section Director, Public Health, University of Sheffield, Sheffield, England, UK



Recent examples of VOI

"an expected value of perfect information of \$4,195 per patient at societal willingness to pay of \$50,000/QALY. The estimated value of partial perfect information regarding the HR was \$3,702 per patient."

"The value of perfect information to reduce uncertainty was <euro>291.6M at its lowest."

Recog. van Assed. Kuiper. Severore. Mass. Dempelor. Knotherus. van Schayok. Eur J Headh Econ. 2013.

"EVPI per patient would be €204 at a
"EVPI per patient would be €204 at a
€20,000 threshold value of society's
€20,000 threshold value of quality-adjusted
willingness to pay for one quality-adjusted
willingness to pay for one quality-adjusted
for one quality-adjusted
willingness to pay for one quality-adjusted
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The expected value of perfect information is £43.1 million. Wilson, Emery, Kinnouth, Prevest, Morris, Humphrys, Hall, Burrows, Bradshaw, Wals, Norris, Johnson, Walter, Value Health, 2013

The expected value of perfect information (EVPI) associated with this decision is substantial (6.9 million pounds for the 20/40 model and 14.5 million pounds for the 20/80 model), with a sizeable EVPI associated with the effect of PDT on quality of life.

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Task Force Objectives

Develop good practice guidance for VOI analysis methods to:

- Characterize uncertainty and perform VOI
- Aid in presentation and interpretation of VOI results
- Reduce barriers to VOI implementation
- Improve patient and health system performance outcomes

The task force will follow directly on from the ISPOR-SMDM Modelling Good Research Practices Task Force on Model Parameter Estimation and Uncertainty (Briggs et al., 2012) and the methods used to address recommendations in the ISPOR Good Practices for Performance-Based Risk-Sharing Arrangements Task Force Report (Garrison et al., 2013).



Specific Aims

- Explain the importance of quantifying uncertainty and the value of further research for research prioritization decisions
- Develop recommendations to assess when additional evidence is required to reduce uncertainty in decision making
- Identify key steps and recommendations for good practices of performing, reporting, presenting and interpreting results of VOI analysis
- Provide clarity on how results of VOI analysis can be embedded into decision making processes
- Develop recommendations for use of VOI in jurisdictions that do not use cost-effectiveness information
- Identify areas where continued methodological development in VOI techniques is warranted

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Report 1 - An Introduction

Audience:

- decision makers / health care payers
- stakeholder groups making research prioritization decisions

Content:

- Role of VOI analysis
- Definition of VOI concepts and terminology
- Overview of steps to conduct a VOI analysis
- Types of healthcare decisions supported by VOI analysis
- Implications for research and policy decisions with discussion of/references to examples



Report 2 - Analytical Methods

Audience:

methodologists or analysts undertaking VOI analysis to inform decision making

Content:

- Characterizing sources of uncertainty for VOI
- Key concepts, definitions and notation of VOI
- · Methods for computing EVP(P) and EVSI
- Reporting of VOI results
- Other considerations
 - minimal modelling describe how to monetize the value of further research
 - · relevance of VOI in different contexts
- Resources, skills and software

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Forum Presentation

- Overview of VOI
- 2. A selection of the Good Practice Recommendations
- Discussion:
- VOI in practice
- Barriers and potential solutions
- Implications

Perspectives:

- Funders of research
- Industry
- Academic/Analyst

SECTION

What is VOI?

Lotte Steuten, PhD, MSc

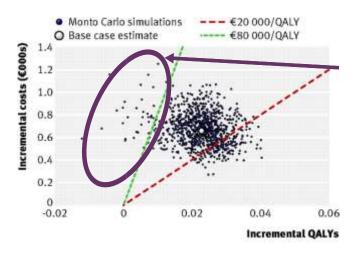
Fred Hutchinson Cancer Research Center and The Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute, University of Washington

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What is VOI?



By a show of hands:

Is it worth to conduct another trial?

A: Yes B: No

C: That depends

D: Only if I am the 1st author



VOI: An intuitive example

- One bag contains \$100, while the other \$0.
- You must choose one (and only one!) bag





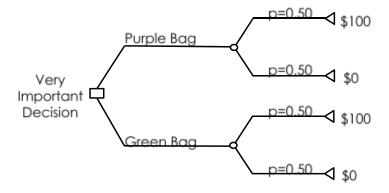
 How much would you pay to look inside one bag before making your decision?

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Decision tree







- Without looking inside you have a 50:50 chance of winning \$100.
 - Expected value = \$50 (50% of \$100)
- After looking inside (i.e. with PERFECT information) there is a 100% chance of winning \$100.
 - Expected value = \$100
- Expected value of perfect information (EVPI)=\$100-\$50 =\$50

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- What happens to VOI when there is more uncertainty?
- Expected value without peeking is now only \$20.
 - 20% of \$100
- Value of PERFECT information is still \$100.
- Expected value of perfect information (EVPI*) =
 - \$100 \$20 = \$80
- Value of information is higher when there is more uncertainty.

*peeking in 4 bags







- One bag now contains \$1000!
- Expected value with CURRENT info is now \$500.
 - 50% of \$1000
- Value of PERFECT information is \$1000.
- Expected value of perfect information =
 - \$1000- \$500 = \$500
- Value of information is higher when consequences of a (wrong) decision are larger.

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VOI metrics

- EVPI = expected cost of uncertainty
- EVPPI = expected cost of uncertainty about (groups of) individual parameters
- EVSI = expected reduction in uncertainty by a trial of a given sample size n
- ENBS = EVSI minus costs of a study with sample size n





Paper I Objectives

- Introduce VOI analysis
- 2. Explain why it should be important to decision-makers
- Identify the types of healthcare decisions that can be supported by VOI analysis, as well as its limitations
- Describe how the methods should be used and how the results should be interpreted
- 5. Explain how VOI analysis can support decision-making in different contexts.

The report does <u>not</u> provide detail on the costing or grading of evidence from specific studies.



Selected Good Practice Recommendations – Report 1

- For a proper quantitative assessment of uncertainty, which accounts for uncertainty in all parameters simultaneously, a probabilistic analysis of the decision model is required.
- The decision model should be determined by the decision problem; NOT simply by data availability.
 - All current evidence should be considered with the uncertainty appropriately characterized.
 - Parameters should not be excluded due to a lack of data as anything not captured in the model structure or parameters will not be captured in VOI.

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Selected Good Practice Recommendations – Report 1

- The size of the beneficiary population should be calculated based on the prevalent and/or incident cohorts as appropriate given the decision problem.
 - The beneficiary population should be reduced by the number of patients to be enrolled in a future study if the decision is delayed to gather more information, as they will generally not benefit from the information yielded.
- Justification for the effective time horizon should be stated explicitly, and the impact of alternative durations on the VOI results should be explored in a scenario analysis.



Selected Good Practice Recommendations - Report 1

- Population EVP(P)I should be calculated and compared against the costs of research to determine if further research is potentially worthwhile.
- EVPPI should be undertaken for groups of parameters where it is likely that further research would be informative for the whole group, rather than for individual parameters.
- EVSI estimates for each proposed study design should be compared to the expected costs of the study to determine if the specific study is valuable.
 - Where the number of proposed study designs is large, optimization methods can be used to identify the study with the greatest Expected Net Benefit of Sampling (ENBS) (Conti and Claxton, 2009).

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Selected Good Practice Recommendations - Report 1

- Other factors with potential relevance to decisions that should be considered in VOI analysis include:
 - 1. likelihood that research will be undertaken if an intervention is generally funded compared with being funded only in the context of research
 - 2. the extent of irreversible costs being incurred in delivering a new intervention
 - 3. whether other information of relevance is likely to emerge over time.

SECTION

2.2

Selected Good Practice Recommendations

VOI Report 2 – Analytical Methods

Anirban Basu PhD,Professor, Department of Pharmacy,
University of Washington

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Paper II Objectives

- Detailed guidance and emerging good practices on the principal methods required for assessing the value of research to inform a range of decisions
- Primary audience for this report are methodologists or analysts who are responsible for undertaking and implementing VOI to support research decisions



Decision-making contexts where VOI helpful

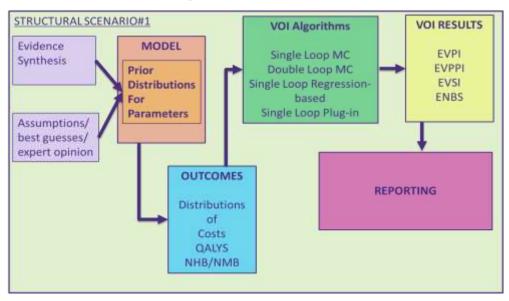
- guiding commissioning and research prioritization decisions among competing research priorities;
- informing conditional coverage decisions within health technology assessment, where decisions about the reimbursement of technologies can be delayed until research that is needed is mandated;
- supporting early development decisions of new pharmaceutical or other medical products; and
- 4. identifying research needs and priorities in areas where there is limited evidence and important uncertainties

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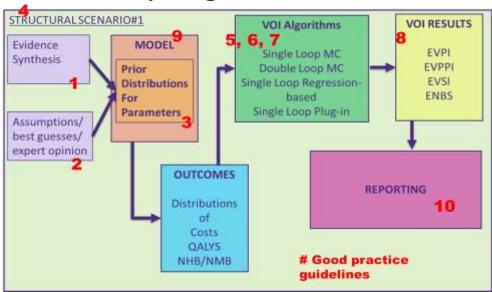
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VOI Calculations & Reporting





VOI Calculations & Reporting



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Software

- Usually implemented using spreadsheets or statistical software or programming language
 - MATA, STATA, R, WinBUGS, TreeAge
- The Sheffield Accelerated Value of Information (SAVI) web-based tool
 - http://savi.shef.ac.uk/SAVI/
- BCEAweb BCEAR package
 - https://egon.stats.ucl.ac.uk/projects/BCEAweb/
- VICTOR Value of Information for Cardiovascular Trial and Other comparative Research
 - 30 https://sop.washington.edu/choice/research/research-projects/victor/

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Panel Discussion

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Topics for Panel Discussion

- 1. How could/should VOI methods be utilized within current decision-making frameworks?
- 2. How could/should decision-making frameworks be altered to allow greater use of VOI?
- 3. What needs to be done to improve understanding of VOI methods?
- 4. How could/should industry use VOI in stop/go decisions
- 5. How best to compare the value of research to the cost of research?



The task force reports will be submitted to *Value in Health* in Summer 2018. Expected publication is Fall 2018.

VALUE OF INFORMATION ANALYSIS FOR RESEARCH DECISIONS: EMERGING GOOD PRACTICES

Value of Information Analysis for Research Decisions Emerging Good Practices:

- . Report 1: Value of Information Analysis for Research Decisions Emerging Good Practices An Introduction
- Report 2: Value of Information Analysis for Research Decisions Emerging Good Practices Analytical Methods

Thank you to those who reviewed these reports. Your insight and expertise contribute to the high quality, multi-perspective and consensus nature of ISPOR Good Practices for Outcomes Research Task Force Reports.

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VOI Task Force Activities at Upcoming ISPOR Conferences

- · VOI Short Course at ISPOR Europe 2018: Barcelona
- · Abstract submission likely for ISPOR Europe 2018: Barcelona

<u>ISPOR Europe 2018</u> | Centre de Convencions Internacional de Barcelona, Barcelona, Spain (10-14 November 2018)

Abstract Submission Deadline: 13 June 2018

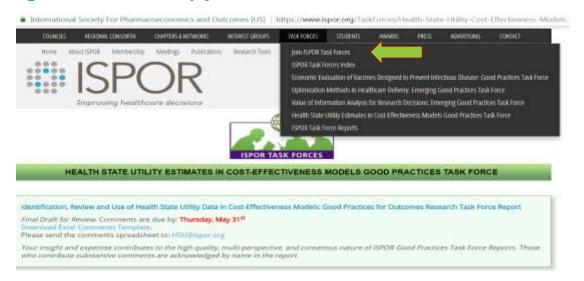
Workshop at ISPOR Asia Pacific 2018: Tokyo

<u>ISPOR Asia Pacific 2018</u> | Keio Plaza Hotel Tokyo, Tokyo, Japan (10-14 November 2018)



JOIN the VOI review group!

Being a member will keep you abreast of future ISPOR VOI activities!





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Slides are available on the ISPOR 2018 Baltimore webpage https://www.ispor.org/Event/index/2018Baltimore

