



Value of Information (VOI) Analysis for Research Decisions Task Force

ISPOR 22nd Annual Meeting – Boston 2017

Workshop 9: Report from the Task Force – Recommendations to Date

MODERATOR



Elisabeth Fenwick, PhD VOI Task Force Co-Chair Senior Principal Health Economics ICON plc Abingdon, England, UK





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- James F. Murray, PhD, Research Fellow, Global Patient Outcomes and Real World Evidence, Center of Expertise, Eli Lilly and Company Indianapolis, IN, USA
- Anirban Basu, PhD, Professor, School of Pharmacy, University of Washington, Seattle, WA, USA

AUDIENCE SURVEY QUESTIONS



 What is your general assessment about the importance of VOI in applied decision-making? (e.g., in HTA, research prioritization / funding)

1.1 In the current situation, the importance is:

- A. High
- B. Medium
- C. Low
- D. Not Sure

1.2 In an ideal world, the importance should be:

- A. High
- B. Medium
- C. Low
- D. Not Sure



- What do you see as the main *Practical Barriers* to conducting a VOI analysis? (maximum 3 answers allowed)
 - A. Access to tools to conduct a VOI
 - B. Complexity of methods
 - C. Lack of expertise on VOI
 - D. Lack of necessary data
 - E. Time required to conduct a VOI analysis
 - F. VOI does not incorporate all uncertainties
 - G. No accepted WTP threshold for endpoint of interest
 - H. Other practical barriers



Survey Question #3

- What do you see as the main barriers for Acceptance of VOI? (maximum 3 answers allowed)
 - A. Lack of uniform VOI Guidelines/Roadmaps
 - B. Unsolved methodological issues in VOI
 - C. No clear criteria for when a VOI should be performed
 - D. Decision makers do not think it is useful
 - E. Optimal research designs indicated by VOI may not be feasible
 - F. Unclear who would/should pay for additional research
 - G. Decision makers do not understand VOI
 - H. The need to define a WTP threshold for the endpoint of interest
 - I. Other



- What would you need the most to be able to conduct a VOI analysis? (maximum 1 answer allowed)
 - A. Training on VOI Basic Concepts w/case studies
 - B. Training on VOI Advanced Concepts w/case studies
 - C. VOI Consultation
 - D. VOI Analytical Software
 - E. Other

ISPOR VOI Taskforce Survey

To complete the survey, go to PollEv.com/voisurvey

Start the presentation to activate live content

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If you see this message in presentation mode, install the add-in or get help at PollEv.com/app

O 1 survey underway



People, Get Ready...



Value of Information Task Force

Introduction & Overview









- Introduce Task Force
- Task Force's Objective and Specific Aims
- Sneak preview of *draft* Task Force Reports
- Key Recommendations to date





- 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, Washington, DC, USA
- Rachael Fleurence, PhD, Executive Director, National Evaluation System for Health Technology (NEST) Coordinating Center, Medical Device Innovation Consortium (MDIC), Arlington, VA, USA
- Salah Ghabri, MD, PhD, Health Economist, Department of Economic and Public Health Evaluation, Haute Autorité de Santé, Paris, France

ISPOR VOI Task Force Members (2)



- Saskia Knies, PhD, Advisor, Pharmacoeconomics at National Health Care Institute - National Health Care Institute (Zorginstituut Nederland), Amsterdam, the Netherlands
- Erik Koffijberg, PhD, Associate Professor of Health Economics, University of Twente, Enchede, The Netherlands
- James F. Murray, PhD, Research Fellow, Global Health Outcomes and Real World Evidence, Center of Expertise, Eli Lilly and Company, Indianapolis, IN, USA
- Gillian D. Sanders Schmidler, PhD, Associate Professor of Medicine and of Biostatistics and Bioinformatics, Duke Clinical Research Institute, Duke University, Durham, NC, USA
- Lotte M.G. Steuten, PhD, Associate Member / Professor, Fred Hutch HICOR / University of Washington – School of Pharmacy, Seattle, WA, USA
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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).



- 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

TASK FORCE REPORT 1



Audience:

- decision makers / health care payers considering comparative or costeffectiveness analysis to inform their decisions
- stakeholder groups making research prioritization decisions across a range of priority areas



TASK FORCE REPORT 1



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- decision makers / health care payers considering comparative or costeffectiveness analysis to inform their decisions
- stakeholder groups making research prioritization decisions across a range of priority areas

Content:

- Decision making under uncertainty and the role of VOI analysis
- Definition of VOI concepts and terminology
- Overview of the 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

"lay terms"

TASK FORCE REPORT 2

- Audience: methodologists or analysts charged with undertaking VOI analysis to inform decision making
- Content:
 - Characterizing the sources of uncertainty for VOI
 - Key concepts, definitions and notation of VOI
 - Methods for computing EVPI, EVPPI 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



SO, WHAT IS VOI ANALYSIS?



CONCEPTUALLY





VOI ANSWERS 2 KEY QUESTIONS

- Which technology should be adopted into clinical practice given existing evidence and uncertainty surrounding outcomes and costs?
- 2. Is additional evidence required to support the use of the technology?
 - How uncertain are the expected benefits?





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 - How uncertain are the expected benefits?
 - Does this uncertainty matter? (Will it change the adoption decision?)





VOI ANSWERS 2 KEY QUESTIONS

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 - How uncertain are the expected benefits?
 - Does this uncertainty matter? (Will it change the adoption decision?)
 - How much does it matter (Consequences of getting it wrong?)





- Probability decision based on existing information will be wrong (probability of error)
- 2. Consequences of a wrong decision
 - health benefit forgone and healthcare costs
- 3. Effective lifetime for the intervention
- 4. Size of the beneficial population over useful lifetime of the intervention

STEPS IN UNDERTAKING VOI



• Conceptualizing the decision problem

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- Determining the effective lifetime of intervention and beneficial population
- Characterizing sources of uncertainty in current evidence base
- Undertaking PSA to determine decision uncertainty
- Calculating EVPI and comparing with costs of research

STEPS IN UNDERTAKING VOI





KEY TASK FORCE RECOMMENDATIONS



- 1. Conceptualizing the decision problem and decision-model
 - Should be determined by the decision problem; **NOT** by data availability
 - Anything not captured in model structure or parameters will not be captured in VOI
- 2. Estimating beneficial population over effective lifetime intervention
 - Beneficial population should be calculated based on the prevalent and/or incident cohorts as appropriate given the decision problem
 - Beneficial population should be reduced by the number of patients to be enrolled in a future study as they will generally not benefit from the information yielded
 - Justification for the effective lifetime should be stated explicitly and the impact of alternative durations on the VOI results should be explored in a scenario analysis

KEY TASK FORCE RECOMMENDATIONS



- 3. Characterizing sources of uncertainty for VOI
 - Parameter uncertainty and data synthesis: For every (set of) parameter(s) for which data are synthesized, the applied synthesis technique should be made explicit, and any uncertainty induced by the technique used should be quantified and included in the VOI analysis.
 - Structural uncertainty and alternative assumptions: Techniques used to handle identified structural uncertainties should be made explicit.
 - When parametrization is not feasible and data for model selection or averaging is lacking, scenario analysis eliciting plausible weights is recommended and a distribution for these weights should be used in a model averaging step and in the subsequent VOI analysis.
 - The discrepancy approach is recommended when a formal quantification of the impact of (separate) modelling choices is required, or guidance is needed on the value of further model improvement.

KEY TASK FORCE RECOMMENDATIONS



- 4. Reporting and interpretation of results
 - Results of VOI analysis should be used with the understanding that a positive EVP(P)I is a necessary but not sufficient prerequisite to deciding that further research is valuable.
 - Population EVP(P)I estimates should be compared to the expected costs of research on all or specific (groups of) parameters
 - EVSI estimates for each possible study design should be compared to the expected costs of the study
 - Other factors with potential relevance to decisions that should be considered are:
 - likelihood that research will be undertaken if an intervention is generally funded compared with being funded only in the context of research;
 - the extent of irreversible costs being incurred in delivering a new intervention
 - whether other information of relevance is likely to emerge over time

Uncertainty and VOI





James F. Murray, PhD



- Cost-effectiveness analysis (CEA) is an important tool in assessing the value of a new technology.
- Assessing uncertainty and its effects on CEA is a critical element of CEA and the subsequent decision.
- Value of Information (VOI) can be an informative part of analysis albeit there are challenges for characterizing uncertainty in the VOI and cost-effectiveness analyses.

VOI Concepts



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- Net Health Benefit (NHB) is the health benefit of a technology or intervention. In a CEA this is expressed by the Quality Adjusted Life Year (QALY) (i.e., survival & quality of life).
- Net Monetary Benefit (NMB) is the cost of achieving a NHB against a pre-determined Cost-Effectiveness Threshold
- Cost Effectiveness Threshold (CET) A Cost-Effectiveness Threshold (CET) must be assumed to conduct the VOI analysis if NMB is the objective function. Comparisons between various assumed CET thresholds is common.
- EVPI=Expected Value of Perfect Information the expected value of eliminating all uncertainty. EVPI is the expected opportunity loss associated with uncertainty. It places an upper limit on the value of further research. (Claxton and Posnett, 1996; Claxton, 1999).

VOI Concepts (2)



- EVPPI, expected value of partial perfect information the expected value of eliminating uncertainty in a subset of parameters. EVPPI is a necessary condition for ruling out research on a particular (subset of) parameter(s).
- EVSI, expected value of sample information the expected value of having additional information from a specific sample or study which reduces but does not eliminate uncertainty. This is used to inform research design.
- ENBS, expected net benefit of sample information the difference between EVSI and the costs of acquiring sample information. ENBS represents the net payoff to the proposed research study.
- EVPI, EVPPI and EVSI may be used for determining the ENBS based on comparisons between expected NHB or NMB and costs of future research projects.



Addressing Adoption and Research Design Decisions Simultaneously: The Role of Value of Sample Information Analysis

Claire McKenna, PhD, Karl Claxton, PhD

Methods to estimate the cost-effectiveness of technologies are well developed with increasing experience of their application to inform adoption decisions in a timely way. However, the experience of using similarly explicit methods to inform the associated research decisions is less well developed despite appropriate methods being available with an increasing number of applications in health. The authors demonstrate that evaluation of both adoption and research decisions is feasible within typical time and resource constraints relevant to policy decisions, even in situations in which data are sparse and formal elicitation is required. In addition to demonstrating the application of expected value of sample information (EVSI) in these circumstances, the authors examine and carefully distinguish the impact that the research decision is expected to have on patients while enrolled in the trial, those not enrolled, and once the trial reports. In doing so, the authors are able to account for the range of opportunity cost associated with research and evaluate a number of research designs including length of follow-up and sample size. The authors also explore the implications for research design of conducting research while the technology is approved for widespread use and whether approval should be withheld until research reports. In doing so, the authors highlight the impact of irrecoverable opportunity costs when the initial costs of a technology are compensated only by later gains in health outcome. **Key words:** Bayesian decision theory; expected value of information; research design; cost-effectiveness analysis. **(Med Decis Making 2011;31:853-865)**

EECP for Angina



- EECP is a non-invasive procedure used to treat chronic stable angina
- Long inflatable pressure cuffs are wrapped around the patient's calves, lower thighs and upper thighs





- The cuffs inflate and deflate to increase blood flow to the coronary arteries
- Typically involves 35 hours of therapy
- The primary outcome is the symptomatic relief of angina symptoms

Is More Evidence Required?

EVPI (£ million)

- If the uncertainty could be resolved (perfect information), the decision maker would choose to maximise the net benefits for each realisation of uncertainty: max_iNB(j,θ)
- But true realisations are unknown, so average over all possible values: $e_{\theta} \max_{j} NB(j, \theta)$
- EVPI = NB (perfect) NB (current)
- Maximum value of additional research
- Societal value = EVPI per patient * Number of patients who can benefit

Claire McKenna, PhD, Karl Claxton, PhD, Addressing Adoption and Research Design Decisions Simultaneously: The Role of Value of Sample Information Analysis. Center for Health Economics EEW Seminar, University of York 11th November 2010



In UK, no. of patients who can benefit:

 $P_0 \approx 68,000$

 $I_t \approx 5,000 \text{ per year}$

EVPI @ £20,000 per QALY \approx £110 m



What Type of Evidence is Required?



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 EVPPI considers the value of particular elements of the decision problem in order to direct and focus research towards those areas where the elimination of uncertainty has the most value



Threshold for cost-effectiveness

Value of Alternative Research Designs



- EVSI provides the value of a decision based on having additional sample information
- It predicts possible sample results that would be obtained from a study with a sample size of n

How it works

(1) Sample from the prior distributions,

e.g. QOL ~ Beta(α = 3.64, β = 47.14)

(2) Predict possible sample results for size n,

nQOL ~ Binomial(QOL, n)

(3) Form predicted posterior results for each sample,

QOL' ~ Beta((α +nQOL), (β +n-nQOL))

Since the actual results of each sample are not known in advance, we average the maximum expected net benefits over the distribution of possible sample results **Expected NB of the proposed** design with sample size n_{37}

EVSI for Different Sample Sizes



The Uses of Value of Information



Anirban Basu, PhD



- VOI theory can be expressed in terms of maximizing a generic utility function
- VOI methods can be applied using different objective functions that align with different perspectives
 - Net monetary benefits (Payer's/Societal perspective)
 - Clinical perspective (PCORI, SWOG)
 - Revenue (manufacturer's perspective)



Section 1181(d)(1) of the ACA specifies that

"The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden ... gaps in evidence in terms of clinical outcomes, practice outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, *the effect on national expenditures associated with a health care treatment, strategy, or health conditions*, as well as patient needs, outcomes, and preferences ... The Institute shall establish and update a research project agenda for research to address the priorities identified [above], *taking into consideration the types of research that might address each priority and the relative value (determined based on the cost of conducting research compared to the potential usefulness of the information produced by research) associated with the different types of research*, and such other factors as the Institute determines appropriate.[emphasis added]"

VOI for PCORI Investments





Value of Information (VOI) Analysis

REQUEST FOR PROPOSAL

RFP # PCO-VOIANALYSIS

Revised: December 13, 2016

Purpose

PCORI is seeking proposals of organizations and their proposed work plan to develop or adapt an existing decision model designed to determine the added value to society of evidence resulting from the conduct of a trial that compares three drugs used as second-line treatments for type 2 diabetes mellitus when glycemic control cannot be maintained with metformin alone.



ORIGINAL ARTICLE

Development and Evaluation of an Approach to Using Value of Information Analyses for Real-Time Prioritization Decisions Within SWOG, a Large Cancer Clinical Trials Cooperative Group

Caroline S. Bennette, MPH, PhD, David L. Veenstra, PharmD, PhD, Anirban Basu, MS, PhD, Laurence H. Baker, DO, Scott D. Ramsey, MD, PhD, Josh J. Carlson, MPH, PhD

Objective. Value of information (VOI) analyses can align research with areas with the greatest potential impact on patient outcome, but questions remain concerning the feasibility and acceptability of these approaches to inform prioritization decisions. Our objective was to develop a process for calculating VOI in "real time" to inform trial calculations. Our process was feasible for 8 of 9 trial proposals and efficient: the time required of 1 researcher was <1 week per proposal. We accommodated stakeholder input primarily by deconstructing VOI metrics into expected health benefits and incremental healthcare costs and assuming treatment decisions within our simulations





- Evaluate a structured approach to prioritizing cancer research using stakeholders with SWOG.
- Evaluated proposals from the Breast, Genitourinary and Gastrointestinal Disease Committees with SWOG
- 9 Phase II or Phase III randomized trials selected for pilot

Summary of 9 trials



 Table 1
 Summary of 9 Trial Proposals Reviewed by SWOG's Executive Review Committee between 2009 and 2013 That Were Used to Develop Our VOI Analyses Processes

Proposal ID	Trial Proposal Title	Phase	Sample Size	Committee	Endpoint	Year Reviewed
A	Prospective Evaluation of the Benefit of a Standard Versus An Extended Pelvic Lymphadenectomy Performed at Time of Radical Cystectomy for Bladder Cancer With Adjuvant Chemotherapy Administration for Node-Positive Disease	Ш	630	Genitourinary	PFS	2010
В	A Phase III Randomized Trial Comparing LHRHa + TAK-700 With LHRHa + Bicalutamide in Patients With Newly Diagnosed D2 Prostate Cancer	III	1486	Genitourinary	OS	2011
С	A Randomized Phase II Pilot Study Prospectively Assigning Treatment for Patients Based on ERCC1 for Advanced/Metastatic Gastric Cancer or Gastroesophageal (GE) Junction Cancer	П	200	Gastrointestinal	PFS	2010
D	Randomized Phase II Clinical Trial of AZD-6244 and MK-2206 v. mFOLFOX in Patients with Metastatic Pancreatic Cancer after Prior Chemotherapy	П	120	Gastrointestinal	OS	2011
E	Randomized Phase II Study Comparing the Novel MEK Inhibitor, Trametinib, to Standard of Care Chemotherapy in Patients With KRAS Mutant Metastatic Colorectal Cancer	П	92	Gastrointestinal	PFS	2013
F	Exemestane v. a Combination of Exemestane and the Monoclonal Antibody IGF-1R Inhibitor IMC-A12 in Patients With Metastatic ER/PgR Positive Breast Cancer	III	690	Breast	PFS	2009
G	Capecitabine and Dasatinib as Adjuvant Therapy in Patients with HER-2/neu Negative Breast Cancer	Ш	720	Breast	RFS	2008
H	Adjuvant Endocrine Therapy +/- Everolimus in Patients With High-Risk, Node-Positive, Hormone Receptor Positive and HER2-neu Normal Breast Cancer	III	3400	Breast	RFS	2011
Ι	Intensive v. Less Intensive Dosing of Zoledronic Acid v. Denosumab as Adjuvant Therapy for Early Stage Breast Cancer	III	680	Breast	OS	2010

OS, overall survival; PFS, progression-free survival; RFS, recurrence-free survival.





- Current level of decision uncertainty (i.e. Probability of making a suboptimal treatment decision based on current knowledge)
- The consequence of making sub-optimal treatment decision in terms of patients' life expectancy, quality of life, and/or health care costs
- How much new information would be collected in the trial, and how that impacts decision uncertainty
- The number of future patients likely to face the decision.





- Current level of decision uncertainty (i.e. Probability of making a suboptimal treatment decision based on current knowledge) – PRIOR INFORMATION
- The consequence of making sub-optimal treatment decision in terms of patients' life expectancy, quality of life, and/or health care costs – DECISION MODEL
- How much new information would be collected in the trial, and how that impacts decision uncertainty -SIMULATION
- The number of future patients likely to face the decision. REGISTRY DATA

Bennette et al. 2016

MINIMAL MODELING FRAMEWORK



Figure 2 Depiction of the Markov modeling framework used in our value of information calculations. Individuals enter the model as "alive, preprimary endpoint" state in the same way they enter the proposed clinical trial. They can remain in this health state, experience the primary endpoint of the trial (e.g., recurrence or progression) and thereafter be in the "alive, postprimary endpoint" state, or die. Patients who experience the primary endpoint of the trial remain in the "alive, postprimary endpoint" health state until death. When the primary endpoint of the trial is overall survival, the health states for "alive, postprimary endpoint" and "dead" are collapsed into a single state.

VOI RESULTS



 Table 2
 Patient Level and Population Level VOI Results for 9 Retrospective Trial Proposals Used to Develop

 Our Modeling Process^a

Proposal ID	1	Patient Level	Population Level			
	Incremental QALYs	Incremental Healthcare Cost, \$	Incremental QALYs	Incremental Healthcare Cost, \$		
A	0.438	1,800	33,000	130 million		
B	0.147	92,000 ^b	10,100	6.32 billion ^b		
C	0.092	32,200	4,900	1.70 billion		
D	0.160	30,500 ^b	21,300	4.06 billion ^b		
E	0.094	15,800	10,500	1.77 billion		
F	0.481	54,000 ^b	65,500	7.35 billion ^b		
G	0.258	23,200	42,300	3.81 billion		
H	0.302	24,800	20,800	1.71 billion		
I	-		-			

QALY, quality-adjusted life year.

a. Expected incremental QALYs gained and expected incremental healthcare costs are shown separately; see Methods section for more details.

b. Calculated using benchmark prices for interventions without a market price (i.e., prior to US Food and Drug Administration approval); see Appendix B for details.



- On-going work
- Previous work showed that such information does influence decision-making:
- 7 stakeholders indicated the results modified their rankings,
- 9 stated VOI data were useful,
- All (13) indicated they would support its use in future prioritization processes

Value-of-Information Analysis within a Stakeholder-Driven Research Prioritization Process in a US Setting: An Application in Cancer Genomics

Josh J. Carlson, PhD, Rahber Thariani, PhD, Josh Roth, MHA, Julie Gralow, MD, N. Lynn Henry, MD, PhD, Laura Esmail, PhD, Pat Deverka, MD, Scott D. Ramsey, MD, PhD, Laurence Baker, DO, David L. Veenstra, PharmD, PhD

Objective. The objective of this study was to evaluate he feasibility and outcames of incorporating value-ofvformation (VOI) analysis into a stakeholder-driven esearch prioritization process in a US-based setting. **Meth-** indicated they would support its use in future prioritization processes. Some stakeholders indicated expected value of sampled information might be the preferred choice when evaluating specific study designs. Limitations. Our study

Portfolio Visualization





Circle size is proportional to sample size of the proposed trial. Red bubbles not funded; green bubbles funded.

Portfolio Visualization





Circle size is proportional to sample size of the proposed trial. Red bubbles not funded; green bubbles funded.

VOI could be potentially applied to Product Development Lifecycle



- Borrow many concepts from existing VOI literature
- Need to explicitly account for Regulatory Success
- Need to explicitly account for Commercial Success
- Manufacture perspective

Second Panel on CEA recommendations



- Recommends VOI to guide decision making under uncertainty
 - Likelihood of conducting research
 - Irreversible costs being incurred in delivering new intervention
 - Likelihood of future information
- Impact Inventory Table
 - To accommodate multiple perspectives





- Working meeting at ISPOR Boston to finalize draft reports
- Both reports will be out for 1st review end of June 2017
- Revisions
- 2nd (final) review early Sept 2017
- Presentation of final task force reports at ISPOR European Congress, Glasgow, Nov 2017
- Expected publication Q1 2018.



QUESTIONS?



AUDIENCE SURVEY RESULTS

In the current world, what is your general assessment about the importance of VOI in applied decision-making? (1 answer max) Respond at PollEv.com/voisurvey Text VOISURVEY to 22333 once to join, then 1, 2, 3, or 4 Answers to this poll are anonymous 6 medium high low unsure Total Results: 19









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Please JOIN our Task Force Review Group



- 1. Go to the ISPOR homepage: www.ispor.org.
- 2. Click on the GREEN TASK FORCE menu at the TOP of the homepage
- 3. Select JOIN on the pull-down menu.

THANK YOU!



FORUM SLIDES are AVAILABLE!

http://www.ispor.org/Event/ReleasedPresentations/2017 Boston

Or via the ISPOR Boston App

Or on the VOI Task Force webpage