F8: New & Emerging Issues in HEOR: Revising the ISPOR Code of Ethics

Presented on behalf the ISPOR Code Of Ethics Task Force

Moderator

Richard Willke
Chief Science Officer
ISPOR
Session Outline

- Members of the task force
- Background on the task force
- Task force objectives
- Organization of the Code
- Discussion
- Q & A

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**ISPOR:**
- Richard Willke, PhD, Chief Science Officer, ISPOR, USA

*All ISPOR Regional Chapters members will be invited to review the draft Code.*
Task Force Members (3)

PATIENT PERSPECTIVE:

- **Louise Binder**, Health Policy Consultant, Canadian Cancer Survivor Network, Toronto Canada
- **Gurmit Sandhu**, Patient Engagement Specialist, Gurmit Sandhu Consulting GmbH, Basel, Switzerland

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Task Force Background

- The existing ISPOR Code of Ethics (Code) was published on the ISPOR website 7 years ago in 2008.
- The stakeholder environment and research landscape has changed dramatically since then with the explosion of **Big Data, genomic information, social media, and privacy issues, rise of health IT, among others**.
- ISPOR should provide the most up to date code of ethics to stay current with these changes.
- **2008 Code available on the purple About ISPOR menu on ISPOR home page**
Task Force Objectives

- Revise the ISPOR Code of Ethics in light of the current environment;
- Provide wide geographic coverage appropriate to the scope of ISPOR;
- Provide researchers with an understanding of how to use the Code in their practice;
- Make recommendations regarding harmonization with ethics codes from other professional societies;

Task Force Objectives (2)

- Provide a code of ethics for transparency in communication across all sectors of ISPOR membership;
- Provide guidelines for areas that are in the current Code but need more development:
  - Sponsorship and Stakeholders
  - Design and Research Practices
  - Publication and Dissemination
The Code will address…

- Importance of the Code of Ethics in conducting health economics and outcomes health care studies using existing databases and primary data collection.
- Professional codes relevant to our members and stakeholders in their respective fields.
- How the current Code has been used
- Potential conflicts with codes of ethics from other professional societies and make recommendations accordingly.
The Code will address...(2)

- Recommendations for areas that are absent in the previous Code or are now developed in more detail, such as...
  - Ethical use and handling of honoraria/incentives
  - Involvement of IRB/EC
  - Ethical interaction with patients
  - Privacy considerations, including patient privacy
  - Social media data collection and communication
  - Ethical conduct in reproducing research results and modelling, e.g., whether basic data should be made available by authors for independent parties to re-analyze.

Speaker

Louise Parmenter PhD MSc
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Real-World Evidence Solutions
QuintilesIMS
ISPOR’s Vision & Mission Revised 2016

**ISPOR Vision**: ISPOR is the leading global scientific and educational organization for health economics and outcomes research and their use in decision making to improve health.

**ISPOR Mission**: to promote health economics and outcomes research excellence to improve decision making for health globally.

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**Review of Global Standards and Guidelines**

- Over 20 International standards/guidelines are referenced in drafting ISPOR Code of Ethics, e.g.
  - The Declaration of Helsinki
  - The Belmont Report
  - ICH GCP
  - GPP
  - GEP
  - CIOMS
  - European Directives and Guidance
  - ICMJE
  - AHRQ
  - EFPIA
  - COPE

- The list is not inclusive for ALL international guidelines, the task force is open for suggestions.
Findings from our Review of Standards / Guidelines for Ethical Conduct

Complex, evolving and diverse landscape of standards / guidelines for HEOR

Ethical guidelines / standards are found embedded in documents of broad (e.g. scientific methods guides) and narrow scope (e.g. publication guides)

No one set of standards / guidelines applies to our multi-disciplinary field

Standards / guidelines can be mandatory or voluntary best practice recommendations

Chapter 2 – Application of Ethical Principles to the ISPOR Code

- **Three principles:**
  - Respect for persons
  - Beneficence
  - Justice
Underlying Ethical Principles

Respect for persons:
• Protecting the autonomy of all people and treating them with courtesy and respect and allowing for informed and voluntary consent. Researchers must be truthful and conduct no deception;

Beneficence:
• The philosophy of "Do no harm" while maximizing benefits for the research project and minimizing risks to the research subjects; and

Justice:
• Ensuring reasonable, non-exploitative, and well-considered procedures are administered fairly — the fair distribution of costs and benefits to potential research participants — and equally.

The Belmont Report

Chapter 2 – Application of Ethical Principles to the ISPOR Code

Additional emphasis:
– Privacy
– Transparency and Integrity
– Civility

Reflects:
– Increased data access
– The global nature of research
– Broad range of research participants and health care system stakeholders
Chapter 2 – Application of Ethical Principles to the ISPOR Code

- **Privacy:**
  - Members who perform HEOR can be privy to data sources containing protected health information (PHI) and other personal data from patients.
  - It is essential that these data are handled with utmost care so that patient confidentiality be maintained at all times and no breaches to patient privacy occur.

- **Transparency and Integrity:**
  - Where possible, Members must disclose research methods in sufficient detail to permit replication.
  - Research sponsors should be clearly acknowledged, and any conflicts of interest declared.
  - Reporting of results should be an unbiased reflection of the full range of findings generated.
Chapter 2 – Application of Ethical Principles to the ISPOR Code

▪ Civility:
  – Members’ research and discussion should respect the dignity of all participants.
  – Respecting the dignity of patients and providers of care is clearly a responsibility.
  – It is also a responsibility to treat fellow researchers with respect.

Chapter 3: Scope of the Code

▪ Oriented towards Health Economics and Outcomes Research but closely related to other common research types
▪ The objective is to evaluate the effect of health care interventions on patient well-being, including clinical, economic and patient-centered and relevant outcomes and functioning of health care systems and health-affecting behaviors.

Members should adhere to the standards of practice for their respective fields of research and identify any official Guidelines/Standards used.
Chapter 4: Research Design Considerations

Primary Data-Related Research Considerations
- Participant recruitment
- Patient population and research setting
- Site selection and collaboration
- Safety /Adverse Events (SAE)
- Incentive /Honorarium

Secondary Data-Related Research Considerations
- Administrative Databases and Other Large Datasets
  - Registration of observational studies
  - Modeling Studies
Chapter 5: Data Considerations

- Privacy and Data Protection
- Combining Research Data/Big Data
- Data Verification
- Transparency of Data
- Scientific Misconduct

Chapter 6: Sponsorship and Relationships with Others
Chapter 7 Patient Engagement

Patient Engagement is

- Meaningful, timely & comprehensive
- Involvement of patients & their representatives
- In research, including HEOR
- That impacts their lives
- Not purely doctor’s or researcher’s needs

Why it matters?

- Content & processes are complete, understandable, relevant & implementable
- Ensures unmet research & patients needs are met
- Reduces redundancy
- Ensures buy in
- Supports comprehensive dissemination of information to participants, including those in vulnerable & hard to reach populations, & the public
- Enhances review of ethical (& moral) considerations
Purpose of Patient Engagement: ISPOR Code of Ethics

**ISPOR researchers can better understand where & when**

- Patient engagement

**before, during & after**

- conducting research is recommended & supported by healthcare decision makers

Patient Engagement is relevant across ISPOR Research Activities

- Clinical Research
- HTA Agencies
- Patient Relevant Outcomes
- Secondary data related research
- Scientific publication policies
- Others, e.g. Social media, pricing & reimbursement

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1 includes research focus, choice of comparator, target product profile, site selection, patient recruitment & retention in trials, patient relevant outcomes and dissemination of study results. Others: describing benefits/harms/uncertainties, safety monitoring
2 Part of defining value of the product being assessed with patient perspectives on adverse events, experiences in clinical trial & disease burden including patient relevant information & outcomes
3 Currently, these were under represented in Canadian HTA submissions. Berglas et al 2016
4 Administrative databases & other large data sets, observational studies & modelling studies
5 also includes scientific congresses & program committees of medical associations. In 2015, ISPOR initiative with patient groups representatives
6 Kitchen H et al. ISPOR Milan Workshop 2015
7 national prescribing rules affecting patient access in selected countries
Challenges: Researchers’ Perspectives
Most of these were addressed by researchers

- Lack of time available to patients for involvement
- Lack of research team time, resources and training
- Limited number of patients with training and/or research experience
- Difficulty in finding appropriate representatives for engagement


Practical Considerations: Implementing Patient Engagement in ISPOR research

<table>
<thead>
<tr>
<th>Practical approaches: collaborating with patient groups</th>
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<tbody>
<tr>
<td>Disease type</td>
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<tr>
<td>- High prevalence vs rare</td>
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<tr>
<td>- Overlapping stake holders in some diseases</td>
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<tr>
<td>- Single or multiple disease focus</td>
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<tr>
<td>Size &amp; their scope</td>
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<tr>
<td>Organizational cultures &amp; priorities</td>
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<td>Geographies and countries</td>
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A number of models for collaboration on going
- Pharma companies
- ISPOR Special Interest Groups SIGs
- Others eg CROs, academia, NGOs

Practical information in Appendices, ISPOR Code of Ethics
Chapter 8: Publication and Dissemination

- Major touchstone for ethical issues in dissemination of medical research is report from International Committee of Medical Journal Editors (ICMJE)

- ISPOR Code of Ethics consistent with ICMJE recommendations, but provides more specificity for HEOR issues.

- Interrelated ethical issues surrounding research dissemination in this chapter:
  - Bias
  - Sponsor-influence
  - Authorship
  - Transparency of reporting
Ethical Issues Surrounding Research Dissemination

- Bias:
  - Publication bias: Not publishing research due to negative, inconclusive or otherwise undesirable findings
  - Analytic bias: Deliberate manipulation of study methods to favor a particular outcome
- Sponsor influence:
  - Concern that study sponsor will seek to introduce analytic bias on front end or publication bias on back end
- Authorship:
  - Issues related to including as authors those not affiliated with work (e.g., a KOL) or excluding those who were (e.g., from study sponsor)
- Transparency of reporting:
  - For HEOR, key issue is that in-depth review may not be possible without reviewer access to underlying data and/or model

Recommendations (1)

- Contracts in sponsored research should clearly establish publication rights & role of the study sponsor (if any) in review and/or approval.
- Where a HEOR study is being conducted alongside a prospective study, members should ensure that the clinical study is registered (e.g. on ClinicalTrials.gov).
- Members should not list an author on any publication where the individual has not performed substantial work nor exclude an individual who has made a substantial contribution.
- Study authors should disclose any current or past relationships with a company or competitor of any product discussed in the work, as requested by the journals to which they submit.
- Members should endeavor to publicly disseminate their work and to publish it in peer reviewed journals when possible.
- Members should work with editors of journals to encourage an appropriate peer review process that examines the quality of the methodological rigor independently of the authors’ affiliation.
Recommendations (2)

- Members serving as peer-reviewers for journals should respect the confidentiality of the material.
- Description of study methods should be complete and transparent enough for a suitably trained researcher to replicate the study.
- Methods sections of papers should give thorough, transparent attention to all measures taken to minimize bias.
- Members should respond favorably to requests from journals for access to original data and electronic copies of models where feasible.
- Otherwise, members should be encouraged to provide supporting material demonstrating model and/or data validity, such as range & logic checks, and assessment of data completeness.
- If submitting to a non-peer reviewed publication or disseminating via electronic media, members should avoid the inclusion of material that is overly technical and/or cannot be supported by basic article references or make it clear that article represents author’s own opinion.

Chapter 9: Conclusions and Limitations

- Fast changing environment
- New data source emerge
- This Code, cuts across virtually all areas of research and dissemination and is meant to be a comprehensive guide for HEOR researchers
Next Steps

- First draft completed
- Welcome reviews and comments
- Publish in 2017

http://www.ispor.org/TaskForces/ISPOR-Code-of-Ethics.asp

Please join the 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.
Summary points

- A summary of points is prepared for quick reference
- New items are highlighted in blue font
Chapter index

- CHAPTER 1: INTRODUCTION
- CHAPTER 2: APPLICATION OF ETHICAL PRINCIPLES TO THE ISPOR CODE
- CHAPTER 3: SCOPE OF THE CODE
- CHAPTER 4: RESEARCH DESIGN AND CONSIDERATIONS
- CHAPTER 5: DATA CONSIDERATIONS
- CHAPTER 6: SPONSORSHIP AND RELATIONSHIPS WITH OTHERS
- CHAPTER 7: PATIENT ENGAGEMENT
- CHAPTER 8: PUBLICATION AND DISSEMINATION
- CHAPTER 9: CONCLUSIONS AND LIMITATIONS

Appendix index

- APPENDIX 1 Summary of Previous ISPOR Codes of Ethics
- APPENDIX 2 Other Existing Codes of Ethics Relevant to HEOR
- APPENDIX 3 HEOR Related Common Research Types
- APPENDIX 4 Examples of HEOR Data Sources
- APPENDIX 5 Primary Research Means of Recruitment
- APPENDIX 6 Patient Safety and the Reporting of Adverse Events
- APPENDIX 7 Incentive and Disclosure Requirements
- APPENDIX 8 Data Protection Considerations
- APPENDIX 9 The role of Institutional Review Boards and Ethics Committees
- APPENDIX 10 Considerations for Research Participant Involvement in Research Development and Design