Introduction to Health Economics and Outcomes Research (HEOR) for Writers

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About Us

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About Pharmerit International

Our mission is to improve patient access to medical care through evidence, worldwide.

- Modeling and Meta-Analysis
- Real World Evidence
- Strategic Market Access
- Patient Reported Outcomes
Topics

- What is HEOR?
  - Definitions of health economics (HE) and outcomes research (OR)
  - Where does HEOR evidence come from?
  - When in the development process is it created?
  - Why do we need HEOR evidence?
- Who uses HEOR evidence?
  - How is it used?
- How can I break into HEOR writing/editing?
  - What roles can medical writers/editors play in HEOR?
  - Tips for freelance writer
  - Tips for writers with nontechnical backgrounds
Definitions of Health Economics & Outcomes Research (HEOR)

Health Economics
- Analyzes the economic aspects of health and healthcare, with a focus on the costs (inputs) and consequences (outcomes) of healthcare interventions.

Outcomes Research
- Evaluates the effect of healthcare interventions on patient-related clinical, humanistic, and economic outcomes.

Source: Berger et al, 2003
What Types of Outcomes?

- **Clinical Outcomes**: Result from the disease or from treatment
- **Economic Outcomes**: Direct and indirect costs derived from the clinical outcomes
- **Humanistic Outcomes**: Also derived from clinical outcomes

**Clinical**
- Effectiveness
- Morbidity
- Mortality
- Function

**Economic**
- Resource use
- Work productivity
- Burden of illness
- Cost-effectiveness

**Humanistic**
- Health-related quality of life (HRQOL)
- Preference
- Caregiver burden

Where Does HEOR Evidence Come From?

- Real-world evidence (RWE)
- Clinical outcomes assessments (COA)
- Patient-reported outcomes (PRO)
  - Symptoms, health status, health-related quality of life (HRQOL), patient preferences, utilities, satisfaction, productivity
- Systematic reviews
- Meta-analyses
- Clinical studies
  - Prospective randomized controlled trials (RCTs)
  - Pragmatic clinical trials
- Post-marketing/phase IV/open-label studies
- Observational studies
  - Retrospective (e.g., chart review studies, claims database analyses)
  - Prospective (e.g., registries, surveys)
Multiple Disciplines Contribute to HEOR

Clinical research

Clinical outcomes assessment

HEOR Evidence

Clinical epidemiology

Health economic evaluation

Policy research

Health service research
HEOR Evidence Generation Occurs Throughout the Product Life Cycle

<table>
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<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IIIb</th>
<th>Launch</th>
<th>Phase IV</th>
<th>Pre-LOE</th>
<th>LOE</th>
<th>POST-LOE</th>
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<tr>
<td>Market Assessment</td>
<td>Burden of Illness</td>
<td>Go/No-Go Modeling</td>
<td>Early Pricing Models</td>
<td>Stakeholder Input</td>
<td>Stakeholder Feedback</td>
<td>Pre-LOE</td>
<td>LOE</td>
<td>POST-LOE</td>
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Why Do You Need HEOR Evidence?

- Identify unmet needs
- Address evidence gaps
- Supplement RCTs with real-world data
  - Primary RCT endpoints (e.g., laboratory test results) may not be the most relevant clinical outcomes for physicians/healthcare decision makers (HCDMs)
  - RCTs may not include humanistic/economic outcomes
  - RCTs may not generate country-specific data, HRQOL data
- Promote patient-centered research and provide evidence about what actually happens to patients
- Helps develop and evaluate cost containment strategies
- Respond to changes in market environments (new products, cost pressures)
- Adapt to different regions/affiliates, HCDMs, populations, local treatment patterns (vs global RCTs with narrow populations and strict inclusion/exclusion criteria)
- Comply with additional requirements for economic information in HTA vs regulatory body submissions (not just efficacy, safety)
Who Uses HEOR Evidence?

- Health Technology Assessments (HTAs)
- Healthcare Decision Makers (HCDMs)
- Physicians
- Patients
How Is HEOR Evidence Used?

Addresses outcomes and provides evidence on what happens to a patient

Produces meaningful evidence to inform selection of appropriate cost-effective therapy

Informs clinical guidelines development

Evaluates product’s cost, budget impact, and cost-effectiveness

Helps illustrate product’s value

Guides formulary coverage and reimbursement
## HEOR in Decision Making

<table>
<thead>
<tr>
<th></th>
<th>Can It Work? (Efficacy)</th>
<th>Does It Work? (Effectiveness)</th>
<th>Is It Worth It? (Value)</th>
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<tr>
<td><strong>Evidence Generation</strong></td>
<td>RCT</td>
<td>Pragmatic clinical trial</td>
<td>Economic evaluation</td>
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<td>Observational studies</td>
<td>Budget impact</td>
</tr>
<tr>
<td><strong>Evidence Synthesis</strong></td>
<td>Systematic review of trials (SRT)</td>
<td>Systematic review of evidence (SRE)</td>
<td>Budget impact</td>
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<td>Clinical guidelines</td>
<td>Clinical guidelines</td>
<td>Coverage reimbursement decision</td>
</tr>
<tr>
<td><strong>Decision Making</strong></td>
<td>Product approval</td>
<td>Product approval</td>
<td>Coverage reimbursement decision</td>
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<td></td>
<td></td>
<td>Physician/patient decision</td>
<td>Price</td>
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</table>

Source: Adapted from Luce et al, 2010.
The Choice of HEOR Tool Depends on Customer Evidence Needs and Feasibility

Epidemiology Study
- Provides accurate, up-to-date, and region-specific estimates of the incidence, prevalence, morbidity, mortality, and natural history of target conditions

Cost-of-illness Analysis
- Determines the economic impact of an illness or condition

Cost-benefit Analysis (CBA)
- Compares costs and benefits, both of which are quantified in common monetary units

Budget Impact Model (BIM)
- Quantifies additional costs and cost offsets associated with adopting new products

Cost-effectiveness Analysis (CEA)
- Compares costs in monetary units with outcomes in quantitative non-monetary units, e.g., reduced mortality or morbidity
  - Cost-minimization analysis – Determination of the least costly among alternative interventions that are assumed to produce equivalent outcomes
  - Cost-utility analysis (CUA) – Comparison of costs in monetary units with outcomes in terms of their utility, usually to the patient, measured in QALYs
  - Cost-consequence analysis – Presentation of costs and outcomes in discrete categories, without aggregating or weighing them

Source: National Library of Medicine, 2014.
### Summary: Value of HEOR

**Addresses business needs**
- Demonstrate the product’s added value

**Addresses physicians and HCDMs’ needs**
- Evidence on “real world” patients
- Outcomes that address evidence gaps (economic and humanistic)
- Broader patient populations with fewer inclusion and exclusion criteria
  - Comorbidities
  - Disease severity
  - Older patients

**Addresses patients’ needs**
- Evidence on patients who look like them
- More “meaningful” outcomes
  - Clinical events not laboratory results
  - Quality-of-life information
  - Patient-centered outcomes research
Roles for Medical Writers/Editors in HEOR

**WRITING**
- Dossiers
  - GVD, AMCP, CVD, EUnetHTA
- Publications
  - Economic models, DBA, SLR, NMA
- Value messaging
- Objection handlers

**EDITING**
- Dossiers
- Publications
- Slide decks
- Reports

**PROJECT MANAGEMENT**
- Dossiers
- Publications
- Reports

Beth’s Path

BCPS

PharmD

Clinical

Medical Writing Fellowship

Freelance

Pharmerit International
Tips for Freelance Writers

Leverage Skill Set
- Manuscript writing
- Editing
- Scientific background
- Slide decks
- Reports

Know Your Audience
- Journal selection,
- HCDMs
- Global
- National

Know Your Resources
- ISPOR website
- AMCP Format for Formulary Submissions
- HealthEconomics.com
Tips for Writers with Nontechnical Backgrounds

- Statistics!
- Promote your Microsoft Word knowledge
- Don’t take your liberal arts skills for granted
  - Audience analysis
  - Big-picture thinking
  - Writing mechanics
  - Idea organization
- Use insight into non-expert audiences
- Attend AMWA workshops
- Focus on your “highest and best use” (i.e., maximally productive skills/tasks)
Where Can I Get More Information?

- Associations (e.g., ISPOR, ISOQOL, AMCP)
- Dossiers: AMCP Format for Formulary Submissions, version 4
- National Information Center on Health Services Research and Health Care Technology (NICHSR)
  - Self-study courses with glossaries
    - HTA 101
    - Health Economics Information Resources
    - Finding and Using Health Statistics
  - Core library recommendations (e.g., Health outcomes, Methodology)
- AMWA events
  - Intermediate HEOR session at 2:00 PM today
- CHEERS guidelines
- Websites
  - HealthEconomics.com
  - Health Affairs blog
**Integrated Overview of HEOR**

**HEOR DATA SOURCE**
- Clinical Studies
  - Prospective RCT, PCT
  - Observational
  - Registry
- Retrospective
  - Observational
  - Database
- Cross-sectional surveys
  - Patients, caregivers
  - Physician experts

**DATA TYPE**
- Humanistic (PRO)
  - Symptoms
  - Health Status
  - HRQOL
  - Preference/Utilities
  - Satisfaction
  - Productivity
  - Adherence/persistence
  - Treatment patterns
  - Resource use / economic
  - Epidemiology

**DATA USE**
- Internal Decisions
- Label Claims
  - Indication
  - Clinical study section
- Value Messages
  - Dossier
  - Promotion
- Publications
  - Economic Models and Analyses

**Regulatory Bodies**

**Stakeholders**
- The Individual (Patient/Physician)
- The Payer (Insurers/HTA/Society)
References

Thank you!