Introduction to Health Economics and Outcomes Research (HEOR) for Writing Professionals

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Catherine O'Connor Mirvis, BA
Agenda

- Introductions
- What is HEOR?
- How can I break into HEOR writing/editing?
- Who uses HEOR evidence?
- How is HEOR evidence used?
Presenters

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Undergrad BS Pharm, PharmD Critical Care Residency, Clinical Pharmacist/Academia, Medical Writing Fellowship, Freelance

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Associate Director, Strategic Market Access

Sr. Communications Analyst, Strategic Market Access
PART 1:
WHAT IS HEOR?
Health Economics & Outcomes Research

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.
**What Outcomes Are Generated?**

**ECHO MODEL**

**Economic**
- Impact of intervention on costs; direct and indirect costs derived from clinical outcomes
- Includes: Resource use, work productivity, loss of work, burden of illness, cost-effectiveness, transportation
- Evaluated using economic or pharmacoeconomic analyses (e.g., cost-benefit, cost-effectiveness, cost-minimization, cost-utility, budget impact models)
- Examples: ICER, QALYs, PPPM, PPPY absenteeism, LOS, office visits

**Clinical**
- Measurable changes in health status due to an intervention
- Includes: effectiveness, morbidity, mortality, function
- Evaluated through clinical trials, post-marketing reports
- Examples: Cure, clinical goal (HbA1c, BP), secondary prevention, remission, adverse event rates, compliance

**Humanistic**
- Impact of an intervention on patient-reported endpoints; also derived from clinical outcomes
- Includes: Health-related quality of life (HRQOL), preference, caregiver burden
- Evaluated using general or disease-based patient/caregiver questionnaires or surveys
- Examples: SF-36, EQ-5D, patient satisfaction, patient preference, validated and unvalidated tools/surveys

References:
Where Does HEOR Evidence Come From?

- Productivity
- Real-world Evidence
- Symptoms
- Prospective RCTs
- Clinical Outcomes Assessment
- Chart Reviews
- Surveys
- Indirect Treatment Comparison
- Patient-reported Outcomes
- Post-marketing Studies
- Observational Studies
- Systematic Reviews
- Health Status
- Registries
- Meta-analyses
- Claims Database Analyses
- Clinical Studies
- Prospective Observational Studies
- Open-label Studies
Who Performs Outcomes Research?

- Health plans/Medical groups
- Academic institutions
- Physicians
- Pharmacists
- Government agencies
- Pharmaceutical companies
- Nurses
- Other healthcare professionals
- Economists
- HTA bodies
# HEOR Evidence and Product Life Cycle

## Preclinical
- Exploratory research
- Market assessment
- Unmet needs/gap analysis
- KOL research
- Very early modelling

## Phase 1 and 2
- Market assessment
- Unmet needs/gap analysis
- Early modelling, early pricing models
- Burden of illness studies
- Piggyback studies
- PRO development, testing, validation

## Phase 3 and 3b
- Payor assessment
- Model development/validation
- Piggyback studies
- Registries
- Comparative effectiveness research
- Value message development
- Pricing and reimbursement
- AMCP dossier
- Global value dossier

## Product Approval and Launch
- Phase 4 studies
- Model refinement
- Piggyback studies
- Registries
- Comparative effectiveness research
- Prospective observational studies
- Retrospective studies
- Database analyses
- Chart reviews
- Safety surveillance
- AMCP dossier
- Global value dossier
- HTA

## Post-launch
- Comparative effectiveness research
- Prospective observational studies
- Database analyses
- Chart reviews
- Safety surveillance
- AMCP dossier
- Global value dossier
- HTA

## Loss of Exclusivity
- Safety surveillance
- Real-world studies
- Comparative effectiveness research
- HTA
- Global value dossier
Why Do We Need HEOR Evidence?

- Identify unmet needs
- Supplement RCT with RWE
- Address evidence gaps
- Promote patient-centered research
- Help develop/evaluate cost containment strategies
- Adapt data to different populations
- Respond to changes in market environments
- Comply with HTA submission
Summary: Who, What, Where, When, How

Who
- Regulators
- Patients
- HCDM
- HCP
- Politicians/Advocacy

What
- Outcomes
  - Economic
  - Clinical
  - Humanistic

Where
- Clinical studies
- Real-world evidence
- Patient-reported outcomes
- Modelling

When
- Pre-clinical
- Phase 1/2
- Phase 3/Pre-launch
- Post-launch
- Loss of exclusivity

How
- Product approval
- Education/awareness
- Reimbursement
- Formulary placement
- Guidelines
PART 2: WRITING AND EDITING IN HEOR
Roles for Writing Professionals in HEOR

**Writing**
- Dossiers
- Publications
- Value messaging
- Objection handlers
- Study reports
- Modelling reports

**Editing**
- Dossiers
- Publications
- Slide decks
- Reports

**Project Management**
- Dossiers
- Publications
- Reports
Tips for How to Enter the HEOR Space

Leverage Your Skills
- Manuscript writing
- Editing
- Scientific background
- Slide decks
- Reports

Know Your Audience
- Journal selection
- HCDMs / Payers
- Global
- National

Know Your Resources
- ISPOR website
- AMCP format
- HealthEconomics.com

Expand Your Knowledge
- ISPOR short courses
- AMCP meetings
- HEOR meetings
**Tips for Nontechnical Backgrounds**

- Learn or brush up on statistics
- Promote your Microsoft Word knowledge
- Know your audience (HCDMs, HTAs, patients)
- Don’t take your liberal arts skills for granted!
  - Audience analysis
  - Big picture
  - Writing mechanics
  - Organizing ideas
- Insight into non-expert audiences
- AMWA workshops
- Focus on your “highest and best use”
Where Can I Get More Information?

- ISPOR: ispor.org
- ISOQOL: isoqol.org
- AMCP: amcp.org
- CHEERS Guidelines
- NICHSR: nlm.nih.gov/nichsr/hta101
- AHRQ: ahrq.gov
- PCORI: pcori.org
- HealthEconomics.com
PART 3:
HEOR EXAMPLES
Pharmacy and Therapeutics (P&T) Committee

- What is a Formulary?
- What is a P&T committee?
- Who is on the P&T committee?
  - Pharmacists
  - Doctors
  - Nurses
  - Lawyer
  - Quality assurance
  - Lay member
Pharmacy and Therapeutics (P&T) Committee

What are their functions

- Manage education programs on drug utilization
- Establish policies to ensure safe and effective drug use
- Develop policies promoting cost-effective drug use
- Provide guidance on drug distribution and control policies
Factors Considered by P&T Committees

- Clinical efficacy and effectiveness
- Safety: RCT, real-world data
- Therapeutic need: first in class, 5 similar agents
- Clinical guidelines
- Standards of practice
- Treatment options
- Economics: costs, PMPM costs, QALY, ICER
## Case Studies

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cost, $</th>
<th>Efficacy</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug A</strong></td>
<td>1 tablet daily</td>
<td>1.25 per tablet</td>
<td>77%-80%</td>
</tr>
<tr>
<td><strong>Drug B</strong></td>
<td>1 tablet daily</td>
<td>1.50 per tablet</td>
<td>78%-80%</td>
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<tbody>
<tr>
<td><strong>Drug A</strong></td>
<td>2 tablets daily</td>
<td>0.60 per tablet</td>
<td>77%-80%</td>
</tr>
<tr>
<td><strong>Drug B</strong></td>
<td>1 tablet daily</td>
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<thead>
<tr>
<th>Dose</th>
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<th>Side Effects</th>
<th>Adherence (DBA)</th>
</tr>
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<tr>
<td><strong>Drug A</strong></td>
<td>1 tablet daily</td>
<td>1.25 per tablet</td>
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<tbody>
<tr>
<td>Drug A</td>
<td>1 tablet daily 1.25 per tablet</td>
<td>77%-80%</td>
<td>Nausea, vomiting, irreversible hepatotoxicity (5%)</td>
</tr>
<tr>
<td>Drug B</td>
<td>1 tablet daily 1.50 per tablet</td>
<td>78%-80%</td>
<td>Nausea, headache</td>
</tr>
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<table>
<thead>
<tr>
<th>Dose</th>
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<th>Efficacy</th>
<th>Side Effects</th>
<th>Nursing Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug A</td>
<td>2 injections daily 30.00 per dose</td>
<td>77%-80%</td>
<td>Nausea, vomiting</td>
<td>5 minutes</td>
</tr>
<tr>
<td>Drug B</td>
<td>2 injections daily 15.00 per dose (drug cost)</td>
<td>78%-80%</td>
<td>Nausea, headache</td>
<td>IV push over 30 min, observe for 30 min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dose</th>
<th>Cost, $</th>
<th>Efficacy</th>
<th>Side Effects</th>
<th>Hospital Length of Stay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug A</td>
<td>2 tablets daily 250.00 per tablet</td>
<td>77%-80%</td>
<td>Nausea, vomiting</td>
<td>5 days</td>
</tr>
<tr>
<td>Drug B</td>
<td>2 injections daily 25.00 per dose (drug cost)</td>
<td>78%-80%</td>
<td>Nausea, headache</td>
<td>7 days / 5 days + 2 days home IV therapy</td>
</tr>
</tbody>
</table>
# Case Studies

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<th>Drug A</th>
<th>Drug B</th>
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</thead>
<tbody>
<tr>
<td><strong>Cost, $</strong></td>
<td>500,000 per dose</td>
<td>1.50 per dose</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>Effective</td>
<td>Effective</td>
</tr>
<tr>
<td><strong>PMPM cost, $</strong></td>
<td>0.0001</td>
<td>0.02</td>
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<td>2 injections daily</td>
</tr>
<tr>
<td><strong>Cost, $</strong></td>
<td>30.00 per dose</td>
<td>10.00 per dose (drug cost)</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>80%</td>
<td>60%</td>
</tr>
<tr>
<td><strong>Side effects</strong></td>
<td>Nausea, vomiting, severe rash</td>
<td>Nausea, headache</td>
</tr>
<tr>
<td><strong>Nursing administration</strong></td>
<td>IV push over 10 minutes</td>
<td>IV push over 10 minutes</td>
</tr>
<tr>
<td><strong>Laboratory testing</strong></td>
<td>Q day (renal)</td>
<td>Q 3 days (renal panel, CBC)</td>
</tr>
<tr>
<td><strong>ICU time</strong></td>
<td>1 day</td>
<td>1.5 days</td>
</tr>
<tr>
<td><strong>Ventilator time</strong></td>
<td>0.5 day</td>
<td>1 day</td>
</tr>
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</table>
Questions?