Evidence Based Medicine Tools for Decision Making

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Learning Objectives

- Identify 3 evidence based medicine tools that payers can use to assist with decision making
- Understand components of the AMCP Format Dossier
- Discuss various types of economic models used
- Define outcomes analyzers and their importance in evidence based medicine
Pre-Test Question

- What types of tools can be used to assist payers with decision making
  A. Economic models
  B. Dossiers
  C. Outcomes Analyzers
  D. All of the above
Pre-Test Question

What type of evidence do you think is most critical for formulary decision-making by payers?

A. Clinical data supporting FDA-approved indications
B. Clinical data supporting off-label usages
C. Product information
D. Health economic information, such as the model
E. Drug price
Pre-Test Question

Which of the choices are considered economic models?

A. Cost utility analysis
B. Budget impact model
C. Cost-effectiveness analysis
D. Price calculator
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Pre-Test Question

What is an outcomes analyzer?

A. Analytics and reporting instrument used by IT departments
B. HIPAA-compliant software tool that uploads pharmacy / medical claims
C. Person that analyzes a person’s golf swing
D. Web-based reporting tool that calculates the weather
Agenda

- Welcome and Introductions
- Pre-Test Questions
- Evidence Based Medicine for Decision Making
- Evidence Based Medicine Tools
  - Dossiers
  - Economic Models
  - Outcomes Analyzers
- Post-Test Questions
Evidence Based Medicine for Decision Making
History of Decision Making

- Historically, P&T committees make decisions based on
  - Reports in the medical literature
  - Promotional materials provided by drug manufacturers
  - Anecdotal information from physicians
  - Discounts

- Decisions focused on consequences to pharmacy budgets, rather than on broader health and economic consequences

- Recent trends are moving toward
  - Evidence-based medicine
  - Cost-effectiveness or “value for money”
### Decision Making Globally

<table>
<thead>
<tr>
<th>Country</th>
<th>Requirements/Institutions/Actions</th>
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<tbody>
<tr>
<td><strong>Australia</strong></td>
<td>Requires cost-effectiveness evidence</td>
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| **United Kingdom** | Optional cost-effectiveness evidence  
  • National Institute for Clinical Excellence (NICE)  
  • Initiates and conducts evaluations itself  
  • Makes nonbinding recommendations to the National Health Service (NHS) |
| **United States** | Formulary committees have informally evaluated pharmacoeconomic data with large variation across plans  
  • In 1998 the Regence BlueShield health plan in Seattle began asking drug manufacturers to submit standardized packages of clinical and economic evidence as a condition for formulary review. |
Evidence Based Medicine Tools

- Dossiers
- Economic Models
- Outcomes Analyzers
Dossiers
What is a dossier?

dossier

a collection or file of documents on the same subject, especially a complete file containing detailed information about a person or topic
What is the AMCP *Format* dossier?

A process to obtain a standardized set of data and information about a drug from its manufacturer to support reimbursement and/or formulary placement consideration.
A Little History Lesson…

1990s
Plans recognize issues with new product information provided by PhRMA. Regional ‘guidelines’ developed.

2000s
AMCP Format v1.0 was born!
2002-2009, 2 major revisions to the format

2012
AMCP Format v3.1 with addenda recognizing the changing marketplaces

Xcenda has been involved since the beginning
Overview of AMCP Format v3.1

1.0 Executive Summary (3 pgs)

2.0 Product Information and Disease Description (20 pgs)
   2.1 Product description
   2.2 Place of product in therapy
   2.3 Evidence for pharmacogenomic tests and drugs

3.0 Supporting Clinical Information
   3.1 Key Clinical Study Summaries (2 pgs)
      – On-label evidence
      – Off-label evidence
      – Evidence table spreadsheet

4.0 Modeling Report (20 pgs)

5.0 Other Supporting Evidence
   5.1 Summary of other relevant evidence

6.0 Supporting Information
   – References
   – CD-ROM of spreadsheet models

2.2.1 Disease Description (1–2 pgs)
   • Epidemiology & relevant risk factors
   • Pathophysiology
   • Clinical presentation
   • Societal & economic impact

2.2.2 Approaches to Treatment (1–2 pgs)
   • How is disease currently treated?
   • How does the new product fit into standard or existing therapy?

2.2.3 Treatment Guidelines
   • National and international bodies

May include retrospective studies, meta-analyses, systematic reviews, quality-of-life or economic studies, comparative observational studies, adherence/persistence studies, patient preference, others
Following the AMCP *Format* Dossier footsteps

Unsolicited request from payer*

Manufacturer determines need for dossier...

...and calls Xcenda

Dossier is developed and approved

Manufacturer provides the dossier to the payer*

Payer uses the dossier in sound clinical evaluation
Economic Models
What is a Health Economic Model?

- A model is a predictive tool to help decision makers make better more informed decisions
  - Example of weather models

- Health economic models synthesize clinical and economic evidence from:
  - clinical trials
  - observational studies
  - insurance claims databases
  - case registries
  - public health statistics
  - preference and quality of life surveys

- To make predictions about clinical and economic outcomes of health care interventions
Why Economic Modeling?

- Decisions must be made about:
  - Coverage and reimbursement for new health technologies
  - Formulary placement of pharmaceuticals
  - Cost-containment strategies

- No clinical trial meets all of the following conditions:
  - Includes all relevant comparators
  - Reflects a health plan’s real-world population
  - Has a time horizon long enough to capture all relevant outcomes
  - Includes clinically meaningful patient outcomes and costs
  - Makes results available in a few months at minimal cost

- Economic modeling is a tool to assist in decision making
  - We do not have a crystal ball
  - Models are better than a hunch or wild guess
Value of Economic Models

• AMCP dossier
  – AMCP dossier guidelines (v3.1) recommend dossiers should include an electronic copy of a working model
  – A cost-effectiveness and budget impact model is recommended

• Field use with managed care payers
  – Used by account managers and medical science liaisons to demonstrate product value to decision makers

• Publications
  – Abstracts, posters, and manuscripts can communicate value to a broader audience of clinicians and payers

• Internal decision making
  – Can assist with pre-launch product value strategy and pricing decisions
Types of Health Economic Models

- **Cost Calculator**
  (How much does a health technology cost?)

- **Cost-effectiveness**
  (How much value does a health technology provide for the money?)

- **Budget impact**
  (How much does a health technology cost across a patient population?)

- **Pricing**
  (How much can a company charge for a health technology?)
Budget Impact Models

- **Payer Question**
  - “What is this going to cost me?”

- **Provides a snapshot of product adoption/market dynamics and financial impact on the health plan**
  - Pharmaceuticals
  - Devices
  - Diagnostics
  - Procedures

- **Budget impact model outcomes include**
  - Cost per-member per-month (PMPM) – difference between baseline and new scenario
  - PMPM provides a concise overall impact on costs given market share changes


**Budget Impact Models**

“…are not intended to establish the overall value of healthcare technologies because they do not include the full impact of the technology on clinical and patient outcomes. They can be useful for estimating system-wide (e.g., pharmacy and medical) budget impacts, however, and are commonly used by managed care payers. These models, as defined here, estimate drug costs, healthcare cost offsets, and adverse event costs, as well as the expected utilization in the healthcare system, to derive projected per-member per-month costs.”

– Academy of Managed Care Pharmacy*

* AMCP - Academy of Managed Care Pharmacy®
# Budget Impact Model Design

## CURRENT ENVIRONMENT

- **Total Population**
- **Sick Population**
- **Target Population**
- **Resource Utilization**
- **Total Treatment Costs**

## NEW ENVIRONMENT

- **Total Population**
- **Sick Population**
- **Target Population**
- **Resource Utilization**
- **Total Treatment Costs**

### Incidence/Prevalence
- % diagnosed
- % treated

### Treatment practice
- Unit costs

### BUDGET IMPACT (difference)
Cost-Effectiveness Models

**Payer Question**
- “What product provides the most value?”

**Cost-effectiveness models compare the value of alternative treatments**
- Within a target patient population
- Over a specified time horizon
- From a particular stakeholder perspective

**Cost-effectiveness model outcomes**
- Incremental cost per clinically relevant outcome measure
- The payer’s willingness-to-pay threshold determines if a treatment is cost-effective

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* Cost-effectiveness Models
  “…are used to establish the value of a new technology relative to an appropriate comparator, and often use decision analysis techniques. They can be based directly on clinical trials. They are disease-based and account for the impact of new technology on clinical outcomes (efficacy, adverse events), resource use, and costs in the short and long term. They also reveal the relation between data inputs and assumptions and outcomes.”

  – Academy of Managed Care Pharmacy*

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Cost-Effectiveness Model Design

- Various methods to compare costs and clinical benefits
  - Decision tree (see example)
  - Markov process

- Would you choose Drug A, Drug B, or Drug C?
  - How would you choose?

- Incremental Cost-Effectiveness Ratio (ICER)
  - Quantifies the value for money of one treatment compared to another
Xcenda’s Economic Models

- Numerous designs
  - Burden of illness
  - Cost-effectiveness
  - Budget impact
  - Productivity impact
  - Value-based pricing
  - Return on Investment

- Various platforms
  - Excel-based models
  - Tree Age models
  - Software-based models (iPad)

- Diverse perspectives
  - US and ex-US
  - Private payer
  - Provider
  - Hospital
  - Medicare
  - Societal
Outcomes Analyzers
Overview of Outcomes Analyzers
PC-based Analyzer
Analyzer Flow Diagram

1. Data Request Form
2. NDCs
   - Plan Export
3. Pharmacy Claims
4. Claims Import
5. ICD-9 Codes
6. Medical Claims
7. Process Pharmacy and Medical Claims
   - Data Mapping
     - Select data files to import and map the claim fields to the Analyzer database fields
   - Claims Processing
     - Load the data from the claims files into the Analyzer database
8. Processed Data
   - Query
9. Utilization Measures
   - Load the data from the claims files into the Analyzer database
10. Results
History of Analyzers
Post Test Questions
Post-Test Question

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Thank you

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Where knowledge, reach and partnership shape healthcare delivery.