Unleash Product Value
PBM Clinical Perspective

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Vice President, Clinical Services
United States per capita spending is more than twice the average of other developed countries.

Health outcomes are no better than the countries that spend less

<table>
<thead>
<tr>
<th>HEALTH STATUS</th>
<th>Country</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life expectancy at birth</td>
<td>South Africa</td>
<td>Worst</td>
</tr>
<tr>
<td>Infant mortality</td>
<td>Iceland</td>
<td>Worst</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QUALITY OF PRIMARY CARE</th>
<th>Country</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unmanaged asthma</td>
<td>Slovak Republic</td>
<td>Worst</td>
</tr>
<tr>
<td>Unmanaged diabetes</td>
<td>Italy</td>
<td>Worst</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>QUALITY OF ACUTE CARE</th>
<th>Country</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety during childbirth</td>
<td>Poland</td>
<td>Worst</td>
</tr>
<tr>
<td>Heart attack mortality</td>
<td>Australia</td>
<td>Worst</td>
</tr>
</tbody>
</table>

As the U.S. health system continues to drive for better value while simultaneously improving outcomes, advanced analytics that highlight opportunities that traverse the outcomes and economic boundaries will become more important for all stakeholders in the health system.
Consumer-centric real-world data

Social, environmental & behavioral data
- Socio-demographic
- Health risk assessment
- Media & digital exposure
- Wearable / device data
- Patient engagement data
- Promotional exposure
- Purchasing patterns
- Loyalty / membership
- Survey responses
- Reported outcomes

Healthcare delivery data
- Electronic health records
- Electronic medical records
- Clinical notes
- Registry data
- Care management program data

Payment & access data
- Medical and pharmacy claims
- Eligibility and enrollment data
- All-payer pharmacy claims
- Point-of-sale data
Real-world data vs real-world evidence

<table>
<thead>
<tr>
<th>REAL-WORLD DATA (RWD)</th>
<th>REAL-WORLD EVIDENCE (RWE)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data collected from the health care and consumer ecosystem that can be used to describe:</td>
<td>Analytics that compare or predict real-world:</td>
</tr>
<tr>
<td>• Utilization and cost of diagnostics, treatments, procedures, etc.</td>
<td>• Population and patient-level risks</td>
</tr>
<tr>
<td>• Clinical values associated with a specific patient’s health care delivery journey</td>
<td>• Effectiveness, safety and cost of treatments or interventions</td>
</tr>
<tr>
<td>• Demographics, geography, consumer purchases and behaviors</td>
<td>• Performance of care providers and institutions</td>
</tr>
<tr>
<td></td>
<td>• Variations in the above across patient populations</td>
</tr>
</tbody>
</table>
Advantages of real-world evidence (RWE)

- Effectiveness in wider clinical practice with real-world behavior
- Study results more generalizable
- RWE evaluates more patient relevant endpoints
- RWE uses multiple data sources (e.g., claims data, chart review, patient surveys)
- Longer follow-up risks and benefits
Perspectives on RWE from managed care entities

- First Focus groups, 1:1 interviews assessing perception of RWE use in decision making
- Reviewed thoughts on two RWE studies in reputable journals
- Results showed: RWE is used sometimes to help with decisions
- Useful when there are limited available randomized controlled trials
- Helps with safety assessment
- Utilization management determinations
- Cost considerations
Is RWE used in Pharmacy and Therapeutics (P&T) Committee reviews?

**Journal of Managed Care & Specialty Pharmacy (2017)**

- **Purpose:** to evaluate actual use of RWE to inform health care delivery decisions in managed care by reviewing the evidence sources cited in P&T committee monographs and therapeutic class reviews
- A total of 6 MCOs supplied 12 monographs and 15 therapeutic class reviews
  - MCOs: 2 PBMs, 2 health plans, 1 quasi-governmental provider, 1 contract pharmacy benefit consulting firm
  - Total references cited: 565

J Managed Care & Spec Pharm. 2017;23(6):613-620.
Is Real World Evidence Used in P&T Reviews?

<table>
<thead>
<tr>
<th>Source</th>
<th>Therapeutic class (n=439)</th>
<th>Single entity (n=126)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer info (e.g., product labels, data on file, “DailyMed”)</td>
<td>18.9%</td>
<td>42.1%</td>
</tr>
<tr>
<td>Published clinical trials</td>
<td>35.3%</td>
<td>15.1%</td>
</tr>
<tr>
<td>FDA website info (e.g., ANDA, committee)</td>
<td>8.4%</td>
<td>8.7%</td>
</tr>
<tr>
<td>Other/unknown</td>
<td>8.4%</td>
<td>8.7%</td>
</tr>
<tr>
<td>Expert/consensus statements</td>
<td>9.6%</td>
<td>7.1%</td>
</tr>
<tr>
<td>Compendia (e.g., Micromedex, Up-to-Date)</td>
<td>5.0%</td>
<td>7.1%</td>
</tr>
<tr>
<td>Systematic reviews/meta-analyses</td>
<td>5.9%</td>
<td>1.6%</td>
</tr>
<tr>
<td>Published RWE studies</td>
<td>4.8%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

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Pharmacy Benefit Managers’ (PBM) focus

The nature of a PBM is to focus on prescription drug costs and less on overall health care spend

- **PBM have excellent real-time access to prescription data**
  - Use of spreadsheets to deduce conclusions

- **Data is typically limited to the impact on prescription benefit**
  - Goal is to reduce overall per member per month (PMPM) of prescription drug costs

- **PBM work with clients to marry medical and pharmacy**
  - Limited in scope and information
PBM pharmacy and therapeutic processes

**Makeup of a P&T committee**
- Typically external practitioners in a variety of different specialties
- Some PBMs include high-level PBM-employed clinicians on the P&T

**Focus of the P&T**
- Members are trained to constructively look at the clinical data
- Cost data is prohibited
- Utilization data is often shared to help explain why one agent is chosen over another
- Makes a clinical designation and utilization management recommendations and criteria review
PBM decision-making process

P&T clinical determinations are reviewed
- Does it have to be available?
- Are there clinical risks?
- Should one product from a therapeutic category be available?
- Is there a utilization management program P&T recommended?

Business review discussion, cost data is reviewed
- Look at lowest overall net cost of the drugs, including rebates
- Evaluate data on market share, shift assumptions
RWE in PBMs

• RWE studies supplement prescription data
• Use of limited medical data with prescription data to internally assess
  − Look at data more closely resembling the PBM population
  − Post marketing utilization differs from clinical trials
• Published outcomes studies bring better light to overall cost of care

Example*:
• Comparison of four DPP-4 inhibitors on major CV inpatient events
• No consistent evidence of significant differences in CVD events
• Therefore, no recommendation to allow for one over another

*Data on file
Total cost of care assessment in PBMs

• Real-world data lends to
  − Review of total cost of care
  − Ability to find trends in disease states that wouldn’t have been found using medical or pharmacy alone
  − Lab data can be tied in
  − Machine reading of medical record notes to find additional detail

• How can this decrease cost of total care?
  • Opening up the assessment from just pharmacy to overall care
  − Change how decisions are made
  − May result in increased coverage of medications in order to drive overall cost of care down
Value-based offerings

Value-based contracting

• Evaluation of effectiveness of a therapy as part of the contracting
• For PBMs — only responsible for drug cost and only have access to that data
• PBMs are partnering with medical, lab and other data for clients in order to enhance these offerings
• Allows for more robust total cost of care VBCs marrying the full patient profile to evaluate outcomes
• PCSK9 example
  − If members don’t reach levels of LDL-c reduction shown in the clinical trials, then the rebate gets further discounted.
  − If members reach or exceed the trial, the rebate rates stay the negotiated rate

Diabetes example
− DPP-IV inhibitors contracting and rebate rates enhanced if members meet various treatment goals

1 in 4 health plans now have “at least one outcomes-based contract” with a drug maker*

30% of [health plans] are negotiating for one or more outcome-based contracts now” with drug makers*

* https://www.forbes.com/sites/brucejapsen/2017/05/31/as-drug-prices-soar-value-based-pay-hits-pharmaceutical-industry/#574f6705493c
Value-based offerings

Value-based formularies
• Using data sources to help develop new ways of formulary management
• Pure cost/clinical of drug vs. overall disease state impact
• Make formulary coverage decisions based on different parameters
• Diabetes
  - Using data to identify participants
  - Evaluate lab data to show
    • Advantage to using exenatide weekly versus basal insulin

Effectiveness and tolerability of therapy with exenatide once weekly vs basal insulin among injectable-drug-naïve elderly or renal impaired patients with type 2 diabetes in the United States

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Driving real-world evidence into decision making
Many unanswered questions leading to further health care evolution

- How can this data be leveraged to create a new type of formulary?
- How do independent PBMs show that increases in prescription drug costs help to decrease medical costs?
- How can PBMs work with their clients to help drive home the benefit of looking at overall cost of care?
  - Prescription benefit costs might go up
Thank you.

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