

Use of Real-World Evidence In Payer Decision-Making: Fact or Fiction?

International Society of Pharmacoeconomics and
Outcomes Research

Issue Panel

May 23, 2016

Speakers

- **Daniel C. Malone**, RPh, PhD – University of Arizona
(Moderator)
- **Steven G. Avey** – Vice-President, Specialty Pharmacy,
MedImpact
- **Craig Mattson**, MS, MBA, RPh, Senior Director,
Formulary Development, Prime Therapeutics
- **Jay McNight**, PharmD, BCPS, Director, HPS Clinical
Strategies, Humana

Today's Discussion

1. When do payers find RWE useful?
2. What factors contribute to the utility of RWE?
3. How can researchers improve RWE studies?

How Payers and PBMs Use HEOR Data to Appropriately Manage High Cost Medications

Steven G. Avey, R.Ph., M.S., FAMCP
Vice President Specialty Pharmacy Programs
Medimpact Health Systems, Inc.

Medimpact Health Systems Environment

Multiple formularies – our own + support client formularies (consultative approach)

- Moderately Managed Formulary – 2 tiers
- Highly Managed Formulary – 4 tiers
- Med D Formulary – As allowed by CMS
- Managed Medicaid Formulary – highly restrictive

Customers across the country – commercial health plans, state-employer groups, state exchanges, union groups, self-insured employers, hospital systems, Medicaid


Goal is lowest net cost and appropriate therapy

- Do not chase rebates + ensure right drug to the right patient

Medical management of specialty medications – late 2016


- Consistent PA and UM criteria + benefits across both benefits
- Site of care channel management

Craig Mattson



Our stats

- **13** Blue Plan owners
- **19** Blue Plan clients
- **22.2 million** members
- **\$22.5 billion** drug spend managed
- **337 million** annual claim volume (weighted)
- **67,000+** retail pharmacies in network
- **7.2 million** Prescriptions shipped via PrimeMail*
- **\$4.4 billion** revenue in 2014
- **3,900** employees



■ Prime owner client	★ Headquarters	● PrimeMail site
■ Prime client	● Satellite office	● Specialty pharmacy
■ Serving members	● Contact center	

Clinical Review Process

- New Drug Monograph
 - RCTs
 - Dossier
 - CDER/CBER
 - Peer reviewed literature
- ➔ Not used
 - Data on file
 - Meeting presentations, posters
- Annual Class Reviews
 - RCTs
 - Peer reviewed literature
 - Guidelines
 - Systematic reviews
 - Meta-Analysis
 - RWE (often do own study)

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Humana

Jay McKnight PharmD, BCPS

Director, Pharmacy Clinical Strategies

Humana Pharmacy Solutions



Humana

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Humana

- Leading health care company that offers a wide range of insurance products and health and wellness services; founded in 1961; headquartered in Louisville, KY
- 2015 revenues of \$54.3 billion
- Total assets of approximately \$26.9 billion
- Over 30 years of experience in the Medicare program
- One of the nation's top providers of Medicare Advantage benefits with approximately 3.2 million members
- Approximately 14.3 million medical members nationwide
- Approximately 7.0 million members in specialty products
- Operates approximately 200 medical centers

Humana

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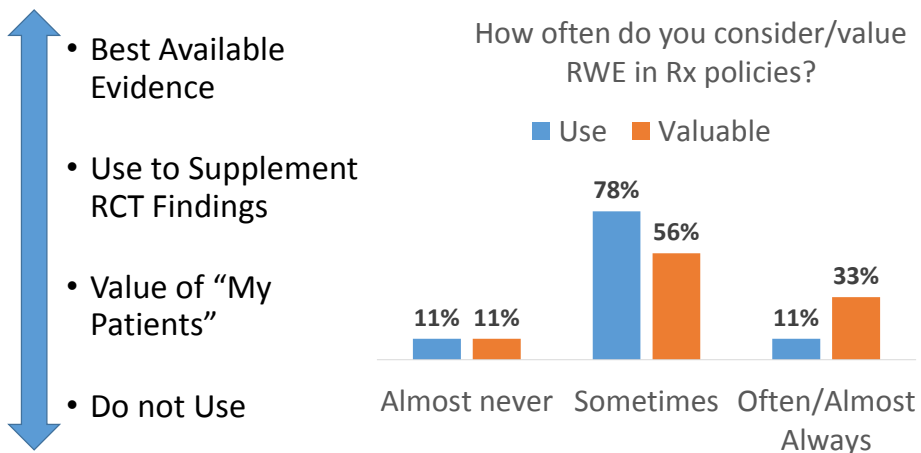
Use of RWE by Healthcare Organizations

- Focus group meetings with 20 “payers”
- Examination of 24 Pharmacy and Therapeutic committee monographs (over 500 references examined)
- Evaluation of 2 published RWE articles
 - Southworth et al. “Dabigatran and postmarketing reports of bleeding.” NEJM 2013; 368:1272-1274.
 - Gershon et al. “Combination long-acting B-agonists and inhaled corticosteroids compared with long-acting B-agonists alone in older adults with chronic obstructive pulmonary disease. JAMA 2014; 312(11):1114-1121.

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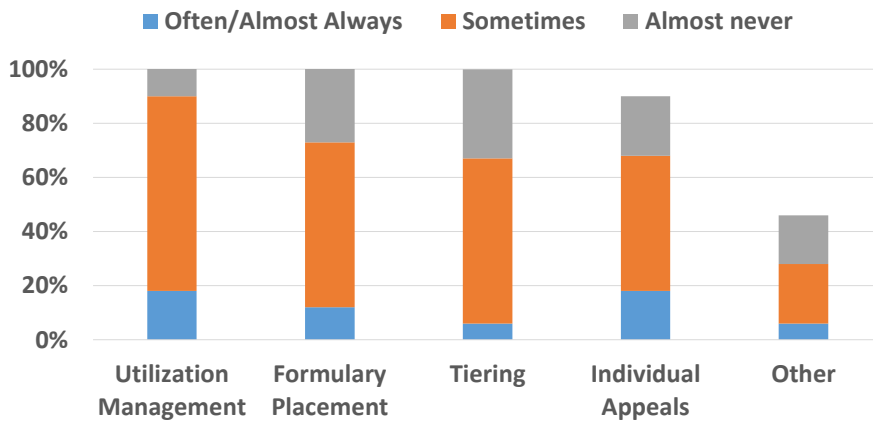
Most, but not all, payers use RWE for some decisions



RWE can be useful for many activities

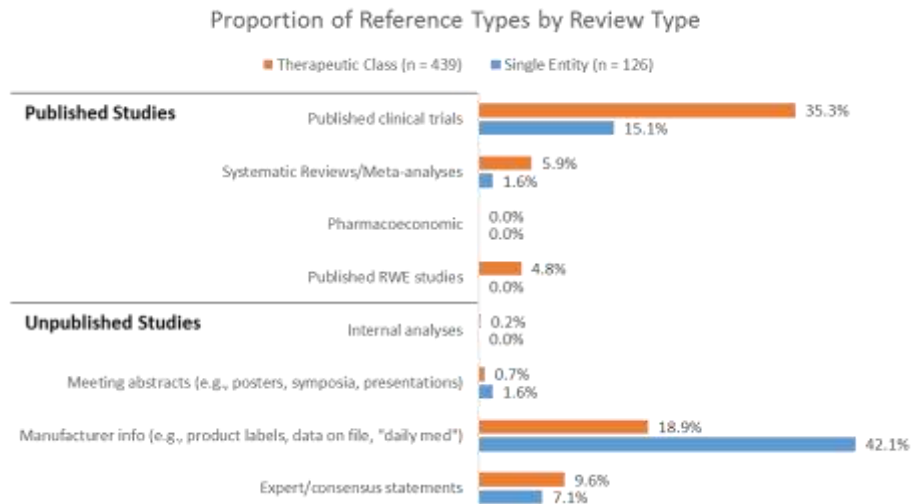
- Safety
- Population management
- Financial considerations
- Comparative evidence
- Rare conditions
- Medical policy
- Adherence
- Utilization management
- Technology assessment

Utilization Management, Formulary Placement Are Most Frequent Use of RWE

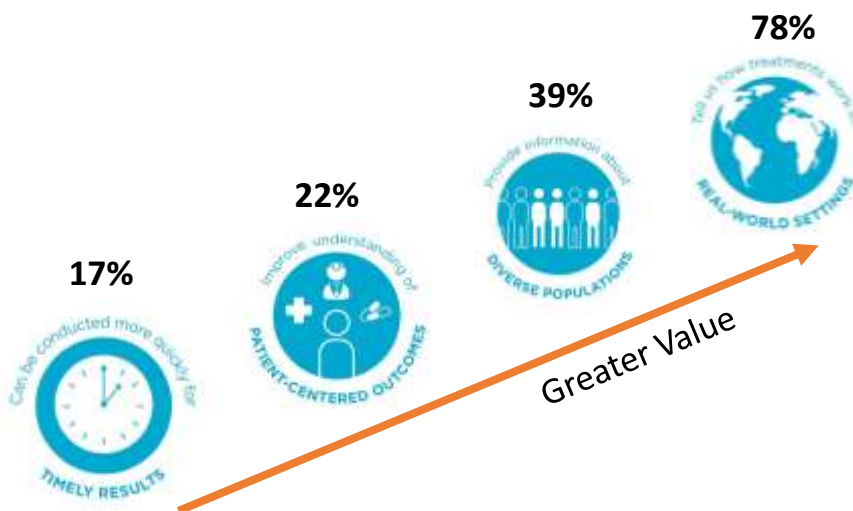


N=18

Use of RWE in P&T monographs/ therapeutic class reviews

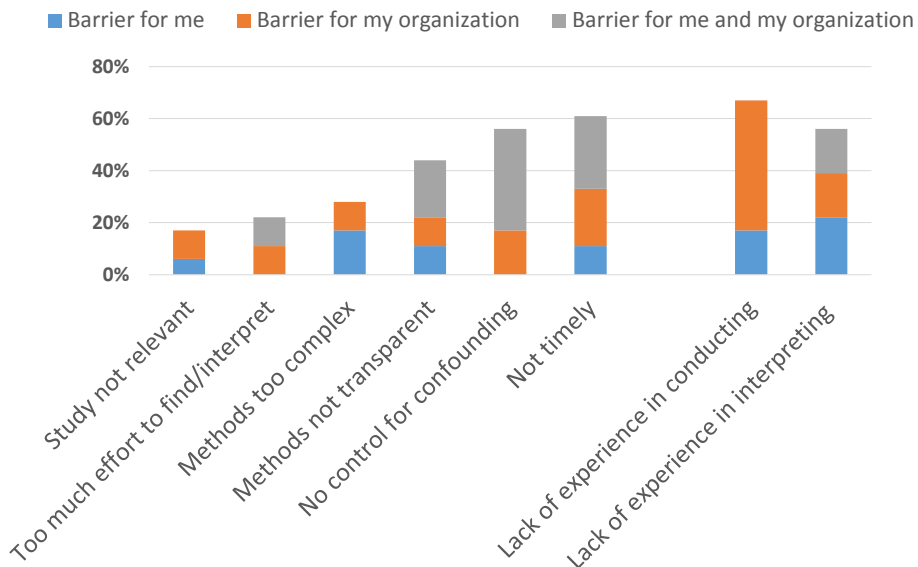


Real-world settings and diverse populations are viewed as advantages of RWE



N=18; Advantages of observation studies compared to RCT

Barriers to Use RWE



N=18; Barriers to use of observational studies in decision-making

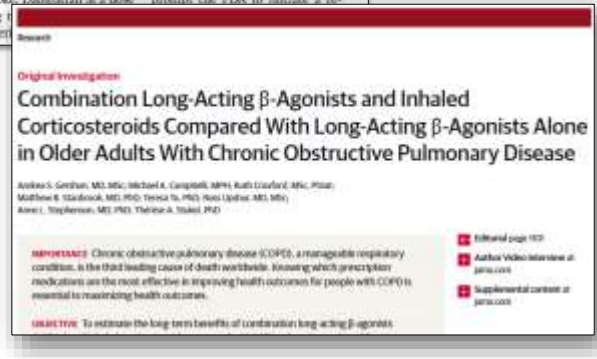
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Payers Views on Published RWE



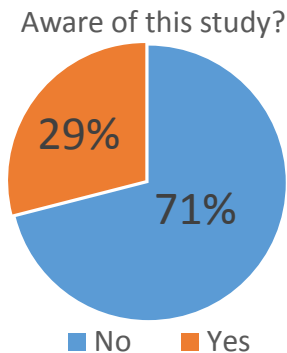
Southworth et al. NEJM 2013; 368:1272-74



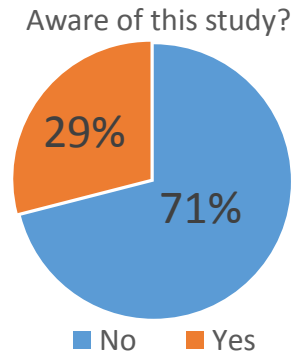
Gershon et al. JAMA 2014; 312(11):1114-1121

Awareness was lacking

Less than 1/3 aware of RWE published in well known journals



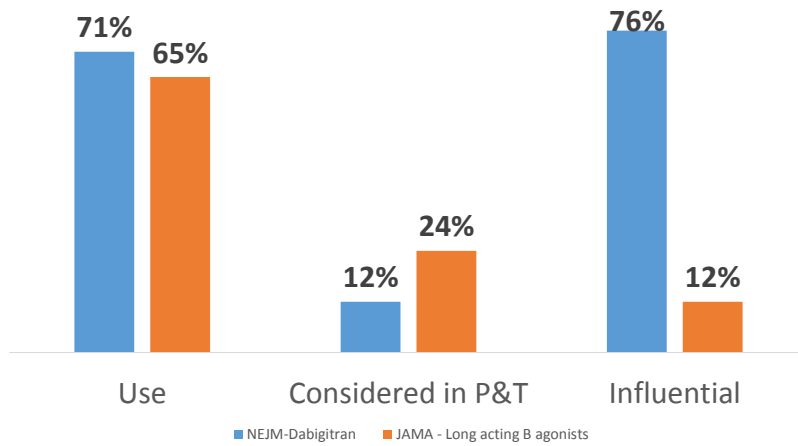
Southworth et al. NEJM 2013; 368:1272-74



Gershon et al. JAMA 2014; 312(11):1114-1121

But....

.... Once aware, RWE studies considered useful



Relevance is Important

- Populations
- Comparators
- Follow-up
- Transparency



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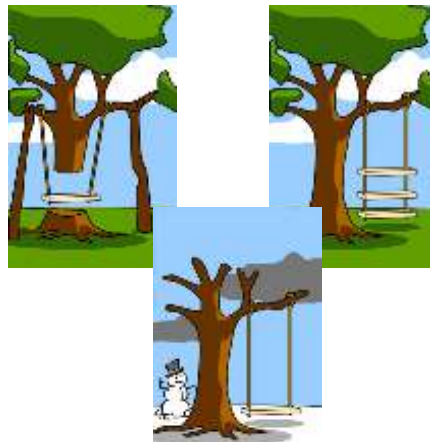
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Asking the right questions?

The question decision-makers need answered



The questions Investigators ask



Endpoints

Composite – No



Separate - Yes



• Clinical measures - Maybe

• Economic - Yes

“Who’s the audience they’re trying to influence and what’s important to them? And so, if you want a payer to pay attention you have to have economic endpoints in the study.” - *Payer*

Transparency



Areas of Concern

- “I know where the holes are” –
- Quality issues
 - No controls / selection bias
- Authorship
- Funding



Does it matter where external RWE studies are published?

How important is getting published in JAMA, NEJM, or other top tier medical journals?



The NEW ENGLAND
JOURNAL of MEDICINE

JAMA
Journal of the
American Medical Association

THE LANCET

Annals of Internal Medicine

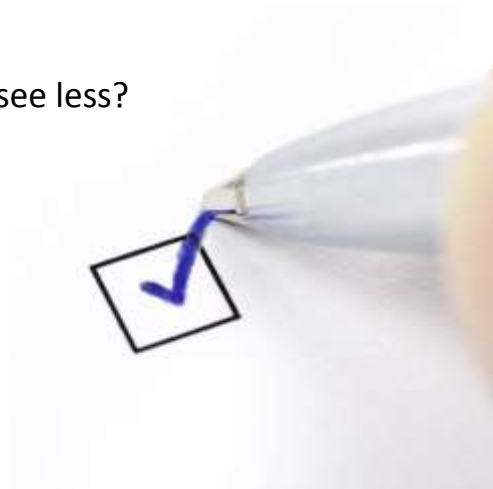
ESTABLISHED IN 1927 BY THE AMERICAN COLLEGE OF PHYSICIANS

What is the most important attribute about conducting RWE that researchers should be cognizant of?



Wish list for RWE

- What would you like to see more of?
- What would you like to see less?



Summary

- Use of acceptance of RWE varies across payers
- RWE is not frequently used in P&T decisions... but is used in other decisions
- Payers are not necessarily RWE methodology experts – but can “sift the garbage.”

Take Home Points for Researchers



Acknowledgements

- Investigators / Collaborators:
 - Mary Brown, PhD
 - Jennifer Graff, PharmD
 - Jason Hurwitz, PhD
 - Loretta Peters, BSc.

- Funding: National Pharmaceutical Council

