



Delivering Health Outcomes Evidence to the Market

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Why Communication Matters

- ▶ Even the very best evidence is useless if no one knows about it, understands it, or acts on it.
- ▶ Poor communication can have a negative impact
- ▶ Consider the example of breast cancer screening recommendations
 - Evidence was strong
 - Communication was confusing, unclear, and uncoordinated
 - Consumer and other stakeholder reaction was negative and practice patterns did not change



Medical practice has been slow to adopt evidence-based findings

- ▶ Less than half of all treatments delivered are supported by evidence¹
- ▶ Many practice guidelines have inadequacies in their evidence base
 - Review of AHA/ACC guidelines found that relatively few recommendations were based on high-quality evidence, and many were based solely on expert opinion, individual case studies, or standard of care²
 - More than two-thirds of recommendations contained in 51 guidelines for treating lung cancer were not evidence-based³
- ▶ IOM Goal: By the year 2020, 90 percent of clinical decisions will be supported by accurate, timely, and up-to-date clinical information, and will reflect the best available evidence

¹IOM (Institute of Medicine). 2007. <http://www.iom.edu/ebm-effectiveness> (accessed April 15, 2009).

²Tricoci, P. *JAMA* 2009;301(8):831-841.

³Harpole, L.H. *Chest* 2003;123(1 SUPPL.):7S-20S.



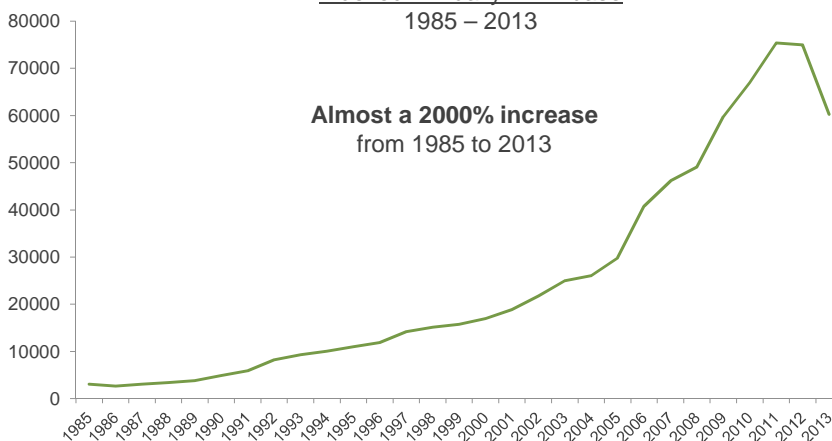
Examples of Health Outcomes and Pharmacoeconomic Studies

- Real-World Observational Studies
 - Retrospective database studies
 - Prospective registries and cohort studies
- Cost Studies
 - Cost-Minimization
 - Cost-Utility
 - Cost-Effectiveness
 - Cost-Benefit
- Models
- Randomized Controlled Trials can include health outcome endpoints



Publication Boon

Number of Pharmacoeconomic and Health Outcomes Papers Indexed Annually in Embase 1985 – 2013



Embase Terms: health economics, pharmacoeconomics, Health Care Costs, Length of Stay, Outcome Assessment (Health Care), Quality of Life, Costs and Cost Analysis, Cost of Illness, Hospital Charges, Costs, cost-benefit analysis, health expenditures, fees and charges, Hospital Costs; Embase Accessed 13 Jan 2016



Why the increase in HEOR?

- ▶ Value is a hurdle to reimbursement
- ▶ Rising cost of healthcare
- ▶ Efficacy vs Effectiveness
- ▶ American Recovery and Reinvestment Act
- ▶ Patient Protection and Affordable Care Act
- ▶ Big Data
 - Availability
 - Technology to collect, analyze, and utilize

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These Data Matter Across Audiences

- ▶ Government/Regulators
- ▶ Population-based health care decision makers
- ▶ Clinicians and prescribers
- ▶ Patients
- ▶ Pharmaceutical and Device Manufacturers

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Who is Conducting Health Outcomes and Economic Research?

- ▶ Federal government
- ▶ Academic centers
- ▶ Payers
- ▶ Third party organizations
- ▶ Pharmaceutical and Device Manufacturers



The Role of Commercial Payers

- ▶ US Payers have amassed huge data sets and have strategically improved their research expertise
- ▶ These payers with R&D capabilities are a competitive force that will play a more important role in research moving forward
- ▶ Payers have been collaborating with other organizations to conduct research on their data



Commercial Payers Utilize their Data

- ▶ Anthem conducted an internal study comparing Boniva to other osteoporosis treatments and used the results to inform formulary decision-making.
- ▶ Express Scripts published an analysis comparing first line SSRI/SNRI to branded therapy use
- ▶ Medco Research Institute and leading French researchers conducted study comparing medications for Acute Coronary Syndrome patients receiving Prevacid
- ▶ Medco Research Institute conducted a head-to-head study of medications for Acute Coronary Syndromes that measures how the effectiveness of the drugs is impacted by their genetic make-up



Commercial Payers As Research Partners

Examples Include:

- ▶ **Anthem/HealthCore and AstraZeneca**
- ▶ **Humana/Comprehensive Health Insights and Pfizer**
- ▶ **Anthem/HealthCore and IBM**
- ▶ **Optum Labs Research Collaborative**
including United, Mayo, AARP, Pfizer, Boston University School of Public Health, Lehigh Valley Health Network, Rensselaer Polytechnic Institute, Tufts Medical Center, University of Minnesota School of Nursing, American Medical Group Association, Boston Scientific, US Dept of Health and Human Services, and more.
- ▶ **Humana/Comprehensive Health Insights and Lilly**
- ▶ **UK National Health Service and the pharmaceutical industry** (Health and Social Care Act)



Pharma-Payer Collaboration Research

Household Members of Persons with Alzheimer's Disease:
Health Conditions, Healthcare Resources, and
Costs

Brandon T. Suebs, PharmD, PhD,* Sonali N. Shah, RPh, ME
Jose Alvir, DrPH,[†] Warachal E. Faison, MD, MS,[†] Nick C. P.
Amerongen, MD, MS,[‡] and Joel Bobula, MA[†]

ORIGINAL RESEARCH

Healthcare Utilization and Costs of Knee or Hip Replacements versus Pain-Relief Injections

Trends and predictors of repeat catheter

Kern et al. *Respiratory Research* (2015) 16:52
DOI 10.1186/s12931-015-0210-x



ang, PhD; Andrew T. Reiners,
IA, DFAPA

replacement procedures among the
Medical Economics Vol. 18, No. 2, 2015, 106-112

Article 0101.R1/979292
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RESEARCH

Open Access

Comparative effectiveness of budesonide/
formoterol combination and fluticasone/
salmeterol combination among chronic
obstructive pulmonary disease patients new to
controller treatment: a US administrative claims
database study

David M Kern^{1*}, Jill Davis², Setareh A Williams³, Ozgur Tunceli¹, Bingcao Wu¹, Sally Hollis⁴, Charlie Strange⁵
and Frank Trudo²

healthcare
with type 2
diabetes and
active health

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Other players

- ▶ Oregon DERP
- ▶ CMS (MEDCAC)
- ▶ BCBS (TEC)
- ▶ Academic institutes
- ▶ Think tanks
- ▶ Pharmaceutical/Medical Device Manufacturers
- ▶ ECRI
- ▶ Value Frameworks (ICER, ASCO, NCCN, etc)

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Industry CER Dissemination

- ▶ Public Disclosures: abstracts, posters, presentations, publications
- ▶ FDAMA 114 pieces
- ▶ Medical Letters
- ▶ Dossiers (AMCP, Anthem)
- ▶ Budget Impact Models and Health Outcomes Tools
- ▶ Company Medical Personnel, including responses to unsolicited medical requests



FDAMA 114

- ▶ Congress added Section 114 to the 1997 Food and Drug Administration Modernization Act (FDAMA)
- ▶ Regulates promotion of health economic information by pharmaceutical companies to formulary committees, such as a claim that a drug reduces health care costs in a given population.
- ▶ Set a new, less stringent standard applicable to promotional dissemination of health care economic information to MCO formulary committees
 - “directly relates to an indication approved”
 - “Based on competent and reliable scientific evidence”
- ▶ Covers health economic data only; Health-related quality of life claims are considered under the established “adequate and well-controlled trials” standard



FDAMA 114

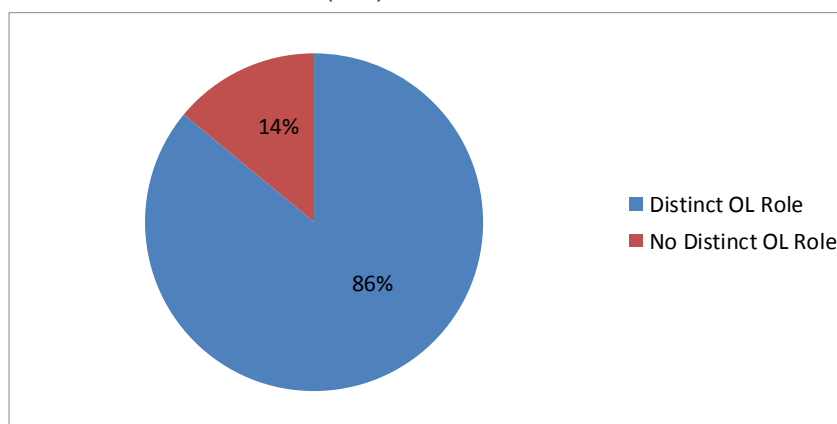
- ▶ 21st Century Cures Act - bipartisan initiative to accelerate development of new medical treatments
 - Includes a section entitled “Facilitating Dissemination of Health Care Economic Information”
- ▶ Passed House 7/2015; Senate to consider in early 2016
 - Applies to health economic information provided to “payers” as well as to a “formulary committee”
 - Information will not be considered false and misleading if it “relates” to an approved indication (vs “directly relates”)
 - Potential for making comparative economic claims for one drug versus another without the need for clinical trials to support the claim
 - Expands the definition to incorporate inputs and methods, including “clinical or other assumptions.”

<https://www.congress.gov/bill/114th-congress/house-bill/6/text/toc-HB9CAFA37435B4512A753A94DA2066BBC>

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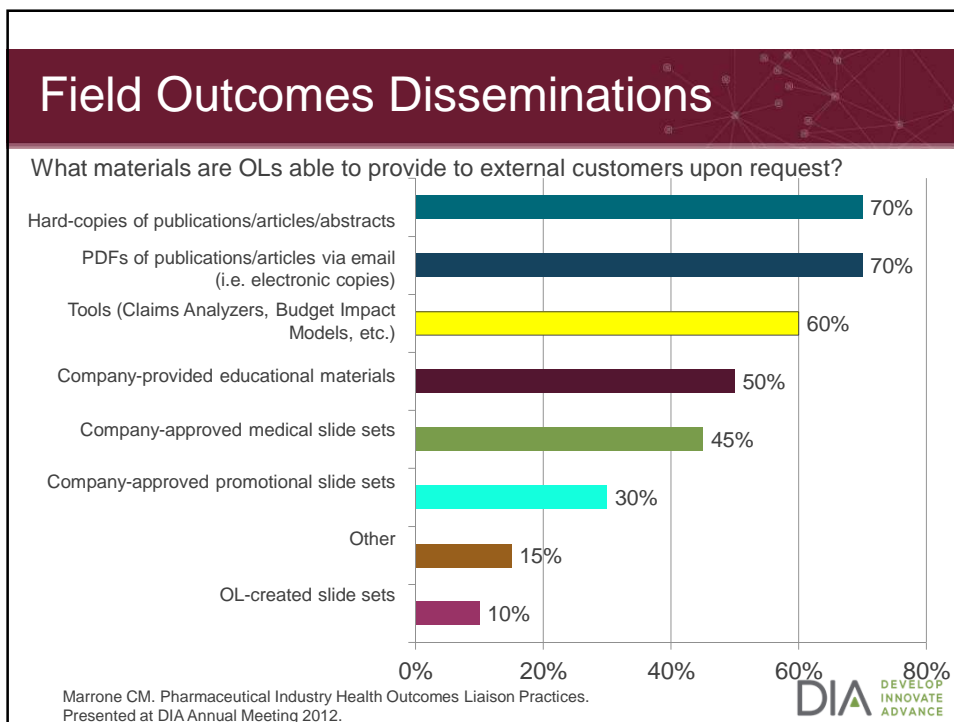
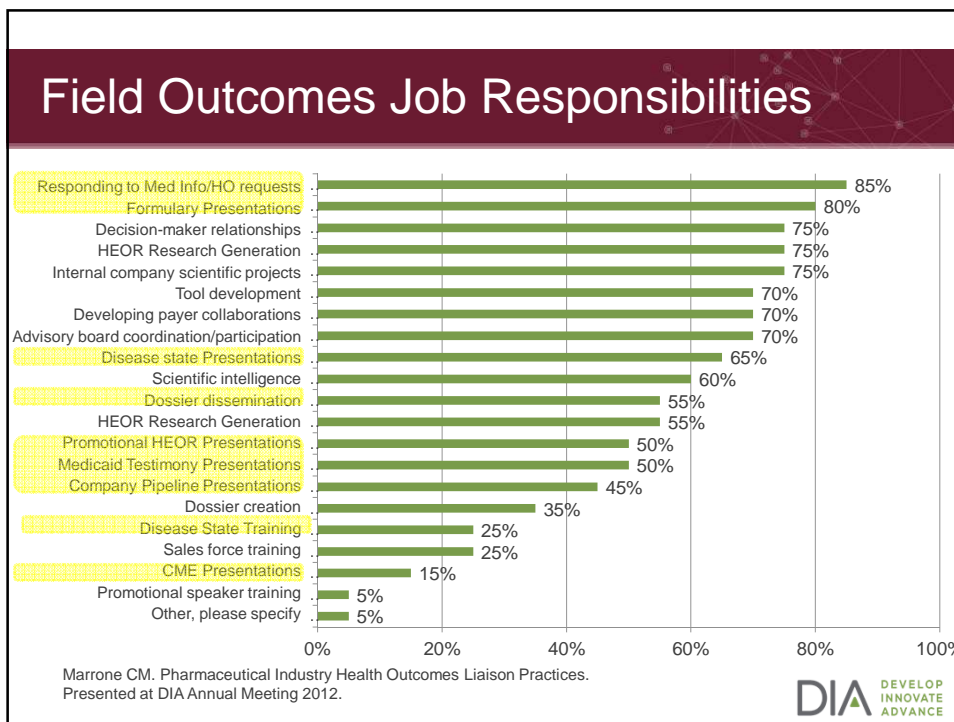
Field Outcomes Personnel

Does your company have separate Medical Liaisons (ML) and Outcomes Liaisons (OL)?



Marrone CM. Pharmaceutical Industry Health Outcomes Liaison Practices. Presented at DIA Annual Meeting 2012.

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Improving Communication of Health Economics and Outcomes Research

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ISPOR VISION 2020 TASK FORCE COMMUNICATIONS WORKING GROUP

- ▶ Improve understanding of outcomes research findings and applications among decision makers and targeted audiences.
 - Collaborate with others to facilitate the translation of outcomes research findings to promote wide spread understanding and use in health care decisions.
 - Empower members to be effective communicators of outcomes research results and their implications in order to enhance use in health care decision-making.
- ▶ Achieve greater exposure and dissemination of outcomes research findings within and outside the field.

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ISPOR Advisory Panel Report

Panel 7: Communication and Reporting Health Economic Information

Keys to more effective communication:

- **Relevance:** Is it needed?
- **Usefulness:** Will the intended audience be able to make use of it?
- **Credibility:** Is it believable?

http://www.ispor.org/workpaper/adpanel/reports/comm_.asp

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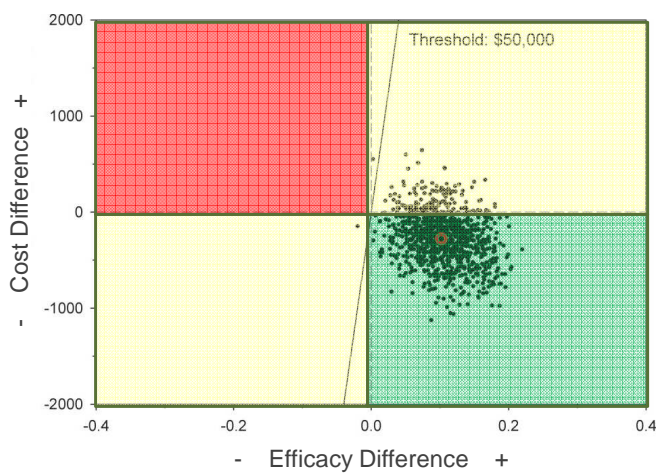
Relevance:

- the varied information needs of end-users and their magnitude of importance;
- the changing environment or time constraints in which decisions are being made;
- the predominant influence(s) over those making them, for example, political, social, budgetary, clinical, or logistical.

http://www.ispor.org/workpaper/adpanel/reports/comm_.asp

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Relevance: Understand the End User



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Relevance

- ▶ Understand the end user
 - Needs
 - Decision Process
 - Knowledge Level
 - Areas of importance
 - Influences
- ▶ Develop Data and Communication Materials that meet the end users' needs

http://www.ispor.org/workpaper/adpanel/reports/comm_.asp

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ISPOR Advisory Panel Report

Panel 7: Communication and Reporting Health Economic Information

Usefulness:

- reporting standards
- communication formats
- content

http://www.ispor.org/workpaper/adpanel/reports/comm_.asp

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Usefulness

- ▶ **R**eporting standards
 - allow for greater clarity and understanding of the content
 - create a sense of familiarity with terminology and format that allows faster integration of new information
 - promote comparability across studies
- ▶ **C**ommunication formats
 - Abstracts
 - Posters
 - Public presentations
 - Reports and articles
 - Health economic communications

http://www.ispor.org/workpaper/adpanel/reports/comm_.asp

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Usefulness

- ▶ Content – One size does not fit all
 - variety of backgrounds and expertise
 - needs of the audience
 - Managed care organizations vs physicians vs consumers

Thumbnail of a journal article cover. The title is "Contemporary Use of Drug A in Interventional Practice (from Blue Cross Blue Shield of Michigan Cardiovascular Consortium)". The authors listed are Amrita M. Karve, MD^a, Milan Seth, MS^b, Manoj Sharma, MD^c, Thomas LaLonde, MD^d, Simon Dixon, MD^e, David Wohls, MD^f, and Hitinder S. Gurm, MD^{h,g}. The journal is the International Journal of Cardiology. Logos for Elsevier, Value Line, and DIA are visible. The DIA logo includes the text "DEVELOP INNOVATE ADVANCE".

ISPOR Advisory Panel Report

Panel 7: Communication and Reporting Health Economic Information

Credibility:

- accepted standards of practice
- the concept of disclosure
- validation of the information

http://www.ispor.org/workpaper/adpanel/reports/comm_.asp

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Strong Communications

- ▶ Identify Users and Their Needs
- ▶ Create Standard Communication Formats
- ▶ Develop Reporting Guidances (RGs)
- ▶ Ensure Public Accessibility

Recipient Feedback

- ▶ What is provided is more important than how it is provided:
 - Head-to-Head Superiority Trials
 - Pertinent Controls
 - Real World Data
 - Actionable Health Outcomes Data
- ▶ Users want communications that are:
 - Fair-Balanced
 - Transparent
 - Credible

Conclusions

- ▶ Comparative Effectiveness Research is being completed and communicated by a variety of entities
- ▶ Not all receivers and users of CER are the same
- ▶ Data must be generated and communications must be created with the intended audience in mind.
- ▶ Users are looking for relevant, credible, and fair-balanced communications of data.



Thank You

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