ISMP University

Improving Health Care Economic Information (HCEI) Communication

July 18, 2018, 11:00 EDT, 15:00 GMT
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Improving Health Care Economic Information (HCEI) Communication

Publication Planning Professionals Are Key Partners in Building Successful HCEI Exchange

July 18, 2018
Introductions

• Peter Fendt, PharmD, MBA, RPh
  Manager, Global Market Insights, Celgene

• Brian Ung, PharmD, RPh, MS
  Manager, US Health Economics & Outcomes Research, Celgene

• Tom Drake, MA, ISMPP CMPP™
  Director and Founder of Global Outcomes Group

• Moderator

• Michael Platt, MS
  Executive Director, Virgo Health Education
Disclaimer

Information presented reflects the personal knowledge and opinion of the presenters and does not necessarily represent the position of their current or past employers or the position of ISMPP.
Objectives

• Describe historic challenges that impeded HCEI communication between Bio/Pharma and stakeholders

• Understand how the 21st Century Cures Act and recent FDA draft guidelines are providing clearer pathways to disseminate HCEI information during pre-approval phases

• Describe key HCEI stakeholders that can be part of a strategic publication plans

• Discuss practical steps to build multidisciplinary teams to incorporate HCEI management into effective publication planning structures
Introduction

Brian Ung
Audience Poll

• Have recent Federal regulations and guidance changed publication planning strategies and tactics at your company?
  – Yes
  – Somewhat
  – Currently under review
  – No
Pre–FDA Approval: Economic Information

2015 premium rates set

06/2014

10/2014

101 Harvoni® claims for 32 patients

2015

Healthcare system cannot plan for the cost of new therapies

Approved $92,000/course

0.14% of patients = 10% of total spend

QualChoice®

Health Insurance

HARVONI®
ledipasvir/sofosbuvir
90 mg / 400 mg tablets
Pre–FDA Approval: Economic Information

Historical deficiency in HCEI communication between payers and drug manufacturers
FDAMA 114 Limitations: ambiguity in language (audience, “competent and reliable scientific evidence”), off-label promotion, pricing not addressed, no further guidance until...
21st Century Cures Act

Section 3037

Clarifies FDAMA 114
Audience Definition
HCEI Content
Recent FDA Final Guidances Address HCEI Exchange

1. Drug and Device Manufacturer Communications With Payers, Formulary Committees, and Similar Entities (2018)
   - Provides examples of HCEI that do, and do not, relate to an FDA-approved indication
   - Highlights information that should be disclosed to audiences receiving HCEI
   - Elaborates on communication of information on investigational drugs

2. Medical Product Communications That Are Consistent With the FDA-Required Labeling (2018)
   - Clarifies communication of material not explicitly included in FDA-required drug labels, but that “may be consistent” with FDA-required drug labels
Joint commentary: importance of increased communication, current challenges, include new indications and treatment line extensions

5 pilot programs testing approaches to payer communication of HCEI
Communication Pre–FDA Approval

Peter Fendt
Audience Poll

• As publication professionals, have you been directly involved with any Payer interaction or communication (eg, HE papers, dossiers, other)??
  – Yes
  – Planning to in the future
  – No
Multi-Stakeholder Communication is Increasingly Important

- Formulary planning is difficult without sharing economic data pre-approval for drugs entering the market after health plan submission of its insurance premiums
- Early communication → payer feedback can influence development programs
- Recommendations for final guidance and future regulations should incorporate feedback from all involved parties
Expedited Regulatory Approval Programs

Expedited approval exacerbates HCEI problem

- Increased Unpredictability
- Approval Before Data
- High Unmet Need
- Improved Therapies
- Faster Access

Payer

Patient
Possible Solutions

- 12-18 months before approval
- Create new regulations
- AMCP Dossier
- Indication, place of therapy, route of admin
- Distribution channels, budget impact

Timing

Preapproval Information Exchange

Specific Format

Safe Harbor
• Supports exchange of healthcare information pre-approval
• Emphasizes maintaining communication channels
• Pre-approval information exchange (PIE) must be “unbiased, factual, accurate, and non-misleading”
• Clear statement that the product, its safety, and efficacy is under investigation
Recent Updates

- Pharmaceutical Information Exchange Act (H.R. 2026) was amended and forwarded January 17, 2018 to full committee in House of Representatives
- Supports proactive information sharing between manufacturers and third-party Payers for emerging therapies/off-label uses
- Allows communication of “competent and reliable scientific evidence” in the form of clinical, pre-clinical, and economic data and results
Future Considerations

Peter Fendt and Brian Ung
Uncertainty Remains

- FDA guidance is vague in regards to sharing HCEI pre-approval, only directly speaking to drug pricing information.
- More clarity is needed from the FDA on what constitutes “unbiased” and “non-misleading” information to be shared with payers for investigational drugs.
- Questions still remain around when and how manufacturers could communicate information related to unapproved uses of their products.
Industry Cautions Against Inaction

Laurent Carter (BMS, VP and Head of Strategic Care Marketing)

“You’ve got this nexus of a desire in the...payer and provider marketplace as well as legislation and regulation to open the door. So it’s incumbent on us to step through.”
Conclusion

• Recent legislation, regulatory guidance from the FDA, and key stakeholder involvement have improved pre-approval and post-marketing HCEI communication

• These steps provide a framework for sharing information beyond traditional clinical trial data, but communication and utilization of HCEI has not been fully embraced in the US

• Barring additional updates to these FDA guidances, drug manufacturers and payers could develop internal processes and best practices supporting the adoption and use of HCEI

• These efforts could result in market-driven regulatory change, ultimately improving formulary decisions and budget forecasting
Acknowledgements

• Peter Fendt and Brian Ung wish to thank:
  – Michael Toscani, Rutgers Pharmaceutical Industry Fellowship program, Rutgers University, for his review of and assistance with this manuscript and Randy Vogenberg, their co-author on their article
How the Changing Environment for HCEI Impacts the Publication Planning Team

Tom Drake
Audience Poll

• Do you routinely work with your HEOR/RWE colleagues in developing and/or executing publication plans?
  – Always
  – Sometimes
  – Rarely
  – Never
HCEI & Pre-Approval Publication Planning

HCEI Stakeholder Focus
“No Outcomes, No Income”

Repeatedly named to *Modern Healthcare*’s list of Most Powerful Persons in Healthcare.

"David Nash, MD, is truly one of the great visionaries in healthcare," said Scott Becker, publisher of *Becker’s Healthcare*.

David B. Nash, MD, MBA
Dean, Jefferson School of Population Health
Thomas Jefferson School of Medicine
Philadelphia, Pennsylvania
Audiences for HCEI Data

- Regulators and/or HTA Agencies
- Providers
- Pharma
- PharmDs, NPs, allied HCPs
- Formulary Decision-makers
- MCOs
- ACOs/IDNs
- Quality Commissions
- Medicare/M’caid
- Medical Associations
- Employers
- Patients/caregivers

Source: Peeples/Drake AMWA HEOR Writer Workshop 2017
AMCP Backs FDA’s Guidance on Product Communications

ALEXANDRIA, Va., June 13, 2018 /PRNewswire-USNewswire/The Academy of Managed Care Pharmacy (AMCP)

AMCP Applauds FDA for Final Guidance on Payer and Manufacturer Communications to Improve Patient Access to Emerging Therapies

AMCP has been leading efforts to clarify and modernize payer and manufacturer communications, both in the pre-FDA approval and post-FDA approval space.
AMCP Partnership Forum - Guidance

• Key stakeholders: managed care organizations, pharmaceutical companies, academia, healthcare professionals, and patients—discussed how they might facilitate communication of HCEI about a drug’s assets before the FDA approval of the drug.

• Allowing for proactive and continuous “preapproval information exchange” of clinical and economic information about investigational drugs between manufacturers and decision makers who manage a population’s health at least 12 to 18 months before a drug’s approval
Pre-Approval Payer Engagement Insights

What Evidence/Information Are Payers Requesting in Pre-Approval Phase from Manufacturers?

1. Specific Product Information
2. Dossier requests (AMCP Dossier)
3. Other requests include: face-to-face meetings, discussions at conferences, and company webinars

Payer Evidence Needs During Pre-Approval

Research finds that Payers are most interested in the following areas in descending order of importance:

1. Clinical Trial Information
2. Product Pricing
3. Economic Information (cost-effectiveness results)
4. Budget Impact Information
5. Current Therapy Backgrounders
6. Disease State Information

Pre-Approval Information - Ideally Payers Want?

1\textsuperscript{st} Health Economic (Requested by nearly 2 to 1)
2\textsuperscript{nd} Clinical Trial
3\textsuperscript{rd} Efficacy
4\textsuperscript{th} Safety

Key Payer Questions – Drives Access

- Does it work in the real world?
- Is it needed?
- Can we afford it?
- Can we get away without funding it?

Effectiveness

Perceived Medical and Clinical Need

Budgetary Impact/Cost Effectiveness

Political Expediency

Building Publication Plans Using HCEI

Utilize ISMPP’s Resources & Educational Archives
Gap Analysis Helps Identify HCEI/HEOR Research Opportunities

HEOR strategies increasingly integrated in earlier product development: Phase 1 through Phase 3

- Assess economic burden of illness
- Develop PRO & endpoint strategy
- Assess humanistic burden of illness
- Assess current therapies & unmet needs
- Develop economic models

Source: “Mind the Gap” Life Cycle Management and HEOR Integration, Kristen Quinn, PhD Senior Medical Director, Peloton Advantage, LLC, Ilia Ferrusi, PhD Associate Director, HEOR, Novartis Pharmaceuticals Corporation, Parallel Session, 14th Annual Meeting of ISMPP 2018
HEOR Evidence Sources for Gap Analysis

Do not forget the grey literature

Source: “Mind the Gap” Life Cycle Management and HEOR Integration. Kristen Quinn, PhD Senior Medical Director, Peloton Advantage, LLC, Ilia Ferrusi, PhD Associate Director, HEOR, Novartis Pharmaceuticals Corporation, Parallel Session, 14th Annual Meeting of ISMPP 2018
# HEOR & RWE Opportunities in Gap Analysis

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<th>Early Clinical</th>
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<td>• Disease state positioning</td>
<td>• Evolution of disease state</td>
<td>• Comparative effectiveness</td>
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<td>• Establish unmet need</td>
<td>• Aspects of patient burden</td>
<td>• Value demonstration</td>
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<td>• Establish value proposition</td>
<td>• Economic evaluations</td>
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<td>• Meta-analyses/comparative effectiveness</td>
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<td>• Quality-of-life studies</td>
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<td>• Patient registries</td>
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<td><strong>Typical HEOR Data</strong></td>
<td><strong>Repeat Analysis Routinely</strong></td>
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<td>• Disease burden surveys</td>
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<tr>
<td>• Cost-analysis / economic burden studies</td>
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Source: “Mind the Gap” Life Cycle Management and HEOR Integration, Kristen Quinn, PhD Senior Medical Director, Peloton Advantage, LLC, Ilia Ferrusi, PhD Associate Director, HEOR, Novartis Pharmaceuticals Corporation, Parallel Session, 14th Annual Meeting of ISMPP 2018
Publication Plan Implications

• Engage HEOR stakeholders early in publication strategy and planning

• Fill Data Gaps: HEOR disease state analysis & publications to establish disease burden

• Payers look for data to support value, much of which cannot readily come from randomized controlled trials

• Incorporate value measures early in clinical program
  – Think about them in Phase 1, test in Phase 2 and construct right measures in Phase 3

Utilizing RWD/RWE Is Essential in Developing a More Complete Value Story

- Generalize/confirm Findings from RCT
- Additional insights into patient treatment journey
- Greater understanding of economic value
- Real-world clinical effectiveness

Strategy to communicate the value proposition

Regulators
Approval (efficacy, safety)

Patients
Education and awareness

Payers
Formulary uptake and reimbursement

Physicians
Guideline inclusions

Source: The Role of RWE in a Value-Based World: Who’s Listening? Melissa Hagan, PhD, MPH Director, HEOR - Value Evidence Generation, Peloton Advantage, LLC, Judy Lenhart, PhD Senior Director, Global Scientific Communications Celgene, Parallel Session, 14th Annual Meeting of ISMPP
Value Communication/Publication Plan*
Has Publication Policy Adapted to the Growing Importance of Real-World Data?

• Over the last decade the number of real-world publications has greatly increased, supporting a growing emphasis on publishing real-world data in the publication policies of clinical journals

• High impact factor journals have significantly increased publication of real-world articles in the last few years in comparison to clinical trials

• Real-world data are increasingly influential in medical research as they enable the assessment of new interventions in the context clinical practice, and are becoming recognised as contributors to regulatory decisions

Poster #34: Has Publication Policy Adapted to the Growing Importance of Real-World Data? Jason McDonough, PhD, CMPP\textsuperscript{1}; Anisha Mehra, PhD\textsuperscript{2}*; Alex Fower, MSc\textsuperscript{2}; Charlotte Bell, BSc\textsuperscript{2} and James Wallis, MRes\textsuperscript{2} \textsuperscript{1}Cello Health Communications, Yardley, PA, USA; \textsuperscript{2}Cello Health Communications, Farnham, Surrey, UK, 14\textsuperscript{th} Annual Meeting of ISMPP 2018
Thank you & Questions!

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# Upcoming ISMPP U

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<td>September TBD</td>
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<td>October TBD</td>
<td><em>Data Sharing and Privacy Regulations</em></td>
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Thank You for Attending!

• We hope you enjoyed today's presentation.
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Thank you!
Have a great day!
References


Parallel Sessions

• “Mind the Gap” Life Cycle Management and HEOR Integration, Kristen Quinn, PhD Senior Medical Director, Peloton Advantage, LLC, Ilia Ferrusi, PhD Associate Director, HEOR, Novartis Pharmaceuticals Corporation

• Incorporating Value into Planning for Early Development Compounds: The Impact of Market Access Trends, Shana Traina, PhD Global Market Access CVM, Janssen, Kimberly Dittmar, PhD, ISMPP CMPPTM Scientific Director, Cello Health Communications

• The Role of RWE in a Value-Based World: Who’s Listening? Melissa Hagan, PhD, MPH Director, HEOR – Value Evidence Generation Peloton Advantage, LLC, Judy Lenhart, PhD Senior Director, Global Scientific Communications Celgene

Posters

• Poster #8: Evaluation of Data Reporting in Real-world Publications in Clinical Versus Health Economic Journals, Alaina Mitsch, PhD, CMPP™1,*; Jason McDonough, PhD, CMPP™1; Kimberly Brooks, PhD, CMPP™1; Erin Brant, CMPP™1; Anisha Mehra, PhD2 1Cello Health Communications, Yardley, PA, USA; 2Cello Health Communications, Farnham, UK.

• Poster #34: Has Publication Policy Adapted to the Growing Importance of Real-World Data? Jason McDonough, PhD, CMPP1; Anisha Mehra, PhD2*; Alex Fower, MSc2; Charlotte Bell, BSc2 and James Wallis, MRes2 1Cello Health Communications, Yardley, PA, USA; 2Cello Health Communications, Farnham, Surrey, UK.

• Poster #35: Real-world evidence (RWE) publications are an integral part of company evidence submissions for payer discussions, Hester van Lier, Miriam de Boeck, Victoria Edwards, Eline Hanekamp, Tessa E. Hartog, Grace Richmond and Remon W.M. van den Broek Excerpta Medica, Amsterdam, Netherlands
FACULTY BIOS
Moderator: Michael Platt, MS

Michael Platt, MS (Virgo Health) has 22 years of experience in the pharmaceutical, biopharmaceutical, medical device, and healthcare delivery fields. His expertise includes pre-launch/launch/post-launch medical communications activities designed to educate and inform healthcare professionals, patients, caregivers, and other stakeholders. He has broad experience in publication planning and adult-based education, including 10+ years in continuing education and pharmacy education credentialing/certification. Michael has managed teams of professional writers, scientific managers, editors, meeting planners, and designers who develop professional, compliant medical and clinical communications, with a focus on clinical data publications and associated meeting activities. He is a past CMPP Board Member, CMPP Vice-Chair, and also an active member of the ISMPP U Committee. As a past-Chair of ISMPP U, Michael assisted in establishing Needs-based sessions for ISMPP U that meet educational gaps for publication professionals.
Tom Drake, MA, CMPP (Global Outcomes Group) has been involved in medical communications for over twenty-five years. In 1990 Tom founded and launched the healthcare trade publication, Product Management Today (PMT). He was publisher and editorial director for its first six years. As PMT’s editorial director, he worked with several the founders of International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Tom has been involved in most areas of medical communications including: global publication planning, continuing medical education (CME), Health Economics and Outcomes Research (HEOR), Real-World Evidence (RWE), thought-leader development and digital and web-based communications. Tom has supported communication projects in all major therapy areas and supported orphan drug programs. In 2014 Tom launched the Global Outcomes Group, an independent healthcare communications agency supporting HEOR/RWE and Medical Communications for the bio/pharma and medical device industries. Tom has been an active member of ISMPP since 2008, was chair of the ISMPP-U committee in 2015 and remains a committee member. Tom is also an active member of AMWA, ISPOR and the recently formed, MAPS (Medical Affairs Professional Society).
Peter Fendt, PharmD, MBA

- **Peter Fendt, PharmD, MBA (Celgene)** is a pharmacist by training who graduated from the University at Buffalo School of Pharmacy, as well as the University at Buffalo School of Management. Throughout pharmacy and business school Peter was involved in various consulting opportunities, including for a local pharmacy school, independent pharmacy and healthcare system. In addition, his School of Management experiences included a focus on the US healthcare system and its ongoing evolution. Peter completed a Global Market Insights post-doctoral fellowship with Celgene Corporation/Rutgers University, during which he was able to gather insights from market research projects as well as business intelligence efforts which engaged practicing physicians, caregivers and patients. During his fellowship he also acted as Adjunct Faculty for Ernest Mario School of Pharmacy, and was a founding member of a pharmacists’ professional network at Celgene. Peter is currently employed as a member of the Global Market Insights team at Celgene Corporation, supporting primarily hematology products and more broadly the hematology/oncology franchise on key focused projects. In his free time Peter enjoys making music, cooking, and writing.
Brian Ung, PharmD, RPh, MS

- Brian Ung, PharmD, RPh, MS (Celgene) is a licensed pharmacist and graduate from the University of Maryland School of Pharmacy. Throughout pharmacy school, Brian gained experience in a variety of managed care pharmacy, market access, health economics & outcomes research settings. Brian completed a Health Economics & Outcomes Research post-doctoral fellowship with Celgene Corporation/Rutgers University, served as Adjunct Faculty for Ernest Mario School of Pharmacy and obtained a Masters of Science in Health Outcomes, Policy & Economics from Rutgers School of Public Health. Brian has authored numerous poster presentations and peer-reviewed manuscripts. He is currently employed as a member of the US HEOR team at Celgene Corporation, supporting both oncology and inflammation/immunology products. Brian enjoys watching basketball, listening to podcasts and writing in his personal time.