ASSESSING THE VALUE OF MEDICAL DEVICES – CHOOSING THE BEST PATH FORWARD: WHERE DO WE GO FROM HERE?

An ISPOR Issue Panel by the Value Assessment of Medical Devices Working Group of the Medical Device and Diagnostic Special Interest Group
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**Moderator:**
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The views expressed in this presentation are those of the speaker, and do not necessarily represent an official FDA position.
Medical Devices: The Basics

- A **medical device**:  
  - diagnoses, cures, lessens, treats, or prevents disease  
  - affects the function or structure of the body  
  - does not achieve primary intended purposes through chemical action

- FDA's Center for Devices and Radiological Health (CDRH) regulates companies that design, manufacture, repackaging, relabel, and/or import medical devices into the United States.

- In addition, CDRH regulates radiation-emitting electronic products  

- CDRH also regulates facilities that perform mammography under the authority of the Mammography Quality Standards Act.

- Combination products are therapeutic and diagnostic products that combine drugs, devices, and/or biological products (e.g., drug-eluting stent, insulin injector pens, metered dose inhalers, transdermal patches, etc.).
Differences in regulatory pathways for each component can affect the regulatory processes for all aspects of product development and management, including preclinical testing, clinical investigation, marketing applications, manufacturing and quality control, adverse event reporting, promotion and advertising, and post-approval modifications.

The Office of Combination Products (OCP) assigns an FDA center to have primary jurisdiction for review of both combination and single entity (i.e., non-combination) products where the jurisdiction is unclear or in dispute.

There are three device classes:
- **Class I** devices present a low risk of harm to the user and are subject to general controls.
- **Class II** devices are more complicated and require special controls for labeling, guidance, tracking, design, performance standards, and post-market monitoring. Most require Premarket Notification 510(k).
- **Class III** devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Most of these devices require Premarket Approval (PMA).
Hurdles to Reimbursement and Market Access: Premarket Requirements

Source: Adapted from http://www.brianmac.co.uk/hurdles/
Hurdles to Reimbursement and Market Access: Premarket Requirements

Source: http://libguides.clemson.edu/med-device
Yes, there is a fourth hurdle....

- The hurdles for reimbursement and market access for a new health technology (e.g., devices, medicines, vaccines) are often referred to as **post regulatory hurdle, fourth hurdle**, or simply **reimbursement hurdle**

- The hurdles represent the increasing data requirements for reimbursement and market access
  - Quality of Life
  - Cost-effectiveness
  - Budget Impact

Source: http://www.toonvectors.com/clip-art/cartoon-high-hurdle/11057
Hurdles to Market Access and Reimbursement

Safety  Effectiveness  Quality  HTA/ Economic Analysis  Training

Regulatory  Health Technology Assessment  Health Technology Management

Source: Adapted from http://www.brianmac.co.uk/hurdles/
Other key challenges facing medical device manufacturers:

- changes in the regulatory environment
- cost containment and rising healthcare expenditures
- adapting to the steady shift in value-based reimbursement
- the level of evidence requirements
- upfront cost of demonstrating clinical and economic value
- competing devices and intellectual property rights (IPR)
“Value — neither an abstract ideal nor a code word for cost reduction — should define the framework for performance improvement in health care. Rigorous, disciplined measurement and improvement of value is the best way to drive system progress. Yet value in health care remains largely unmeasured and misunderstood”

Michael E. Porter, N Engl J Med 2010
“Companies that do attempt to match product features and capabilities more closely to their customers’ perceptions of value must answer a difficult question: Who are their customers?”

McKinsey & Company, 2010
“This new game is challenging in developed and emerging markets alike. Success in emerging markets requires a deep understanding of stakeholders’ needs—which is hard to get from a design office halfway around the world.”

McKinsey & Company, 2010
7 Key Questions in Discussing Value: Who, What, Why, When, Where, How, How Much?

Who are the stakeholders?

What evidence is needed to secure reimbursement and market access?

Why consider identifying economic and clinical value data to justify reimbursement and market access?

How well does my device work in comparison with the alternatives?

How much health gain do we get for the money paid?

When should device manufacturers engage with CDRH and Payers?
Demonstrating Value of a New Medical Device

Evaluations of medical devices and the price conundrum

Source: Adapted from www.clker.com
Value Metrics: Demonstrating the Value Case

Value Drivers:
- Effectiveness
- Price
- Ease of use, Convenience
- Adherence, Compliance
- Tolerability
- Safety
- Patient Reported Outcomes (PROs)
Other Value Metrics: Demonstrating the Value Case

- Budget Impact Analysis
- Time and Motion Analysis
Value Metrics: PRO Examples

- Health-related quality of life (HRQoL)
- Function
- Satisfaction
- Adherence
- Preferences
- Convenience, Ease of Use, Usability, Acceptability

Symptoms
Value Metrics and Value Claims

CDRH

Class I, II, III Medical Device
Value Metrics and Value Claims

CDER

Drug/Device Combination

Guidance for Industry
Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims

U.S. Department of Health and Human Service: Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Medical Evaluation and Research (CDER)
Center for Devices and Radiological Health (CDRH)

December 2009
Clinical Medical
Opportunity for payers to engage early with the FDA and medical device sponsors

May shorten the time from FDA approval or clearance of a medical device to coverage

May allow for the design of clinical trials that may produce required outcomes for both regulatory approval or clearance and coverage determinations

Identification of the right evidence early in the development process that support the value proposition

Assist with the development of the value strategy

Strengthen the value proposition

Increase differentiation in the market
Where do we go from here?
References

- Overview of Medical Devices and Their Regulatory Pathways. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm203018.htm
- Frequently Asked Questions About Combination Products. http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm
- Payer Communication Task Force (PCTF). http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHInnovation/ucm456149.htm
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A MANUFACTURER’S PERSPECTIVE

MAY 23, 2016

Drew Baker
Director of Health Policy & Reimbursement
Stryker Corp.
Allendale, NJ
Medical device spend as proportion of national health expenditure has remained flat for 25 years

Percentage of National Health Expenditures by Category
1990-2014

Source: Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.
Consumer prices and other healthcare price inflation have outpaced medical device inflation.

Source: US Census Bureau and OECD.
Manufacturers have numerous stakeholders demanding evidence of product value.
Evidence thresholds differ for regulatory authorization vis-à-vis coverage and reimbursement

Safe and Effective (FDA)

Reasonable and Necessary (CMS & Some Private Payers)
Market forces confronting device industry’s clinical and economic research efforts

• Payment and quality policy reform
  – New delivery models
  – Power shift to providers and payors

• Few financial incentives for US providers and payers to care about long-term outcomes

• In-market research demands by some OUS markets (clinical and HTA) → Can impact US research resources

• Price pressure globally, including foreign average reference pricing

• Responsibility to serve all socioeconomic classes
As the US healthcare system is decentralized, so too are value assessment activities.
Value assessment is employed by medical device firms throughout the product lifecycle.

**Market Access and Health Economic Research Focus**

- **Investment Decisions / Early-to-Mid-Stage Development**
  - Early modelling to forecast patient and HC system benefit
  - Inform investment decisions
  - Identify and quantify value drivers

- **Late-Stage Development to Launch**
  - Strengthen regulatory filings
  - Value proposition refinement
  - Commercialization planning

- **In-Line / Growth**
  - Post-marketing evidence generation
  - Competitive positioning
  - Understand “real world” effectiveness
  - Meet evolving stakeholder evidence needs

- **End-of-Lifecycle / Decline**
  - Inform “evergreening” strategy
  - Assess value of line extensions

Time

Revenue
Products are triaged to determine potential health economic value

1. Understand payment environment & technology’s proportion of customer spend
2. Determine clinical / economic advantages vs appropriate comparator(s)
3. Identify data necessary to influence stakeholders
4. Model economics to determine variables to which results are most sensitive
5. Evaluate technical feasibility of generating evidence to support messages
6. Assess how messages / supportive data will resonate with stakeholders
7. Prioritize messages based on potential commercial impact & execute research
Legislatively, Medicare prohibited from using CEA data to *determine* coverage / reimbursement decisions.

Pragmatically, CMS reviews publicly accessible economic data to *inform* coverage / reimbursement policy.

*Conditional coverage while additional evidence gathered through registry or trial.*
• Product market authorization (FDA) and federal coverage and reimbursement (CMS) decisions are distinct

• Medicare National Coverage Determination (NCD)
  – Scans and selects technologies based on cost, M’care budget impact, potential adoption
  – Define scope of HTA and assesses evidence base
  – Commissions HTA via AHRQ (who contracts with an academic or private Evidence-Based Practice Ctr)
  – Medicare Coverage Advisory Committee (MCAC) votes on evidence strength, but does not provide recommendation to Medicare
Medicare National Coverage Determinations and commercial payer decisions often are not aligned.

Source: Chambers, Chenowith, Thorat, Neumann. Private payers disagree with Medicare over medical device coverage about half the time. *Health Affairs* 2015.
Often, the value of a medical device may not be as obvious as that of a life-saving drug, creating practical challenges in conducting value assessment

- Few pre-market clinical trials due to evolutionary innovation and short product lifecycles
- Operator variability
- Learning curve
- Limited class effect (as there may be in Rxs)
- Device prices often change over time, limiting robustness of CEAs
- Clinical approach and organizational dynamics can limit ability to isolate technology’s impact, thereby restricting external validity
Stakeholders often have different, and frequently conflicting, interests and incentives (1 of 2)
Stakeholders often have different, and frequently conflicting, interests and incentives (2 of 2)

- **Payers**, historically, want the least expensive product that “fixes” the basic problem.
  - Plaster cast

- **Physicians** may want to be the first to try a new endoscopic imaging technology.

- **Patients** generally accept what the physician or payer deems appropriate because they may lack sufficient data or can’t afford—cost and time—to shop around.

  - Fiberglass cast

  (despite significantly lower breakdown rate)
Medical device value encompasses many dimensions (1 of 2)

- **Clinical**
  - Efficacy and effectiveness — outcomes, compliance
  - Safety
  - QoL — patient, family, caregiver
  - Patient experience

- **Economic**
  - Lower cost site of service
  - Costs over stakeholder’s time horizon (e.g., acute, 90 days, 1 yr, 3 yrs, lifetime)
  - Patient out-of-pocket
  - Productivity, absenteeism, presenteeism
Medical device value encompasses many dimensions (2 of 2)

- **Care Delivery Quality and Efficiency**
  - Performance-based reimbursement metrics — HACs, readmissions, LOS
  - Lower cost variability / increased predictability
  - Improved workflow

- **Population health management**
  - Improved health
  - Less acute care
  - Lower overall costs
Device innovation is essential part of meeting Triple Aim goals via Value-Based Care (VBC)

- Proposed solutions to maintain innovation under VBC*
  - Adopt broader set of quality measures
  - Improve data availability, transparency and integration
  - Identify unmet and under-met needs
  - Assess financial risk-sharing arrangements

*Deloitte LLP
Industry welcomes, and regularly seeks, opportunities to meet with payers

- Obtain guidance on **product development** vis-à-vis potential role in care and potential for reimbursement
- Input on **research** goals, design, endpoints
- Understand **criteria** for obtaining appropriate codes and optimal coverage and payment
- Explore research **collaboration**, particularly as VBC models proliferate and payers and providers become more closely aligned
- **Communicate** evidence on product value
Recommendations from a manufacturer’s perspective (1 of 2)

• Be creative and flexible—while clinical studies may not lend themselves to integration of HEOR endpoints, parallel research on external data sources (e.g., claims, EHRs, registries) may generate appropriate evidence.

• Consider coverage with evidence development (CED) for technologies with high expected value to providers, patients, and payers.

• Encourage demand matching so technology is appropriately implemented → “right solution, right patient.”

• Amount and level of evidence should be based on level of product risk, incremental cost, diffusion potential.

• Integrate viewpoints of patients, providers, and others before decisions are finalized.
Recommendations from a manufacturer’s perspective (2 of 2)

• Allow mechanisms for assessment updates as innovation, care standards, and new data emerge

• Fairly consider benefits of technology over timeframe consistent with patient benefits beyond episode of care

• Cost assessment should include both costs incurred and those averted

• Avoid dismissing industry-sponsored economic data due to perception of bias; no more biased than manufacturer-sponsored clinical data

• Understand that devices often can be part of sophisticated patient care processes where operator expertise and the care setting can influence outcomes as much as the technology itself
Thank You
BACKUP
Value assessment is not a step, but rather a process throughout the product lifecycle

• Portfolio management
• Assessment of clinical and delivery system needs
• R&D
• Marketing Authorization
• Coverage & Coding
• Payment
• Adoption
• Clinical guidelines