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ISPOR Value Analysis Panel

Are Existing Regulatory Evidence Standards Adequate for Informing Decisions on Medical Device Adoption by U.S. Healthcare Providers/Hospitals?

Accepted Panel Abstract

Description of the Issue

ARE EXISTING REGULATORY EVIDENCE STANDARDS ADEQUATE FOR INFORMING DECISIONS ON MEDICAL DEVICE ADOPTION BY U.S. HEALTHCARE PROVIDERS/HOSPITALS?

Moderator: Nicole Ferko, MSc, Value & Evidence Division, Marketing and Market Access, EVERSANA, Burlington, ON, Canada;

Panelists: Barbara Strain, MA, CVAHP, Association of Healthcare Value Analysis Professionals (AHVAP), Albany, NY, USA; Gloria Graham, DNP, RN, CVAHP, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA; Paul Delatore, MBA, Alcon, Fort Worth, TX, USA

ISSUE: With cost containment pressures and the need to optimize health and healthcare delivery, U.S. healthcare providers/hospitals must consider economic value, in addition to clinical evidence and feasibility of adoption, to inform medical device adoption decisions. As the majority of devices do not receive additional reimbursement by payers, providers often need to absorb the costs within operating budgets. Adoption decisions are frequently deliberated by hospital Value Analysis (VA) Committees which evaluate how a device may address a current problem, what evidence exists to demonstrate efficacy and safety, cost, and feasibility of integration to justify adoption. There are no guidelines to inform such evidence development needs, and requirements can vary considerably across institutions. Traditional HEOR methods may be important sources of data; however, hospital decision-makers may not be trained in such methods and may perceive bias in evidence provided by manufacturers. There is a need for clear guidance to consolidate the type of evidence required to support provider decision-making.

Scheduled Date and Time:

Monday May 18th
11-12 PM Eastern Time

- Need for considering a range of evidence to support cost containment pressures
- VAC evidence needs and decision-making factors can vary considerably
- HEOR methods and evidence types can help support these new decision-making needs but challenges can exist
- Evidence can be provided by manufacturers but bias may be perceived

Panel Members

Moderator: **Nicole Ferko**, MSc, Vice President, Value & Evidence Division, Marketing and Market Access, EVERSANA, Burlington, ON, Canada.

Nicole has been involved in leading global and U.S. health economic, outcomes research, and reimbursement activities for the pharmaceutical and medical device industry for close to 20 years. She has had positions in academic, government, and industry settings. Nicole is trained in Health Research Methodology and is co-author of the book: "*The Science of Commerce: Succeeding in a Changed Medical Device Market.*"

Panelist: Barbara Strain, MA, CVAHP, Association of Healthcare Value Analysis Professionals (AHVAP), Albany, NY, USA.

Barbara Strain was the Director of Value Management at the University of Virginia Health System. In that role she directed the Value Management Program which collaborated with executive leadership, physicians, clinicians and suppliers across the care continuum providing the infrastructure to standardize product selection and reduce practice variation. As part of this panel, Barbara will discuss the hospital value analysis perspective on the utilization and challenges of such evidence for innovative and disruptive technologies and provide suggestions for manufacturers.

Panelist: Gloria Graham, DNP, RN, CVAHP, Association of Healthcare Value Analysis Professionals (AHVAP) Cincinnati, OH, USA.

Dr. Gloria Graham is a Past President of AHVAP as well as Chair of the Industry Business Education Collaborative Committee. She has served as the Eastern Region Director and currently participates on the Conference and CVAHP Committees for AHVAP. Currently, Gloria is a Clinical Value Analyst within the division of Contracts & Value Analysis for Supply Chain Management at Cincinnati Children's Hospital. As a panel member, Gloria will provide perspectives on value analysis and evidence needs across product types in a pediatric academic setting.

Panelist: Paul Delatore, MBA, Global Head of Market Access, Alcon, Fort Worth, TX, USA.

Paul Delatore has held leadership positions for health economics and market access teams across several medical device companies, including Johnson & Johnson (Ethicon), C.R. BARD (now Becton Dickinson), and Alcon. As a panel member, Paul will discuss HEOR methods have been successfully used with hospital providers and value analysis, and the challenges that evolving evidence requirements pose for industry.

Conflicts of Interest

The panelists have no conflicts of interest to declare for this presentation.

Agenda

3 min	Polling Questions
7 min	Background Context of the Issue
10 min	Question 1
10 min	Question 2
10 min	Question 3
5 min	Case Studies
10 min	Question and Answer Period

Context of the Issue

Panel Moderator

Nicole Ferko

1. **Please indicate which area your study/work primarily represents?**
   - Manufacturer/Supplier
   - Academia/Student
   - Hospital Provider/Clinician/Staff
   - Consulting
   - Government

2. **Please indicate your familiarity with hospital value analysis?**
   - Very familiar
   - Somewhat familiar
   - Not familiar at all

Polling Questions

A New Device Landscape

Evolving Medical Device Landscape

- US healthcare costs exceed **$3.6 trillion** annually; hospital costs comprise a substantial portion.[1]
- **Healthcare reform** has helped to limit growth of such costs, while improving quality of care and patient outcomes, with penalties and rewards (e.g., HACs, readmissions).[2]
- Medical devices and supplies are an important source of **hospital costs**; however, can also be a source of **hospital savings** if efficiency and outcomes are improved.[3]
- Many hospitals now have **VACs** which have expanded processes and evaluation criteria.[4;5]
- With evolving needs and complexity of medical device landscape, **HEOR** can be very relevant to VACs, but challenges exist.[6]

ACA = Affordable Care Act; HAC = Hospital Acquired Conditions; HEOR = Health Economics & Outcomes Research; VAC = Value Analysis Committee

HEOR Methods

HEOR: Application to Drugs vs. Devices

- HEOR methods well-utilized for over the last 2 decades to help **inform HTA submissions for drugs** globally.
- Most international guidelines involving HEOR and economic evaluations were developed with drugs in mind.[7]
- Several differences between drugs and devices necessitate an **adapted approach** to the application of HEOR methods for medical devices:[7]
  - FDA regulation needs (PMA (more data) vs. 510K)
  - Challenges with RCTs (e.g., learning curve, blinding)
  - Product modifications across lifecycle
  - Implementation can have wider economic implications
  - Challenges with comparative data
  - Variations in how medical devices used and administered

FDA = Food and Drug Administration; HEOR = Health Economics & Outcomes Research; HTA = Health Technology Assessment; PMA = Premarket Approval; RCT = Randomized Controlled Trial

HEOR Methods

HEOR: Application to Drugs vs. Devices

Many types of HEOR evidence may be applied to support medical device evaluation for VACs in the context of data-related challenges:[7]

- Primary research (e.g., database analyses)
- Secondary research (e.g., indirect comparisons, Delphi's)
- Value Tools (e.g., dossiers, economic models)

HEOR = Health Economics & Outcomes Research; VAC = Value Analysis Committee

HEOR and VACs: Value Analysis and Evidence Assessment

Common features of VACs across the United States:[8]

Decision-Making:

- Establish criteria for approval and rejection
- Recommend product classes / products for purchase
- Issue purchasing advisories or aid purchasing decisions
- May involve conditional approval if require more data

Data Assessment:

- Information gathering
- Review period (e.g. hospital utilization of product)
- Clinical discussions and cost analysis

Products for Review:

- New Technologies: capital, implant, supplies, etc.
- Review often triggered by physician interest
- Supply chain typically gate-keeper on VAC initiation

Objective:

- Product evaluation and selection
- Balancing cost (reduced) with quality (improved)
- Promote efficiency in hospital resource use

Structure:

- **Individual Hospitals**: single or department-specific VACs
- **Hospital Systems:** VACs often involve centralization

Team Members:

- **Clinical:** clinical evaluation & product utilization
- **Administrative:** cost analysis, contract aid, gate-keeping

VAC = Value Analysis Committee

HEOR and VACs

Value Analysis and Evidence Assessment

- To align with healthcare reform, VACs are moving beyond price to consider **clinical and economic evidence**.[4;6]
- Evidence may be informed by:
  - Literature review
  - Third party reports (e.g., ECRI)
  - Physician guidance
  - Hospital trial experience
  - Manufacturer information
- Evidence evaluation criteria (e.g., type, quality, outcomes) can vary across hospital VACs.
- Unclear if **HEOR evidence** is consistently or optimally made available and utilized by VACs.

HEOR = Health Economics & Outcomes Research; VAC = Value Analysis Committee

Panel Discussion Questions

Panel Discussion Questions

1. **Regulatory evidentiary requirements for medical devices are often insufficient for VAC product adoption decisions.**
   - Do you agree with this statement?
   - Characterize potential challenges and solutions.

2. **Do you feel that industry experts can provide unbiased evidence (e.g., through HEOR) to help support VAC decision-making?**

3. **How can HEOR evidence be better utilized and applied to the VAC process for medical devices in the future?**

HEOR = Health Economics & Outcomes Research; VAC = Value Analysis Committee

Question 1

Question 1

Regulatory evidentiary requirements for medical devices are often insufficient for VAC product adoption decisions.

- Do you agree with this statement?
- Characterize potential challenges and solutions.

VAC = Value Analysis Committee

Question 1: Regulatory evidentiary requirements

VAC Perspective – Talking Points

- Value = Quality (i.e., clinical, safety, or economic outcomes) ÷ Cost
- Considerable lack of evidence to support product value; data either not generated (e.g., 510K) or not presented in a way that matters.
- A key need is for data that differentiates products by clinical, economic, and efficiency outcomes relevant to hospitals (e.g., readmissions).
- Value analysis processes are expanding to include more HEOR evidence, including economic models, an integrated comparison of costs and outcomes, and real-world data.
- There is increased emphasis on evidence-based assessment of commodity products to help limit substantial variation.
- VAC processes and data evaluation methods in non-hospital settings (e.g., ASC) may be more limited.

ASC=Ambulatory Surgical Center; HEOR = Health Economics & Outcomes Research; VAC = Value Analysis Committee

Question 1: Regulatory evidentiary requirements

Industry Perspective – Talking Points

- For 510K products, it is up to manufacturers to build evidence to support the product's differentiating value proposition. Often, this may not need to be clinical trials, and HEOR evidence can be used to support this need (e.g., database analysis, time-and-motion studies).
- Industry has a key responsibility to bring true solutions to market that meet today's hospital challenges (e.g., enabling reduction in procedure times, faster device preparation time, cost-savings).
- Premium-priced products need to be substantiated with differentiating evidence and a comprehensive value proposition.
- Ongoing engagement with stakeholders and integration of relevant HEOR endpoints very early on in the process in clinical trials of products submitted through PMA.
- The solution is to "get it done early" and "get it done right" to optimize success for product adoption with VACs.

HEOR = Health Economics & Outcomes Research; PMA=Premarket Approval; VAC = Value Analysis Committee

Question 2

Question 2

Do you feel that industry experts can provide unbiased evidence (e.g., through HEOR) to help support VAC decision-making?

HEOR = Health Economics & Outcomes Research; VAC = Value Analysis Committee

Question 2: Can industry experts provide unbiased evidence?

Industry Perspective – Talking Points

- Industry has responsibility to provide evidence to hospitals that is as unbiased as possible.
- There are many methods that can be used to minimize the risk of bias in industry-supported research:
  - Use of databases hospitals are familiar with
  - Investigator partnerships and 3rd party independent firms
  - Designing trials with robust and comprehensive endpoints
  - Comprehensive evidence reviews
  - Relying on many evidence pieces / publications and types to support value propositions rather than one or two sources
  - Consider and present all evidence – positive and negative studies – with fair balance
- Utilization of qualified, experienced, reputable and trained, and non-compensated data experts to help deliver the evidence-based value proposition to hospital stakeholders.
- Advice is for industry to get ahead and be proactive (build trust and credibility) vs. being on defense.

Question 2: Can industry experts provide unbiased evidence?

VAC Perspective – Talking Points

- HEOR methods may allow industry to work with the information and evidence they have to make it applicable to VAC (i.e., a marriage of clinical and financial outcomes).
- Industry-funded studies can often be perceived as biased, but the situation is improving.
- There is an opportunity for cross-functional discussions between industry personnel and VAC regarding evidence and value proposition of products for the hospital.
  - Present data on outcomes relevant to the VAC/ hospital.
  - Having industry help inform how data supports or doesn't support specific populations (e.g., pediatrics)
  - Inform product use when published evidence is lacking (e.g., provider reference accounts)
- Data generation to suit hospital value analysis needs may often not need to be resource-intensive.

Question 3

Question 3

How can HEOR evidence be better utilized and applied to the VAC process for medical devices in the future?

HEOR = Health Economics & Outcomes Research; VAC = Value Analysis Committee

Question 3: How can HEOR evidence be better utilized and applied to the VAC process for medical devices?

VAC Perspective – Talking Points

- HEOR is a much newer concept to value analysis. Several HEOR concepts are integrated within processes, but this may not be as systematic and formalized as HTA given high complexity of devices.
- Ideally, hospital VAC could develop an initiative to help standardize guidance
  - A description of minimum evidence requirements, ideal tools or data to support value analysis, with the goal of aligning manufacturers with value analysis needs, and standardizing the requirements across hospitals
- Currently, industry provided materials add time to the existing processes. Suggestions for industry are:
  - "Less is more" approach to value briefs, to enable better dissemination and discussion with subject matter experts in the hospital
  - Provide a list of literature available, with key information for each study (e.g., design, population, results, and conclusions) to help clinicians and VAC determine which studies are pertinent to the hospital
  - Provision of economic models
- Economic models should reflect a real and relevant situation:
  - Include a wide range of parameters applicable and adaptable to the hospital's unique setting
  - Consideration of logistical challenges
  - Incorporation of all important hidden costs
  - Be "realistic" rather than "too simplistic"

HEOR = Health Economics & Outcomes Research; HTA=Health Technology Assessment; VAC = Value Analysis Committee

Question 3: How can HEOR evidence be better utilized and applied to the VAC process for medical devices?

Industry Perspective – Talking Points

- Would argue that guidance and education needed on what HEOR is and how it can be optimally used before VACs can provide answer to this question.
- An opportunity for health economic teams to develop and foster an understanding of how their research can be optimally used in decision making.
- Collaboration, such as through inclusion of the VAC member perspective in our research, can help accelerate this understanding.
- One solution is to have qualified HEOR representatives more consistently involved in value analysis interactions to help bridge this gap to help educate, and help inform decision-making with appropriate explanation of data sources supporting the value propositions for the products.

HEOR = Health Economics & Outcomes Research; VAC = Value Analysis Committee

Case Studies

Case Study 1 – Hernia Mesh

Miller & Bourque (2016):[9] Technology that does not receive incremental reimbursement outside of procedure

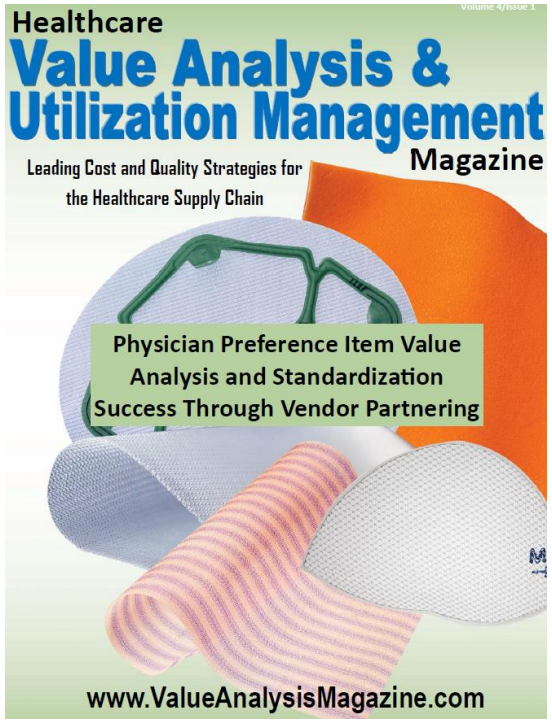
Thomas Jefferson & BARD collaboration with Hernia Mesh products

Problem: 8 different vendors in use, with high variability in products and limited comparative data.

Goal: Try to achieve the best outcomes at the most reasonable cost and reduce variability for providers to help optimize care.

Methods:

- Multidisciplinary “standardization” team led by surgeon champions assessed vendors for optimal portfolio of meshes
- Developed program to educate surgeons on cost-effective product choice
- Evaluated clinical outcomes with literature review and tracked hospital outcomes over 1 year (e.g., readmissions)
- Considered **total** costs and outcomes for standardization decision



Miller S, Bourque M (2016) *Healthcare Value Analysis & Utilization Management Magazine* 4 (1): 7-12.

Case Study 1 – Hernia Mesh

Miller & Bourque (2016):[9] Technology that does not receive incremental reimbursement outside of procedure

RESULTS

- Widespread standardization from 8 to 3 vendors
- One primary vendor with widest product portfolio
- Similar clinical outcomes with revised vs. original portfolio
- Achieved over $1.5 million in cost-savings related to product acquisition costs by choosing less expensive and similarly effective options

HEOR RELEVANCE

- Used RWE to assess both clinical and cost outcomes
- Given similar efficacy, used cost-minimization methods for decision-making
- Considered economic variables beyond product price (i.e., contract and ordering efficiencies, reduced variability in product use and training needs)

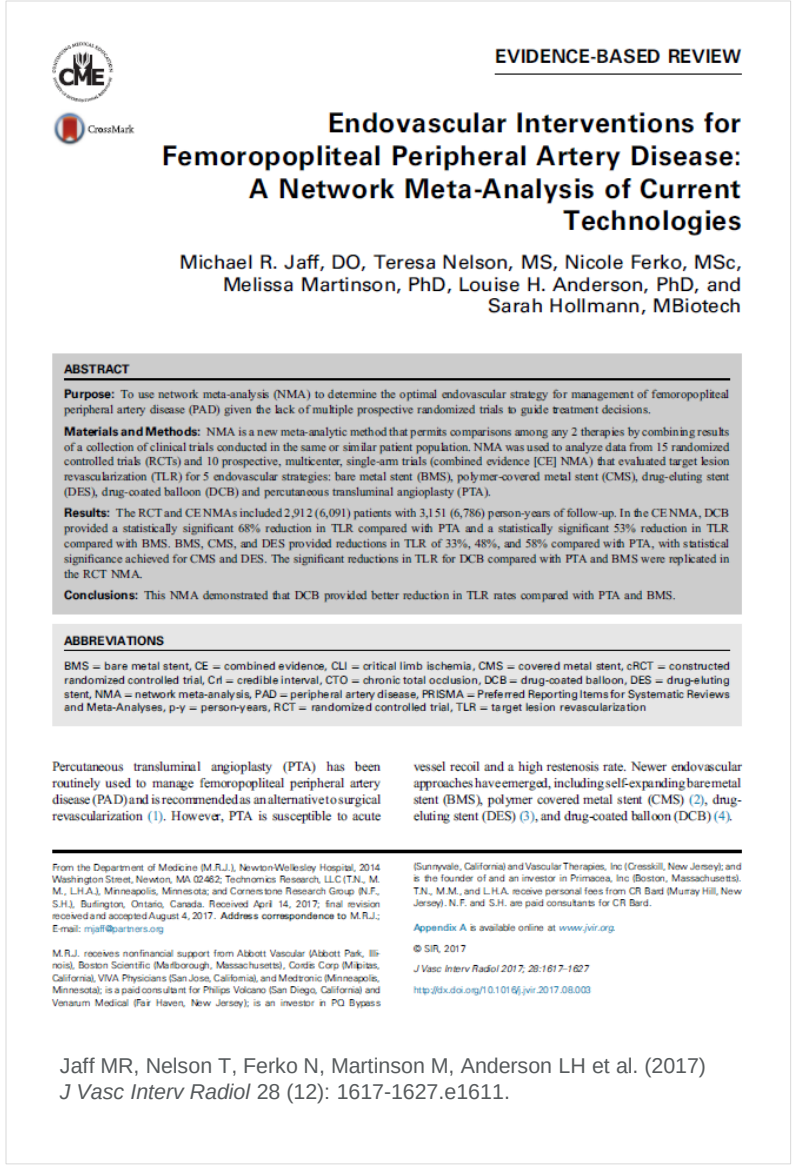
HEOR = Health Economics & Outcomes Research; RWE = Real-world Evidence

Case Study 2 – Drug-Coated Balloon

Jaff et al., (2017):[10] Disruptive technology that can receive incremental reimbursement

Budget impact model tailored to hospital

- Assessed multiple relevant comparative devices for peripheral artery disease
- Included product costs and re-interventions
- Utilized hospital data and published literature
- Model predicted cost impact or cost savings of introducing the new technology
- Held follow-up with stakeholders after 3 – 6 months to reassess model predictions
- Facilitated productive discussions between industry and hospital stakeholders



EVIDENCE-BASED REVIEW

Endovascular Interventions for Femoropopliteal Peripheral Artery Disease: A Network Meta-Analysis of Current Technologies

Michael R. Jaff, DO, Teresa Nelson, MS, Nicole Ferko, MSc, Melissa Martinson, PhD, Louise H. Anderson, PhD, and Sarah Hollmann, MBiotech

ABSTRACT

Purpose: To use network meta-analysis (NMA) to determine the optimal endovascular strategy for management of femoropopliteal peripheral artery disease (PAD) given the lack of multiple prospective randomized trials to guide treatment decisions.

Materials and Methods: NMA is a new meta-analytic method that permits comparisons among any 2 therapies by combining results of a collection of clinical trials conducted in the same or similar patient population. NMA was used to analyze data from 15 randomized controlled trials (RCTs) and 10 prospective, multicenter, single-arm trials (combined evidence [CE] NMA) that evaluated target lesion revascularization (TLR) for 5 endovascular strategies: bare metal stent (BMS), polymer-covered metal stent (CMS), drug-eluting stent (DES), drug-coated balloon (DCB) and percutaneous transluminal angioplasty (PTA).

Results: The RCT and CE NMAs included 2,912 (6,091) patients with 3,151 (6,786) person-years of follow-up. In the CE NMA, DCB provided a statistically significant 68% reduction in TLR compared with PTA and a statistically significant 53% reduction in TLR compared with BMS. BMS, CMS, and DES provided reductions in TLR of 33%, 48%, and 58% compared with PTA, with statistical significance achieved for CMS and DES. The significant reductions in TLR for DCB compared with PTA and BMS were replicated in the RCT NMA.

Conclusions: This NMA demonstrated that DCB provided better reduction in TLR rates compared with PTA and BMS.

ABBREVIATIONS

BMS = bare metal stent, CE = combined evidence, CLI = critical limb ischemia, CMS = covered metal stent, cRCT = constructed randomized controlled trial, CrI = credible interval, CTO = chronic total occlusion, DCB = drug-coated balloon, DES = drug-eluting stent, NMA = network meta-analysis, PAD = peripheral artery disease, PRISMA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses, p-y = person-years, RCT = randomized controlled trial, TLR = target lesion revascularization

Percutaneous transluminal angioplasty (PTA) has been routinely used to manage femoropopliteal peripheral artery disease (PAD) and is recommended as an alternative to surgical revascularization (1). However, PTA is susceptible to acute vessel recoil and a high restenosis rate. Newer endovascular approaches have emerged, including self-expanding bare metal stent (BMS), polymer covered metal stent (CMS) (2), drug-eluting stent (DES) (3), and drug-coated balloon (DCB) (4).

Jaff MR, Nelson T, Ferko N, Martinson M, Anderson LH et al. (2017) *J Vasc Interv Radiol* 28 (12): 1617-1627.e1611.

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THANK YOU

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