Farm to Market

Bringing In A New Product To Value Analysis For Approval And Implementation

Vancouver, B. C. IPAC

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I am a Senior Clinical Advisor with Diversey
Objectives

Identify 2 Reasons Why Value Analysis Committees / Teams have gained momentum

State 3 key questions that need to be answered for Product Approval at Value Analysis Committee

Describe how to identify issues related to cost
Goal: To bring a diverse perspective from various Hospital and Clinical departments and challenge current practices, promote innovative solutions and to advance the provider to the next generation of Supply Chain optimization and savings. Most organizations feel that working together they will gain synergy from the collective power and experience.
What does the Value Analysis Committee / Team In Your Facility look like?
Value Analysis Team

Influencers (varies depending on topic/item presented)
- Materials Management
- Biomed Engineering
- Infection Prevention
- Occupational Health & Safety
- Sterile Processing
- Users – Physicians, Surgical Staff, Nursing, EVS
The Rise of Value Analysis Committees

- To contain cost
- Optimize patient outcomes
- Standardize decision making process
- Evaluate products and services available to the organization
- Reduce redundancy
- Create standardized product usage
- Ensure contract compliance
- Lower overall cost

https://valueinhealthjournal.com/article/S1098-3015(15)00349-6/pdf
Clinical supplies typically represent the second largest and fastest growing cost category for hospitals. Uninformed clinical supply decisions account for more than $35 billion in wasteful spending annually.
5 Top Items

1. Hip and Knee Replacement Hardware
2. Demineralized Bone Matrix
3. Spinal Fusion Implants
4. Pacemakers and Implantable Cardio-verter Defibrillators (ICDs)
5. Surgical Meshes
Transition from reactive to proactive processes: Dedicate a steadily increasing portion of the value analysis agenda for proactive assessment of critical procedures or DRGs, with a call to examine what is used within a procedure when issues with cost, quality or outcomes are identified.

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Goals of Value Analysis

- Cost effective
- Soft vs. hard dollars
- Evidence based
- Reduce current SKUs
- Implementation issues
- Stocking
http://purchasing.uclahealth.org/workfiles/PUR055_20141204.pdf
Key Questions to have answers to

Is the Product Safe and Effective?
What does it replace?
What is the cost?
Is it on the GPO Contract?
Who presents to committee?
Will this impact clinical outcomes – reduce HAIs?
What defines “Safety”?

Approval by FDA
Approval by EPA
CDC recommendations
Any “Recalls” - Recalls, Market Withdrawals, & Safety Alerts

https://fda.gov/ForPatients/Approvals/Devices/ucm405381.htm
## Criteria of an Ideal Disinfectant – 5 Considerations

<table>
<thead>
<tr>
<th>Consideration</th>
<th>Question to Ask</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kill Claims</td>
<td>Does the product kill the most prevalent healthcare pathogens</td>
</tr>
<tr>
<td>Kill Times and Wet-Contact Times</td>
<td>How quickly does the product kill the prevalent healthcare pathogens. Ideally, contact time greater than or equal to the kill claim.</td>
</tr>
<tr>
<td>Safety</td>
<td>Does the product have an acceptable toxicity rating, flammability rating</td>
</tr>
<tr>
<td>Ease-of-Use</td>
<td>Odor acceptable, shelf-life, in convenient forms (wipes, spray), water soluble, works in organic matter, one-step (cleans/disinfects)</td>
</tr>
<tr>
<td>Other factors</td>
<td>Supplier offer comprehensive training/education, 24-7 customer support, overall cost acceptable (product capabilities, cost per compliant use, help standardize disinfectants in facility)</td>
</tr>
</tbody>
</table>

Selection of the Ideal Disinfectant, William A. Rutala, PhD, MPH; David J. Weber, MD, MPH, Infection Control and Hospital Epidemiology, Vol. 35, No. 7 (July 2014), pp. 855-865
Safety

HMIS Ratings: Health – 2-3-0

HMIS –0-0-0
Key Questions to have answers to

Is the Product Safe and Effective?
What does it replace?
What is the cost?
Is it on the GPO Contract?
Who presents to committee?
Will this impact clinical outcomes – reduce HAIs?
Is it replacing a product that is currently used?

What is the scientific evidence that supports the desire to replace
Key Questions to have answers to

Is the Product Safe and Effective?
What does it replace?
What is the cost?
Is it on the GPO Contract?
Who presents to committee?
Will this impact clinical outcomes – reduce HAIs?
Is the product on current GPO? What is a GPO?
Is this brand new technology?
Cost of an HAI
APIC Cost Calculator
Forms

Value =
Quality (Clinical Outcomes + Patient Safety + Service Delivery)+Cost (Effectiveness, Reduction or Avoidance)

medicalconstructiondata.com
CLABSI’s = $45,814
VAE = $40,144
SSI = $20,785
CDI = $11,285
CAUTI = $896

Health Care–Associated Infections
A Meta-analysis of Costs and Financial Impact on the US Health Care System

## Oxivir Tb Wipes vs Easy Wipes Pricing Calculator

### Section 1: Oxivir Tb Wipes Options

<table>
<thead>
<tr>
<th>SKU</th>
<th>Product Name</th>
<th>Wipe Size (in)</th>
<th>Tubs/Case</th>
<th>Wipe Area (sq in)</th>
<th>Price/Case</th>
<th>Wipes/Case</th>
<th>Price/Tub (of Wipes)</th>
<th>Price/Wipe</th>
<th>Price per sq in</th>
</tr>
</thead>
<tbody>
<tr>
<td>5627427</td>
<td>Oxivir Tb Wipes, 4x160 count</td>
<td>11 x 12</td>
<td>4</td>
<td>132.0</td>
<td>$0.00</td>
<td>160</td>
<td>$0.00</td>
<td>$0.0000</td>
<td>$0.0000</td>
</tr>
<tr>
<td>4599516</td>
<td>Oxivir Tb Wipes, 12x160 count</td>
<td>6 x 7</td>
<td>12</td>
<td>42.0</td>
<td>$0.00</td>
<td>160</td>
<td>1,920</td>
<td>$0.00</td>
<td>$0.0000</td>
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</tbody>
</table>

### Section 2A: Easy Wipes Options

<table>
<thead>
<tr>
<th>SKU</th>
<th>Product Name</th>
<th>Wipe Size (in)</th>
<th>Tubs/Case</th>
<th>Wipe Area (sq in)</th>
<th>Price/Case</th>
<th>Wipes/Case</th>
<th>Price/Tub (of Wipes)</th>
<th>Price/Wipe</th>
<th>Price per sq in</th>
</tr>
</thead>
<tbody>
<tr>
<td>5768748</td>
<td>EasyWipes, 6x120 Wipes</td>
<td>10.6 x 12.5</td>
<td>6</td>
<td>132.5</td>
<td>$0.00</td>
<td>120</td>
<td>720</td>
<td>$0.00</td>
<td>$0.0000</td>
</tr>
<tr>
<td>5831874</td>
<td>EasyWipes, 6x120 Wipes Refill</td>
<td>10.6 x 12.5</td>
<td>6</td>
<td>132.5</td>
<td>$0.00</td>
<td>120</td>
<td>720</td>
<td>$0.00</td>
<td>$0.0000</td>
</tr>
</tbody>
</table>

### Section 2B: Liquid Disinfectant Options

<table>
<thead>
<tr>
<th>SKU</th>
<th>Product Name</th>
<th>Case Vol (Gal)</th>
<th>Dilution</th>
<th>RTU Gal/Case</th>
<th>Price/Case</th>
<th>Price/RTU Gal</th>
<th>Wipes/Tub</th>
<th>RTU Oz/Tub</th>
<th>Price/RTU oz (64 RTU oz)</th>
<th>Disinfectant Price/Wipe</th>
<th>Loaded Price/Wipe (bucket)</th>
<th>Loaded Price/Wipe (refill)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4277285</td>
<td>Oxivir Tb RTU, 12x32 oz</td>
<td>3.0</td>
<td>0</td>
<td>3.0</td>
<td>$0.00</td>
<td>$0.00</td>
<td>120</td>
<td>64</td>
<td>$0.00</td>
<td>$0.0000</td>
<td>$0.0000</td>
<td>$0.0000</td>
</tr>
<tr>
<td>4963331</td>
<td>Oxivir Five 16 Conc, 2x2.5 L J-Fill</td>
<td>1.32</td>
<td>16</td>
<td>22.5</td>
<td>$0.00</td>
<td>$0.00</td>
<td>120</td>
<td>64</td>
<td>$0.00</td>
<td>$0.0000</td>
<td>$0.0000</td>
<td>$0.0000</td>
</tr>
<tr>
<td>4963357</td>
<td>Oxivir Five 16 Conc, 2x1.5 L RTD</td>
<td>0.79</td>
<td>16</td>
<td>13.5</td>
<td>$0.00</td>
<td>$0.00</td>
<td>120</td>
<td>64</td>
<td>$0.00</td>
<td>$0.0000</td>
<td>$0.0000</td>
<td>$0.0000</td>
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<tr>
<td>5019296</td>
<td>Oxivir Five 16 Conc, 2x1.4 L SmartDose</td>
<td>0.74</td>
<td>16</td>
<td>12.6</td>
<td>$0.00</td>
<td>$0.00</td>
<td>120</td>
<td>64</td>
<td>$0.00</td>
<td>$0.0000</td>
<td>$0.0000</td>
<td>$0.0000</td>
</tr>
<tr>
<td>4963314</td>
<td>Oxivir Five 16 Conc, 4x1 gal</td>
<td>4.0</td>
<td>16</td>
<td>68.0</td>
<td>$0.00</td>
<td>$0.00</td>
<td>120</td>
<td>64</td>
<td>$0.00</td>
<td>$0.0000</td>
<td>$0.0000</td>
<td>$0.0000</td>
</tr>
</tbody>
</table>

### Steps to use

1. Select the Oxivir Tb Wipe to compare in Section 1
2. Edit the Price/Case as appropriate (cells in yellow), leaving the other sizes zero if not part of the review
3. Enter EasyWipes pricing in Section 2A (cells in yellow). You may compare either pack - buckets or refills.
4. Enter the disinfectant pricing in Section 2B (cells in yellow). You may compare any of the five options.
5. Add your choice from 2A and 2B together and compare to the prewetted pricing in Section 1

DON'T FORGET TO ADD THE DISTRIBUTOR MARGIN IF APPLICABLE TO ALL PRICES!
Key Questions to have answers to

Is the Product Safe and Effective?
What does it replace?
What is the cost?
Is it on the GPO Contract?
Who presents to committee?
Will this impact clinical outcomes – reduce HAIs?
Who Presents to Committee
Who needs convincing?

What are the biggest mistakes device companies make in presenting their products to hospital value analysis committees?

Berkowitz: They don't fully examine the environment they are selling into. They tend to focus on features and benefits and not on evidence and comparative effectiveness. There must be a compelling clinical and/or economic reason for change, not simply a user preference. Also, they don't fully engage everyone in the value analysis process—many tend to focus only on the clinicians on the reported benefits of their products.

https://www.mddionline.com/how-win-over-hospital-value-analysis-committee
Is the Product Safe and Effective?
What does it replace?
What is the cost?
Is it on the GPO Contract?
Who presents to committee?
Will this impact clinical outcomes – reduce HAIs?
Evidence-based Decisions

- Patient’s Values
- Patient’s Expectations
- Best Available Clinical Evidence

Individual Clinical Expertise

Patient Outcomes
Show me the Evidence...

- Meta-Analysis
- Systematic Review
- Randomized Controlled Trial
- Cohort studies
- Case Control studies
- Case Series/Case Reports
- Animal research/Laboratory studies
Why Use Scientific Literature?

- People trained in science prefer to use evidence to make decisions
- Evidence-based decisions are shown to have high reproducibility and to correlate well with patient outcomes
- Important Considerations:
  - Credibility of data – data has a hierarchy to scientists
    - Peer reviewed studies (first hand data) published in scientific journals
    - Review articles (summaries of other studies) published in scientific journals
    - Expert opinion articles (not generally peer reviewed)
    - White papers/position papers (such as a manufacturer would generate)
    - Non-scientific articles (non-reviewed articles or marketing materials)
  - Age of the data – newer is better
  - Importance of author – credibility of previous work
  - Importance of journal
What Journals do we Follow?

- **American/Canadian Journals of Infection Control**
  - Read by IP community in NAM
  - Primary publication of APIC / IPAC
  - Scientific quality: Med

- **Infection Control and Hospital Epidemiology**
  - Read by: SHEA members (epidemiologists) and IP community
  - Primary publication of SHEA
  - Scientific quality: High

- **Clinical Infectious Diseases**
  - Read by: IDSA members (infectious disease doctors) and epidemiologists
  - Scientific quality: Very High

- **JAMA**
  - Read by: physicians and health care professionals around the world.

- **Journal of Hospital Infection**
  - Read by IP community in Europe
  - Primary publication of HIS
  - Scientific quality: Low/Med

- **Journal of Clinical Microbiology**
  - Read by: Clinical Microbiologists
  - Primary publication of ASM
  - Scientific quality: High

- **BMC Infectious Diseases**
  - Read by: Epidemiologists and IP Community in Europe
  - Scientific quality: Med
  - Articles are published on-line

- **New England Journal of Medicine**
Dr. Rutala’s Properties of an Ideal Disinfectant

1. **Broad spectrum** – kills pathogens of concern relevant to Healthcare
2. **Fast acting** – short kill and contact times listed on label
3. **Remains wet** – must keep surfaces wet for entire contact time in single application
4. **Unaffected by environmental factors** – not affected by organic matter, compatible with cleaners
5. **Non-toxic and non-irritating to the user** – should have lowest possible safety risk to user
6. **Compatible with surfaces** – should be proven compatible with common Healthcare surfaces and equipment
7. **Persistence** – should have a residual effect on surfaces
8. **Easy to use** – available in multiple forms to align with highest convenience for users
9. **Acceptable odor** – should have an acceptable odor for patients and staff
10. **Economical** – should not be cost prohibitive for facility
11. **Soluble in water** – so will not cause issues when it contacts water
12. **Stable** - in concentrate and end use dilution
13. **Cleaner** - good cleaning ability
14. **Nonflammable** – should have a flash point over 150°F

Does an evaluation need to be conducted?
If so, where?
Evaluation forms
Consensus
KEY QUESTIONS / INFORMATION TO COLLECT FOR NEW PRODUCT REQUESTS:

Product and manufacturer information
- Product/service name:
- Description of the purpose and function of product/service:
- Vendor/manufacturer:
- Catalog/manufacturer:
- Sales representative name, email, and phone number:

Requester or contact information
- Primary requester (name, title, email, phone, pager):
- Clinical resource/subject matter expert (name, title, department, email, phone, pager):

Current practice and product/service request rationale
- On what diagnoses/procedures would you expect to use the requested product? (description/CPT codes):
- Anticipated number used per year:
- What are you currently using to treat the types of patients on whom you would use the requested product?
  - Current Product(s) Name:
  - Current Product(s) Catalog #
  - Current Product(s) MMS #: List any concerns with existing product(s):
- How is this product more effective than what you are currently using to treat the same types of patients?
- What other physicians or healthcare providers have agreed to change their practice if the requested product is approved?
- Where will this product be used?
  - ☐ Main OR  ☐ ASC  ☐ CSC  ☐ Other
  - ☐ Cath Lab  ☐ Endo  ☐ Imaging Services  ☐ Clinical Lab
  - ☐ Patient Care Units  ☐ Other
- Will this product be used in conjunction with a piece of equipment?
  - ☐ Yes  ☐ No
  - If yes, define:
  - Is the required equipment already available within the health system?
- Does this product require training or in-service?
- Does this product fall into the classification of green initiative?
- Are there budgeted/approved funds for this product/equipment?

Disclosures
- Are you aware of any conflicts of interest (e.g., vendor, staff, and physician)?
  - ☐ Yes, please indicate circumstances surrounding potential conflict:
- Physician requestors:
  - Do you now or have you in the past received research support from the manufacturer?
  - Do you have a consulting agreement with the manufacturer?
  - Are you a member of advisory board or consulting panel for the manufacturer?
Change in Policy/Procedures

Order Sets

Name: ORANGEGWON. Orange
MRN: 06600118
Sex: M
Room Bed: 7101B
Date of Birth - Age: 2-Feb-1980=45
ADMD LOS: 9-Mar-10=343

Order Name: Foley Protocol-Insert and/or Maintain

Frequency: once
Priority: R
P RN

Indication:
- Urinary Retention
- Close monitoring of urine output
- Pre-Perc, & Post Operative
- Incontinence w/Stage 3 & 4 skin breakdown
- Bladder Training
- Unstable hip or spinal injury
- Palliative Care
- Urology Service Patient
- Type in indication if not listed above

Ordered By: DRUMM
Signed By: DRUMM
Start Date: 15-FEB-2011 Time: 12:59
End Date: 15-FEB-2011 Time: 12:59

Order Reference

Foley Catheter Protocol No. 2.016: All patients who need a Foley catheter inserted will have an order placed in JefChArt. One of two orders will be chosen:

1. Urology patients, patients with urology consults, or patients with extensive pelvic surgery will have Foley Orders for Urology/Nonprotocol Orders entered. The physician must document the reason for this order.

2. All other patients will have Foley Protocol Orders entered.

PLACE ORDER
Allergies Lab Results Med Profile Print Ref Cancel Order

file:///C:/Users/x51416/Google%20Drive/Computer/Documents/UTI/nurse-driven-foley-cath.pdf
Education
Competency
Conclusions/Summary

• It is important to understand what your organization’s process

• Have all the necessary information for the members of the committee to thoroughly assess the value proposition

• Engage with the key users to obtain commitment/consensus prior to bringing to committee