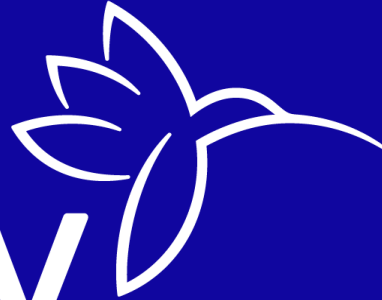


Diversey



Farm to Market



Farm to Market

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

Vancouver, B. C. IPAC

Carol Calabrese, R.N., B.S., C.I.C.



Disclaimer

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



Begin With The Unit..... The Value Analysis Team (VAT)

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



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.

THE NEW RULES LUMERE.COM of Clinical Supply Chain Management



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.

Robin_Czajka@premierinc.com

<http://actionforbetterhealthcare.com/future-value-analysis-hint-not-new-product-approvals/>



Goals of Value Analysis

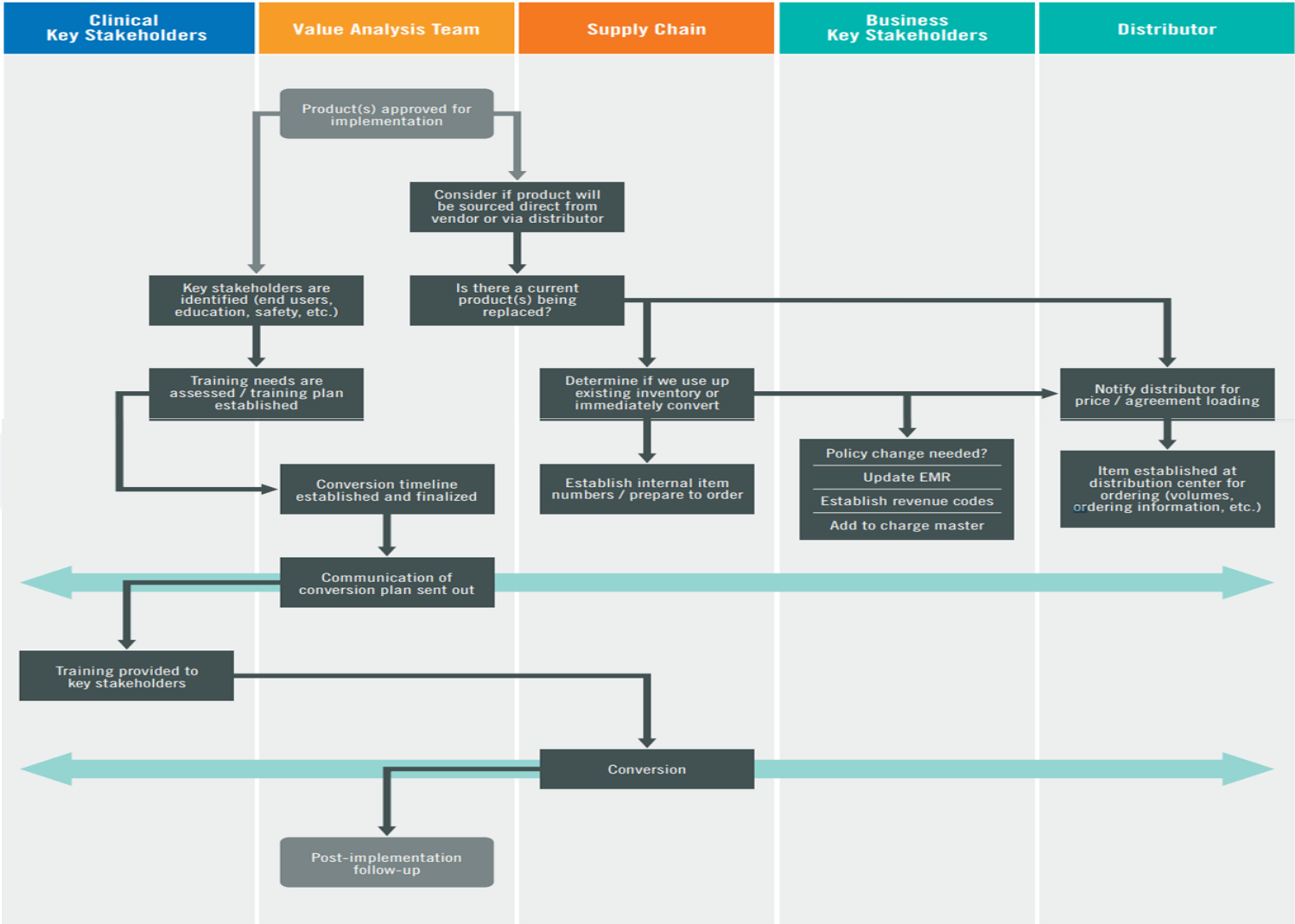
- Cost effective
 - Soft vs. hard dollars
- Evidence based
- Reduce current SKUs
- Implementation issues
- Stocking





Facility Process

http://purchasing.uclahealth.org/workfiles/PUR055_2014_1204.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](https://fda.gov/ForPatients/Approvals/Devices/ucm405381.htm)**



Criteria of an Ideal Disinfectant – 5 Considerations

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

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



CHEMICAL NAME	PROTECTIVE EQUIPMENT INDEX	
	A	G
HEALTH	B	H
FLAMMABILITY	C	I
REACTIVITY	D	J
PROTECTIVE EQUIPMENT	E	K
DATE	F	X Ask your supervisor for special handling instructions.



HMIS Ratings: Health – 2-3-0

HMIS –0-0-0



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Cost Analysis

- 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)



Use of the HAI Cost in Calculation

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

Zimlichman, E, et. al; Health-care Associated Infections, A Meta – analysis of Costs and Financial Impact on the US Health Care System, Jama 2013:173(22):2039-2046



Cost Benefit

Realistic

Oxivir Tb Wipes vs Easy Wipes Pricing Calculator												Rev 02-03-14	
SKU	Product Name	Wipe Size (in)		Wipe Size (in)	Tubs/ Case	Wipe Area (sq in)	Price/ Case	Wipes/ Tub	Wipes/ Case	Price/Tub (of Wipes)	Price/Wipe	Price per sq in	
Section 1: Oxivir Tb Wipes Options													
5627427	Oxivir Tb Wipes, 4x160 count	11	x	12	4	132.0	\$0.00	160	640	\$0.00	\$0.0000	\$0.00000	
4599516	Oxivir Tb Wipes, 12x160 count	6	x	7	12	42.0	\$0.00	160	1,920	\$0.00	\$0.0000	\$0.00000	
Section 2A: Easy Wipes Options													
5768748	EasyWipes, 6x120 Wipes	10.6	x	12.5	6	132.5	\$0.00	120	720	\$0.00	\$0.0000	\$0.00000	
5831874	EasyWipes, 6x120 Wipes Refill	10.6	x	12.5	6	132.5	\$0.00	120	720	\$0.00	\$0.0000	\$0.00000	
Section 2B: Liquid Disinfectant Options													
SKU	Product Name	Case Vol (Gal)	Dilution	RTU Gal/ Case	Price/ Case	Price/ RTU Gal	Wipes/ Tub	RTU Oz/ Tub	Price/Tub (64 RTU oz)	Disinfectant Price/Wipe	Loaded Price/Wipe (bucket)	Loaded Price/Wipe (refill)	
4277285	Oxivir Tb RTU, 12x32 oz	3.0	0	3.0	\$0.00	\$0.0000	120	64	\$0.00	\$0.0000	\$0.0000	\$0.0000	
4963331	Oxivir Five 16 Conc, 2x2.5 L J-Fill	1.32	16	22.5	\$0.00	\$0.0000	120	64	\$0.00	\$0.0000	\$0.0000	\$0.0000	
4963357	Oxivir Five 16 Conc, 2x1.5 L RTD	0.79	16	13.5	\$0.00	\$0.0000	120	64	\$0.00	\$0.0000	\$0.0000	\$0.0000	
5019296	Oxivir Five 16 Conc, 2x1.4 L SmartDose	0.74	16	12.6	\$0.00	\$0.0000	120	64	\$0.00	\$0.0000	\$0.0000	\$0.0000	
4963314	Oxivir Five 16 Conc, 4x1 gal	4.0	16	68.0	\$0.00	\$0.0000	120	64	\$0.00	\$0.0000	\$0.0000	\$0.0000	

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.

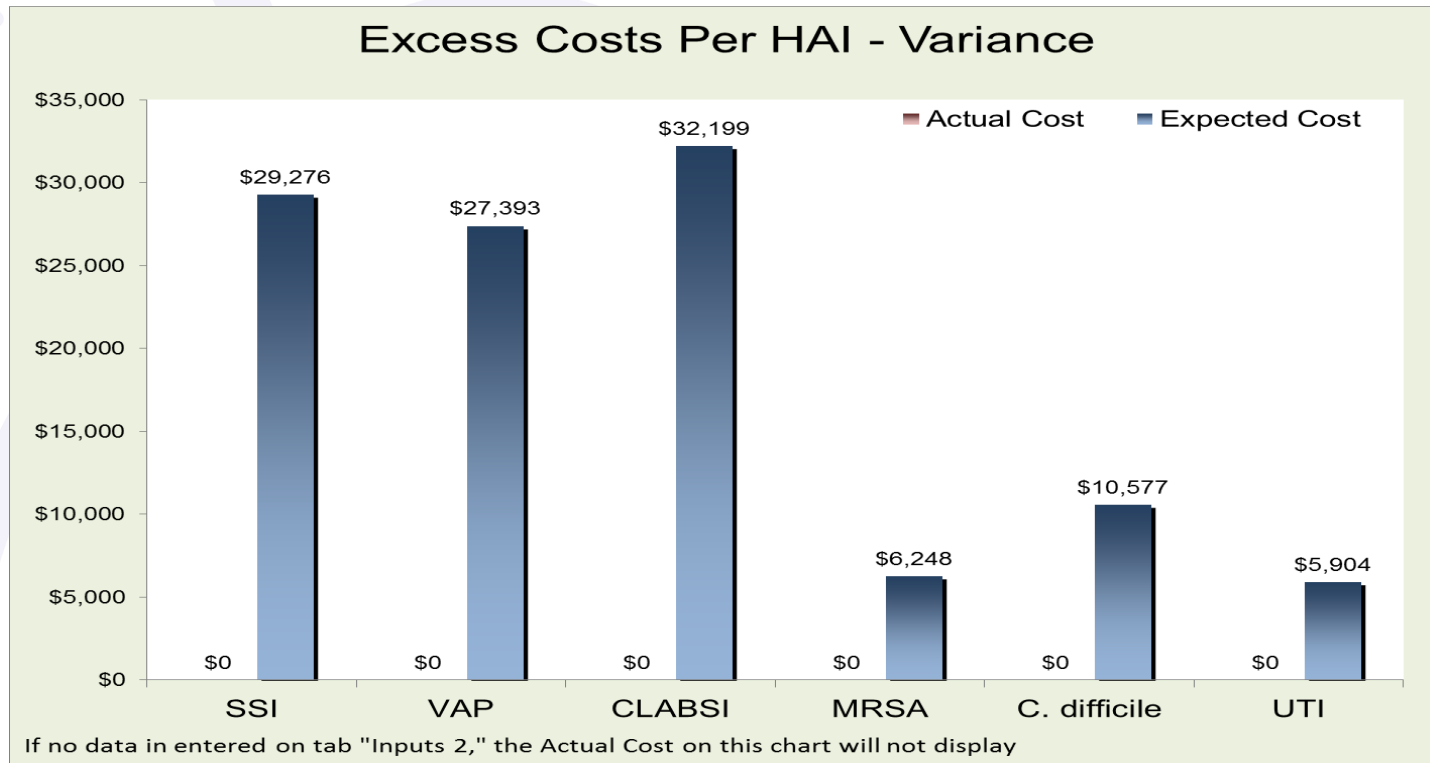
4. Enter the disinfectant pricing in Section 2B (cells in yellow). You may compare any of the five options.

5. Add your choice from 2A and 2B together and compare to the prewetted pricing in Section 1

DONT FORGET TO ADD THE DISTRIBUTOR MARGIN IF APPLICABLE TO ALL PRICES!



APIC Cost Calculator



https://apic.org/Resource_/.../Resources/TMIT_V1_CostCalculator02082011.xls



Key Questions to have answers to

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Who Presents to Committee



Vector Toons





Gaining Acceptance

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>



Key Questions to have answers to

Is the Product Safe and Effective?

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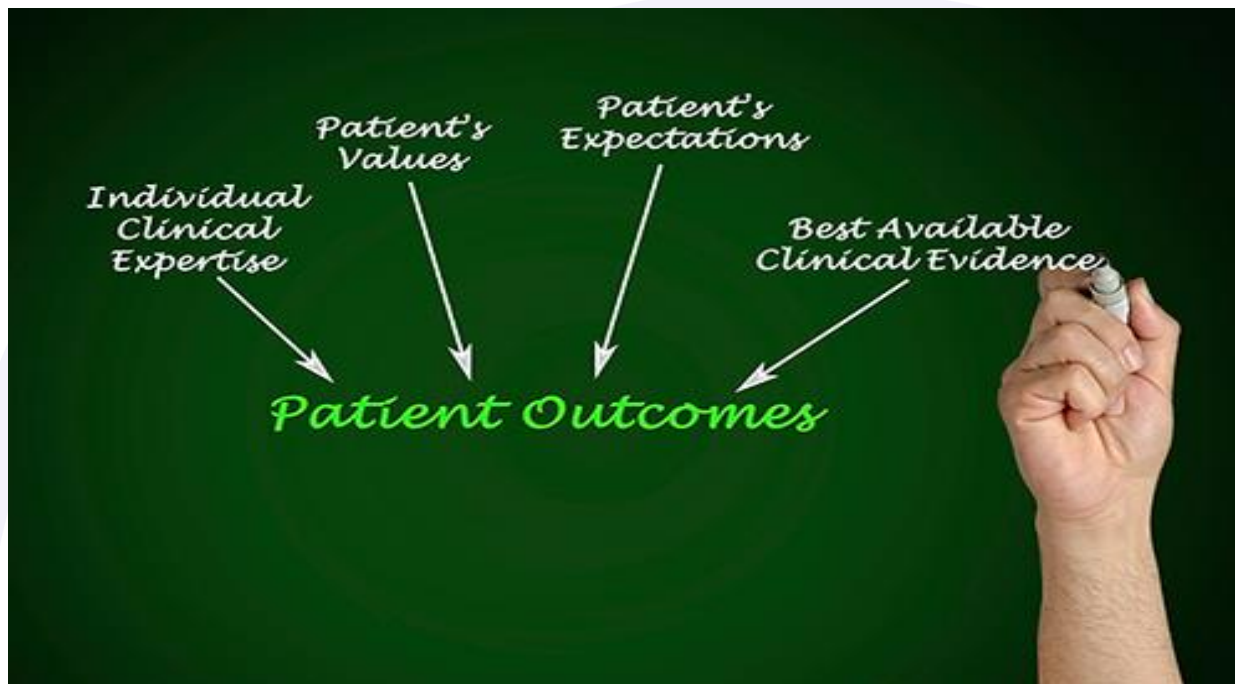
Is it on the GPO Contract?

Who presents to committee?

Will this impact clinical outcomes – reduce HAIs?



Evidence-based Decisions





Show me the Evidence...





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



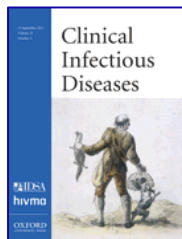
- **Infection Control and Hospital Epidemiology**

- 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

HEALTHCARE SURFACES AND EQUIPMENT DISINFECTANTS – 10001, 10010, 10011, 10012, 10013, 10014, 10015

COMMENTARY

Selection of the Ideal Disinfectant

William A. Rutala, PhD, MPH, MPT¹; David J. Weber, MD, MPH²

Healthcare-associated infections (HAIs) remain an important source of morbidity and mortality, with an estimated 1.7 million HAIs and 99,000 deaths annually.¹ A major source of nosocomial pathogens is through touch. In patients' exclusive time, the environment (20%–30% of HAIs) have been attributed to cross-colonization in the hands of healthcare personnel.² Contamination of the hands of healthcare personnel is the most likely cause for cross-colonization of healthcare from touching contaminated environmental surfaces. Healthcare personnel have frequent contact with the environment surface in patient's rooms, providing ample opportunity for contamination of gloves and/or hands. The results of this study have shown that the hands of healthcare workers are not only able to contaminate the hands of healthcare workers in their contact with the patient,³ but also to spread the bacteria between and toward the caregiver's nose, hand, and clothing and toward the caregiver's mouth.

By long tradition, as well as public health facilities must control such pathogens on the most sensitive surfaces of HAIs, the most common cause of infection and most difficult to clean and the most common cause of HAIs, the hands of healthcare workers. While disinfectants are used to prevent transmission of pathogens from high-touch surfaces and environmental surfaces, the purpose of this article is to describe the use of the selection of the optimal disinfectant for use with environmental surfaces and associated patient care areas (patient rooms, waiting areas, etc.). The most important factor in the selection of an ideal disinfectant is the ability to kill the most resistant species of bacteria, fungi, and viruses.

HAIs would be used for high-touch disinfectants, however, the contact time would be longer and the antimicrobial activity would be needed to be longer (i.e., 10–15 minutes). To date, the perfect product for healthcare disinfection has not been identified. However, there is a wide range of disinfectants available for use in healthcare facilities. The selection of the optimal disinfectant for use with environmental surfaces and associated patient care areas (patient rooms, waiting areas, etc.) is a complex task. It is necessary to check the product label to ensure that the disinfectant meets or exceeds the requirements of the American Society for Healthcare Disinfection and Sterilization (ASHDIS) and the National Sanitation Foundation (NSF) and is registered with the Environmental Protection Agency (EPA) registered to kill a range of pathogens listed in Table 1.⁴

While the process of selecting an optimal disinfectant is a complex task, there are several key factors to consider. While the process of selecting an optimal disinfectant is a complex task, there are several key factors to consider. While the process of selecting an optimal disinfectant is a complex task, there are several key factors to consider.

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Evaluation

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

Requestor or contact information

- Primary requestor (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 code)
- 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) MMIS # _____
 - 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
 OSC
 Buyers
 Cath Angio
 Endoscopy
 Imaging Services
 Clinical Lab
 Patient Care Units
 Other _____

- Will this product be used in conjunction with a piece of equipment?
 - 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 physicians)?
 - If 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 an advisory board or consulting panel for the manufacturer?



Change in Policy/Procedures

Order Sets

05600118 ORANGEGWN, Orange - M

File Patient Session Navigate Help

Pt/Phys Search Pt Info Clin Data Results Meds Orders Viewer Charges User Info Pat Lists

Name: ORANGEGWN, Orange **MRN:** 05600118 **Sex:** M
Account: 45600473 **Room Bed:** 7101B
Date of Birth - Age: 2-Feb1966=45 **ADMD LOS:** 9-Mar10=343

Order Name: Foley Protocol-Insert and/or Maintain

Frequency: Priority: PRN

Indication:

FOLEY INDICATIONS - 8466

- Urinary Retention
- Close monitoring of urine output
- Pre, Peri, & 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:
Signed By:

Start Date: Time:
End Date: Time:

Order Reference

Foley Catheter Protocol No. 2.016: All patients who need a Foley catheter inserted will have an order placed in JeffChart. 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

PLACE ORDER Allergies Lab Results Med Profile Print Ref Cancel Order

\$PMQ5 AIS6532 OCDNUR56 DRUMM, D... 15Feb11



Education





Competency





<http://kascope.com/pass-or-fail-why-value-analysis-committees-matter-and-what-they-look-for-in-medical-device-design-2/#prettyPhoto>



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**

