The Affordable Care Act & Product Selection:

The Clinician's Role

Kim Delahanty, is a paid consultant of Ethicon, Inc.

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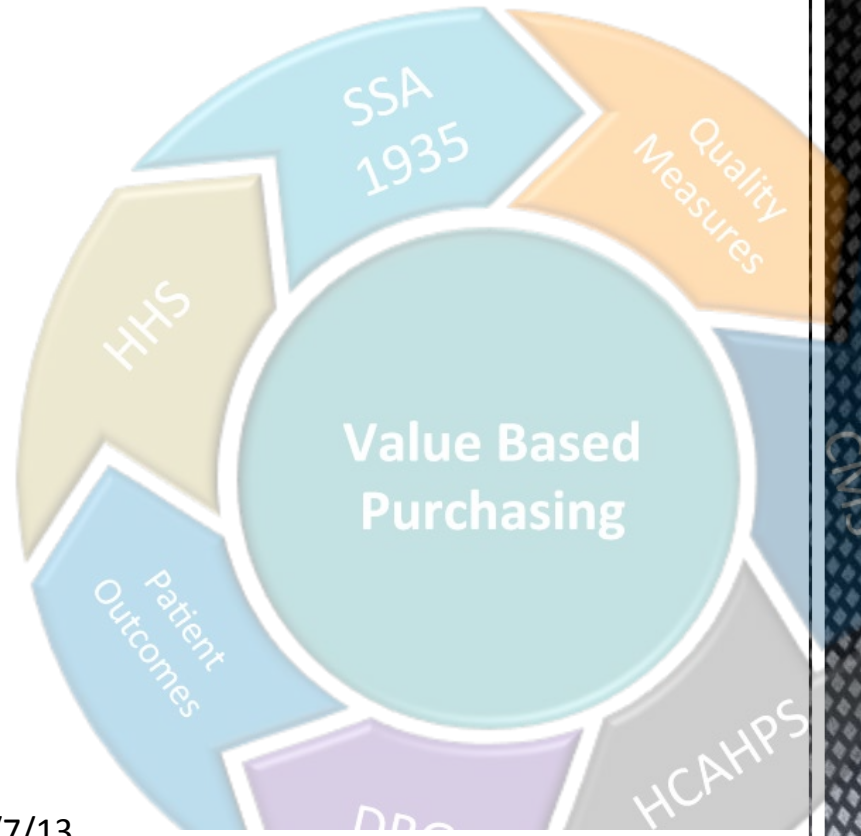
Objectives

- Describe one way that the ACA can be used to benefit the ICU nurses in advocating for a product
- Identify the best study design to evaluate a product's effectiveness
- Describe one governmental resource for identifying potential concerns about a product
- Identify why product labeling and written claims are superior to verbal claims

In this new environment
Top 10 Concerns of Hospital CEOs

- ✓**Financial challenges**
- ✓**Patient safety and quality**
- ✓**Healthcare reform implementation**
- ✓**Patient satisfaction**
- Governmental mandates
- Care for the uninsured
- Physician-hospital relations
- Technology
- Population health management
- Personnel shortages
- Creating an accountable care organization



http://www.ache.org/PUBS/research/cecissues.cfm Accessed 7/7/13

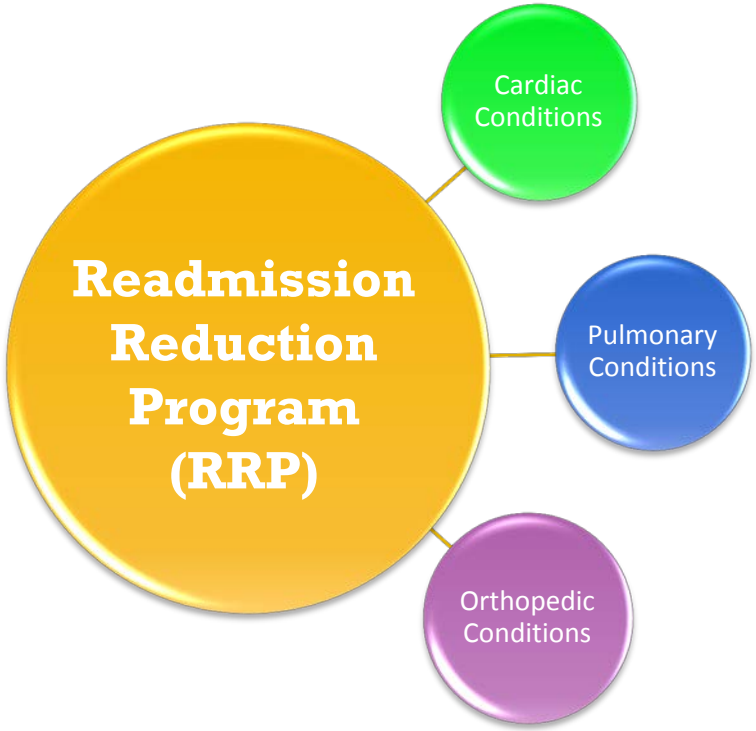
Affordable Care Act

Medicare has begun implementing penalties and/or offering incentive payments for improved patient outcomes, so choosing evidence based products with proven clinical outcomes has never been more important

http://www.cms.gov/Outreach-and-Education/Medicare-Learning-NetworkMLN/MLNProducts/downloads/Hospital_VBPurchasing_Fact_Sheet_ICN907664.pdf Accessed January 16, 2014

Financial

- Penalizes hospitals for readmission rates above the national average for specific conditions
- Defined readmission as an admission **within 30 days of discharge** from the same or another subsection hospital
- Requires CMS to reduce payments to hospitals with excess readmissions (effective for discharges beginning October 1, 2012)



http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html Accessed January 16, 2014

How Clinicians Impact Readmission Reduction Program

- Discharge Planning[1,2]
  - Readiness
  - Simplicity/clarity of educational materials & discharge instructions to increase compliance
- Coordination of Care[1,2]
  - Interdisciplinary planning
  - Post discharge follow up
  - Post-acute care standards
- Products[2]
  - Choosing products/devices that help to reduce readmissions

1. Baumgarten, et Al., Bridging the Gap: A Collaborative to Reduce PICC Infections in the Home Care Environment, poster presentation SHEA/ IDSA September 2012
2. The Advisory Board Company, Healthcare Industry Committee. Hospital Readmissions Reduction Program. C-Suite Cheat Sheet Series. August 2013.

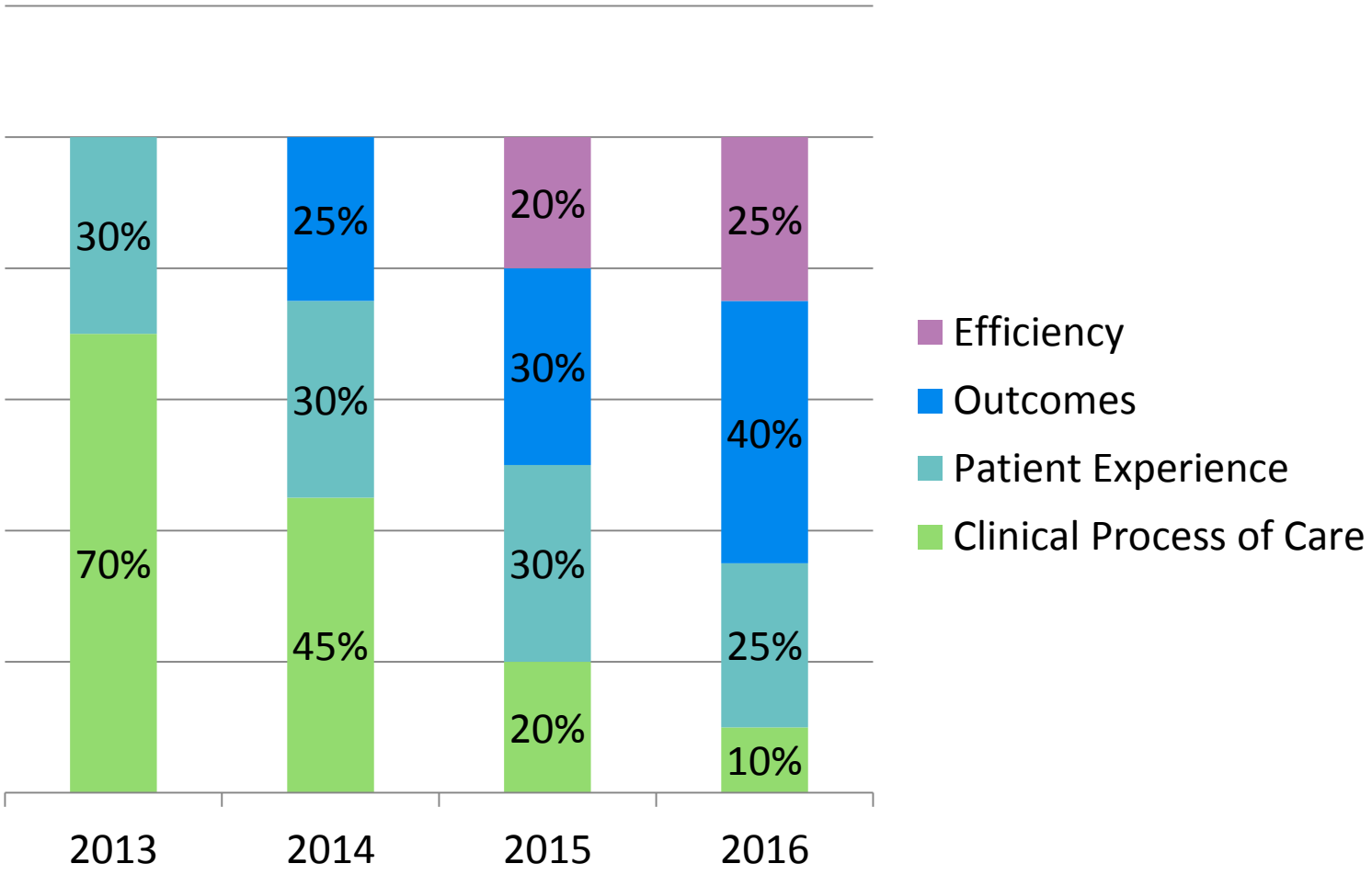
- Value Based Purchasing is a CMS initiative designed to ensure quality patient outcomes.
- Under VBP, CMS withholds a portion of Medicare reimbursement which a hospital could earned back by performing well on a set of metrics
- **Value Based Purchasing is NOT about purchasing the lowest price items**
- **VBP is about Patient OUTCOMES and IMPROVEMENT**

http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing/ Accessed on April 26, 2013

The Advisory Board Company, Healthcare Industry Committee. Hospital Value-Based Purchasing. C-Suite Cheat Sheet Series. August 2013.

Value Based Purchasing

CMS rewards hospitals based on the **quality** of care provided

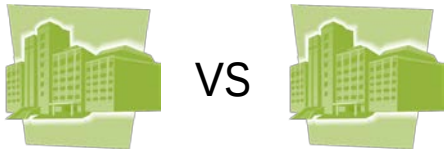


The Advisory Board Company, Healthcare Industry Committee. Hospital Value-Based Purchasing. C-Suite Cheat Sheet Series. August 2013.

Value Based Purchasing Scoring: 2 Ways

Improvement

- Hospitals will be assessed on how much their ***current performance changes from their own baseline period performance***
- **YOU MUST CONTINUALLY IMPROVE AGAINST PREVIOUS YEARS**



Achievement

- Hospitals measured based on how much their *current performance differs from all other hospitals' baseline period performance*
- **YOU MUST CONTINUALLY IMPROVE OVER YOUR NEIGHBORS**

Total Performance Score (TPS)

- TPS calculated by combining the greater of the hospital's achievement or improvement points on each measure to determine a score for each domain, multiplying each domain score by the proposed domain weight and adding the weighted scores together

1. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing/ Accessed on April 26, 2013

How Does VBP Impact You?

Overall points achieved will determine how much of the percent payments withheld each hospital gets back

CMS Redistributes the percent withheld across hospitals with highest achievement

VBP is Budget neutral, meaning CMS will not keep any portion of the percent withheld nationally

- Redistributed, based on performance
- Best performers win, others break even or lose

So what does that mean?

Your hospitals 1-2% could be paid to other facilities that outperform you!

1. http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing/ Accessed on April 26, 2013

For Example

Hospital Revenue: $1.5 Billion

CMS Patients: 40% x $1.5 Billion Revenue= $600,000,000

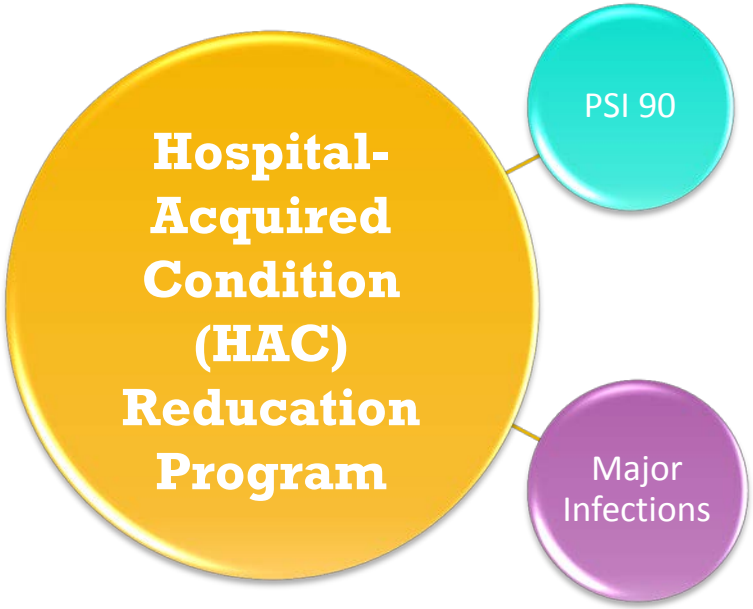
2015 Withholding: 1.5%= $9 Million

With $9 Million withheld, consider the

dollars at stake when maintaining/implementing new practices

- Requires CMS to reduce hospital payments by 1% for hospitals that rank among the lowest performing 25 percent with regard to HACs (beginning in FY 2015)

- The 2 Domains of this program are:
  - Domain 1 (35%)
    - Patient Safety Indicators (PSI) PSI 90 composite measure
  - Domain 2 (35%)
    - Major Infections



http://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2013-fact-sheets-items/2013-08-02-3.html Accessed March 2014

Metric	FY 2015	FY 2016	FY 2017
CLABSI	✓	✓	✓
CAUTI	✓	✓	✓
SSI – Colon		✓	✓
SSI- Abd Hysterectomy		✓	✓
MRSA			✓
C. Difficile			✓

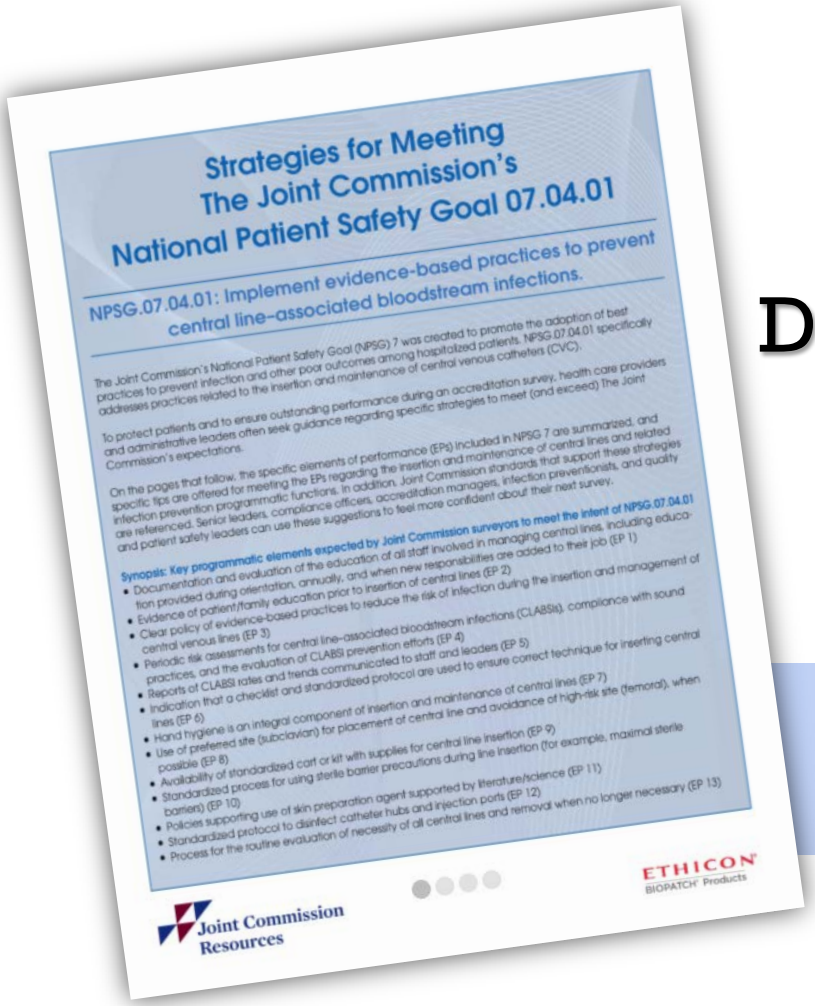
Major Infections

Upcoming Changes to the HAC Program

The Advisory Board Company, Healthcare Industry Committee. Hospital-Acquired Condition Reduction Program. C-Suite Cheat Sheet Series. August 2013.

Goal of this new Healthcare Environment:

To Ensure Optimal Reimbursement by Delivering First Class Care



Strategies for Meeting
The Joint Commission's
National Patient Safety Goal 07.04.01

NPSG.07.04.01: Implement evidence-based practices to prevent central line–associated bloodstream infections.

The Joint Commission's National Patient Safety Goal (NPSG) 7 was created to promote the adoption of best practices to prevent infection and other poor outcomes among hospitalized patients. NPSG.07.04.01 specifically addresses practices related to the insertion and maintenance of central venous catheters (CVC).

To protect patients and to ensure outstanding performance during an accreditation survey, health care providers and administrative leaders often seek guidance regarding specific strategies to meet (and exceed) The Joint Commission's expectations.

On the pages that follow, the specific elements of performance (EPs) included in NPSG 7 are summarized, and specific tips are offered for meeting the EPs regarding the insertion and maintenance of central lines and related infection prevention programmatic functions. In addition, Joint Commission standards that support these strategies are referenced. Senior leaders, compliance officers, accreditation managers, infection preventionists, and quality and patient safety leaders can use these suggestions to feel more confident about their next survey.

Synopsis: Key programmatic elements expected by Joint Commission surveyors to meet the intent of NPSG.07.04.01

- Documentation and evaluation of the education of all staff involved in managing central lines, including education provided during orientation, annually, and when new responsibilities are added to their job (EP 1)
- Evidence of patient/family education prior to insertion of central lines (EP 2)
- Clear policy of evidence-based practices to reduce the risk of infection during the insertion and management of central venous lines (EP 3)
- Periodic risk assessments for central line–associated bloodstream infections (CLABSIs), compliance with sound practices, and the evaluation of CLABSI prevention efforts (EP 4)
- Reports of CLABSI rates and trends communicated to staff and leaders (EP 5)
- Indication that a checklist and standardized protocol are used to ensure correct technique for inserting central lines (EP 6)
- Hand hygiene is an integral component of insertion and maintenance of central lines (EP 7)
- Use of preferred site (subclavian) for placement of central line and avoidance of high-risk site (femoral), when possible (EP 8)
- Availability of standardized cart or kit with supplies for central line insertion (EP 9)
- Standardized process for using sterile barrier precautions during line insertion (for example, maximal sterile barriers) (EP 10)
- Policies supporting use of skin preparation agent supported by literature/science (EP 11)
- Standardized protocol to disinfect catheter hubs and injection ports (EP 12)
- Process for the routine evaluation of necessity of all central lines and removal when no longer necessary (EP 13)

Joint Commission Resources

ETHICON BIOPATCH® Products

NPSG 07.04.01

Implement evidence-based practices to prevent central line-associated bloodstream infection[1]

1. http://www.jointcommission.org/assets/1/18/NPSG_Chapter_Jan2013_HAP.pdf Accessed on April 26, 2013

Are products the solution to healthcare associated bloodstream infections?

CDC Recommendations – The Dos

- 2% chlorhexidine based preparation is preferred for skin preparation prior to catheter insertion and dressing changes
- Clean injection ports with 70% alcohol or an iodophor before accessing the system
- Use single-dose vials for parenteral additives or medications when possible
- Use a midline catheter or PICC when the duration of IV therapy will likely exceed 6 day
- Use a chlorhexidine-impregnated sponge dressing for temporary short-term catheters in patients older than 2 months of age if the CLABSI rate is not decreasing despite adherence to basic prevention measures, including education and training, appropriate use of chlorhexidine for skin antisepsis, and MSB [93, 96–98]. Category 1B

http://www.cdc.gov/hicpac/BSI/BSI-guidelines-2011.html Accessed March 2014

CDC Recommendations – The Don'ts

- Do not apply organic solvents (e.g., acetone and ether) to the skin before insertion of catheters or during dressing changes
- Do not use topical antibiotic ointment or creams on insertion sites (except when using dialysis catheters) because of their potential to promote fungal infections and antimicrobial resistance
- Do not use in line filters routinely for infection-control purposes
- Do not administer intranasal or systemic antimicrobial prophylaxis routinely before insertion or during use of an intravascular catheter to prevent catheter colonization or BSI
- Avoid the use of steel needles for the administration of fluids and medication that might cause tissue necrosis if extravasation occurs
- No recommendation can be made for the use of impregnated catheters in children

http://www.cdc.gov/hicpac/BSI/BSI-guidelines-2011.html Accessed March 2014

- Types of products are endorsed by the CDC but never brands
  - Sometimes there is only one manufacturer of a product
  - Similar products may come to market
- What product is cited in the supporting literature used by the CDC?
  - Can I extrapolate to all products or not?
  - “Class Effect” does not apply to medical devices

No products are endorsed by the CDC

Evidence You Should Ask For…

- ✓ FDA Cleared Indication for Reduction of CRBSI
- ✓ Highest Level of Evidence/ Studies
- ✓ National Guideline Recommendations

It's up to you to decide what fits best in your hospital's protocol

FDA Cleared Indications

- Products on the market will have an FDA Approved Indication.
- It is important to understand exactly *what is the intended use for the product*
  - **Read the Product Insert, under "Indication for Use"**

FDA Resources

- FDA MAUDE

(Manufacturer & User Facility Device Experience)

  - http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM

- Search all of the FDA

  - http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm181502.htm

- Possible Conflicting Goals
  - Patient Safety
    - *Infection risks*
    - *Potential for errors*
    - *Compatibility of devices*
    - *Special population needs*
    - *Unintended side effects/complications*
  - Employee safety
    - *Injury*
    - *Exposures*
  - Financial
    - *Purchase Price*
    - *Additional equipment or materials needed*
    - *Impact of Efficacy (or non-efficacy)*
  - Employee satisfaction
    - Level of difficulty
    - Impact on workload

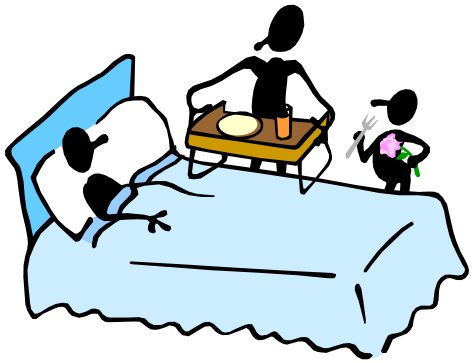
Products Need to be Viewed Holistically

- What are the legal/safety/ quality implications for using/not using this product?
- What is the greatest priority for my staff?
- Is there an increased risk of exposure/harm to staff?
- How is it better than what we use today?
- Who else is using it?
- Who has stopped using it and why? What are the educational needs for staff?
- Where else will the patient go with the device?
  - Both in house (areas of hospital) and post discharge

Impact on Facility/ Staff

- What is the quality of the product?
  - FDA approved indication
  - Review recalls and FDA citations
- Does this address the greatest threat of real harm to my patients?
- Are there potential unintended side effects/complications of using this product?

Impact on Patient Outcomes



Weighing the Evidence

Evidence Based Medicine

Best designs double blinded, randomized

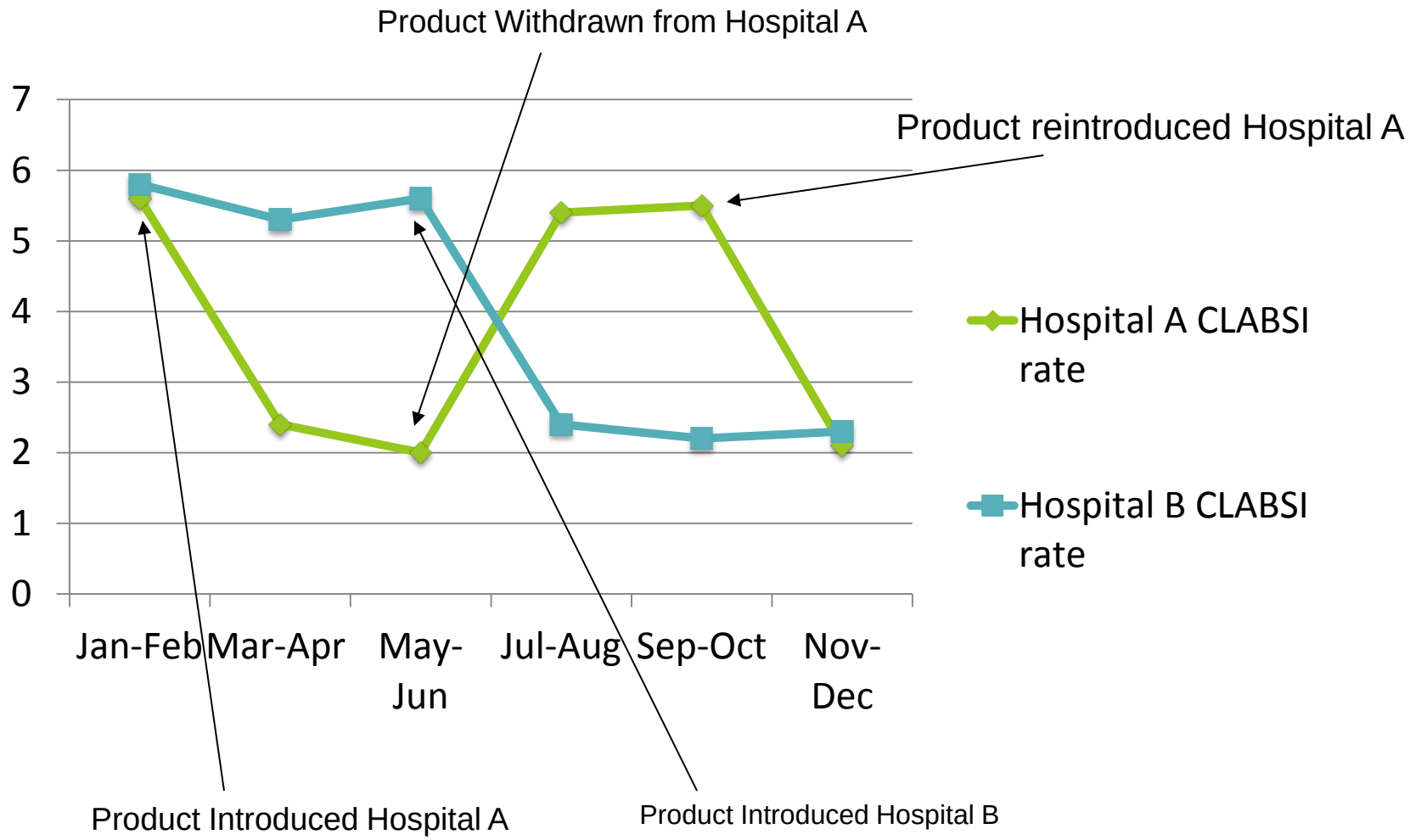
- Double blinding may not always be possible
- Define
  - Double Blinded
  - Randomized
- Ensures that the change in behavior occurs in both treatments being measured
- Look at the more common negative outcome
  - Example: infection vs. mortality
- Make sure the definition of the negative outcome uses the accepted standard
  - Use NHSN definitions

Hawthorne Effect

- The **Hawthorne Effect** refers to a phenomenon which is thought to occur when people observed during a research study temporarily change their behavior or performance. Others have broadened the definition to mean that people's behavior and performance change following any new or increased attention. The Hawthorne studies have had a dramatic effect on management in organizations and how people react to different situations

http://www.newworldencyclopedia.org/entry/Hawthorne_effect

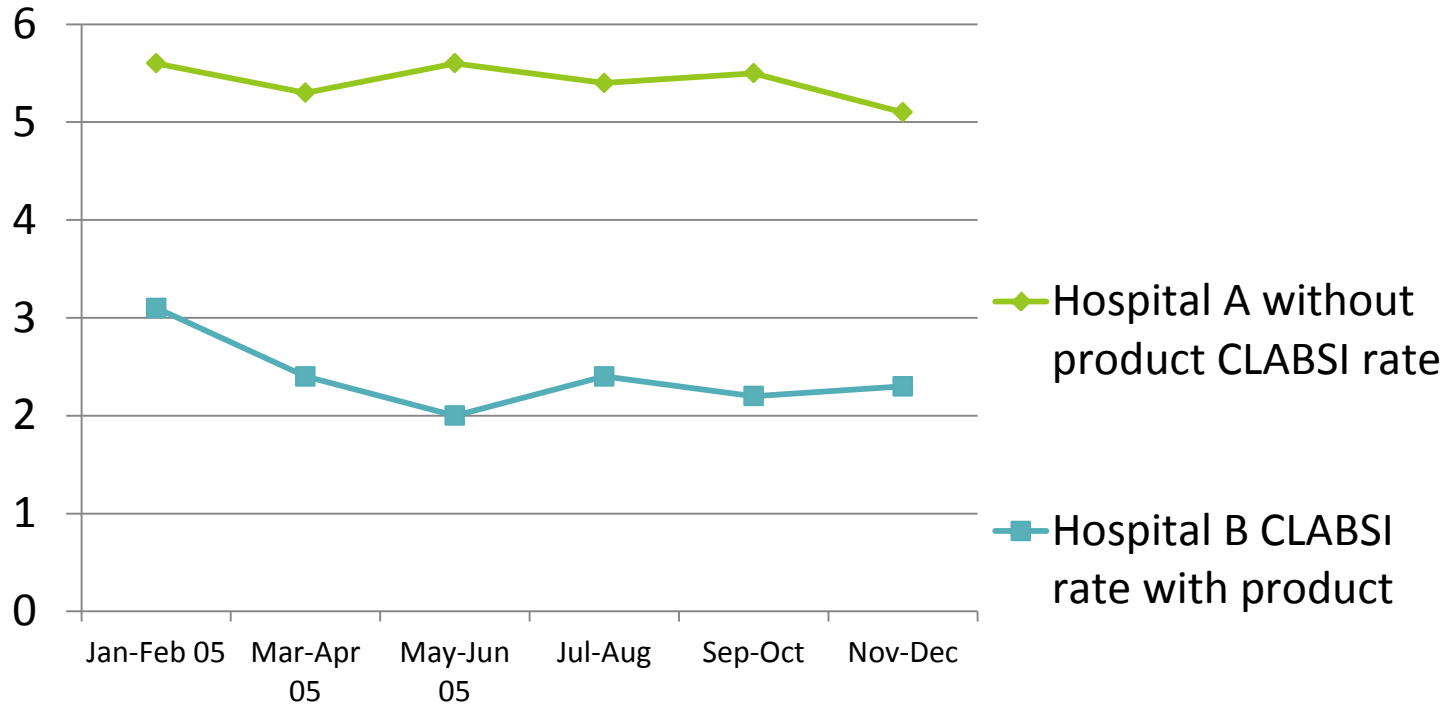
Great Product for CLABSI *(Example)*



- Reduces variables that may impact outcome
- Things to pay attention to
  - What is their baseline rate?
  - What was their reduction?
    - Given your rate and the reduction found would your institution benefit?
  - What is the number needed to treat for same results to be accomplished in your institution?

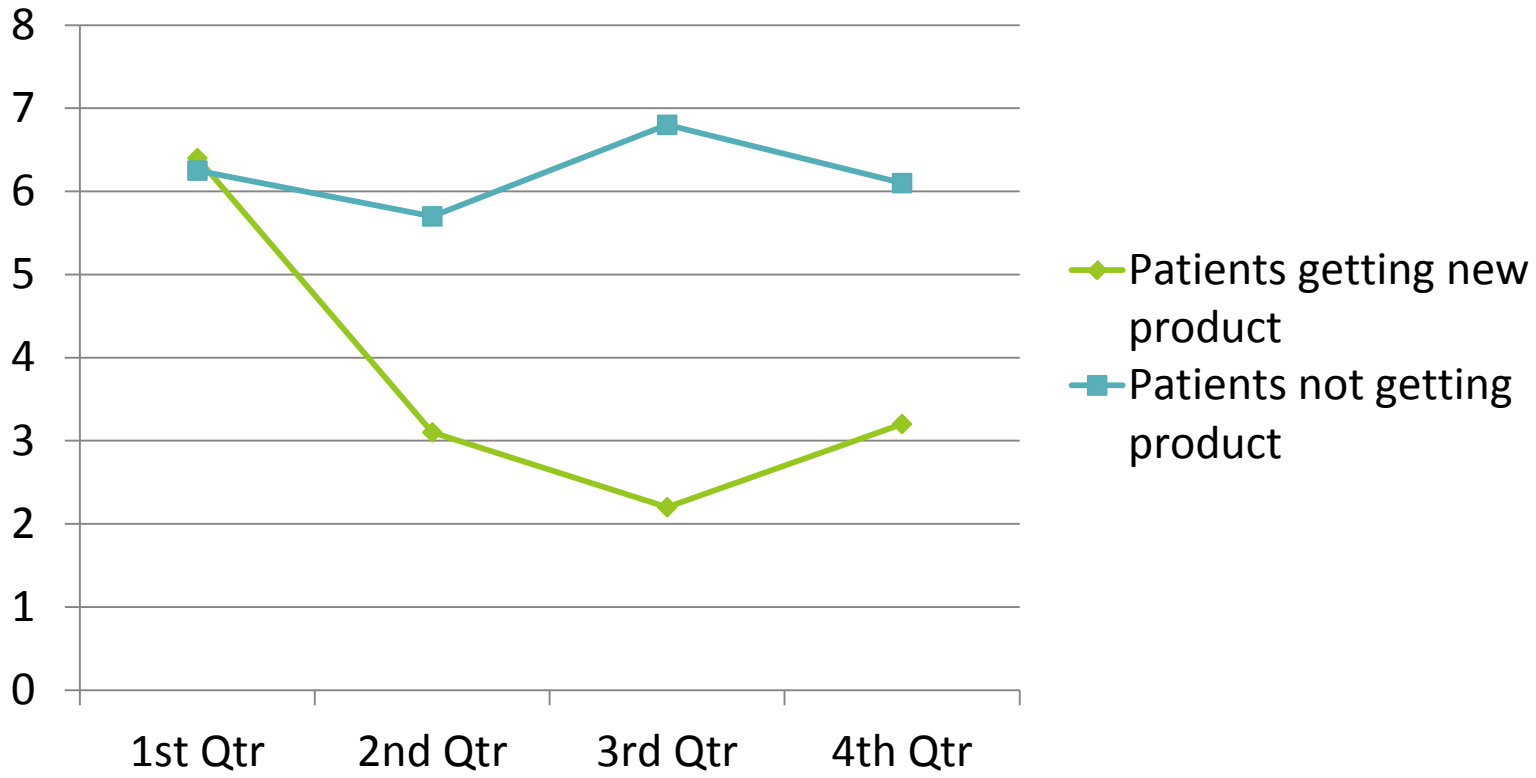
Analysis of randomized controlled trial design

Great Product for CLABSI? Study issues (Example)



Randomized Controlled Trial

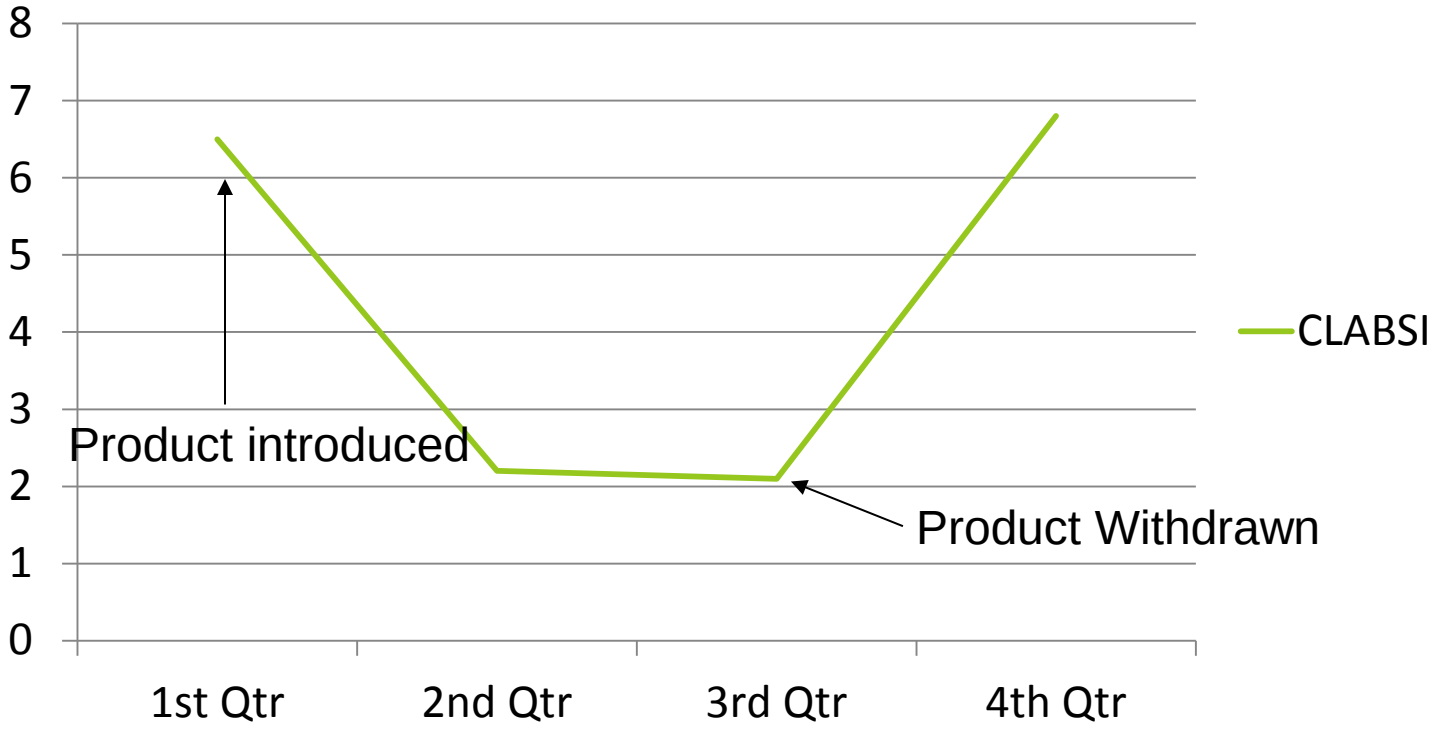
(Example)



Randomized approaches

- Considered Level 1/ Highest Level of Evidence
- Bias is possible in some cases
  - how obvious is the device vs. the control
- Blinded randomized is best
- Was who benefited decided before the trial or afterwards (data mining)
  - Examples:
    - Patients in ICU and with a triple lumen central line with antimicrobial dressing in place over 4 days
    - Trauma patients with a Glasgow Coma score <7 benefited from the product

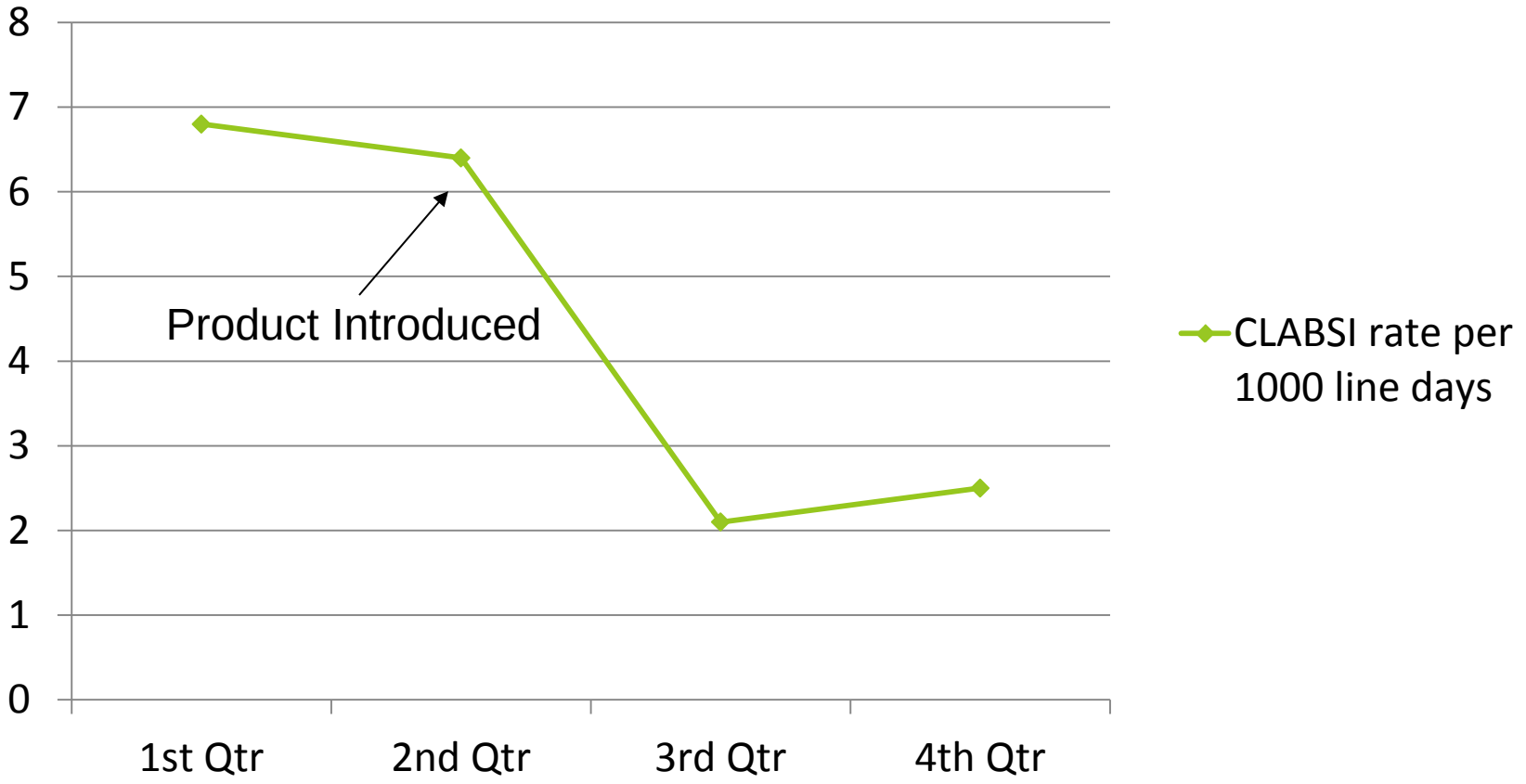
Introduction Withdrawal Trials (Example)



Introduction and Withdrawal Trials

- Only common explanation is seasonal variation or that another event occurred at the same time
- Things to pay attention to
  - What is their baseline rate
  - What was their reduction
    - Given your rate and the reduction found would your institution benefit?
  - What is the number needed to treat for same results to be accomplished in your institution?

Intervention Trials
(Example)



Intervention Trials

- Can be problematic as usually these occur during outbreaks, and more than one intervention is tried simultaneously
- Hawthorne effect
- What happened after the trial? Did rates gradually return to normal?
- Things to pay attention to
  - What is their baseline rate
  - What was their reduction
    - Given your rate and the reduction found would your institution benefit?
  - What is the number needed to treat for same results to be accomplished in your institution?

In Vivo (Example)

Patient #	CFU of bacteria on the hub of Product A	CFU of bacteria on the hub of product Product B
#1	165	202
#2	175	212
#3	185	215
#4	578	225
#5	200	230

- May not correlate with outcomes
  - why are they not showing outcomes?

- Prefer individual results (as shown on previous slide) rather than mean or median results *alone*.
  - If only one value is given median is preferred over mean as mean is susceptible to outliers

  - EXAMPLE:
    - Product A Mean = 260.6 Median = 185
    - Product B Mean = 216.8 Median= 215

In Vivo Proxy Marker

In Vitro Proxy Studies

- Laboratory environment different than clinical environment
  - Outcomes may not be repeatable
- May not correlate with clinical outcomes
- Prefer individual results (as shown on previous slide) rather than mean or median results *alone*.
  - If only one value is given median is preferred over mean as mean is susceptible to outliers

- Repetition of the same data using different methodologies from different sources adds credibility to the data set

Same song, different singers

Product Training

- Attempt to use the device with no training (but not on a patient)
  - Did you use it correctly?
- When the vendor teaches you how to use it, how much time did it take, how intense was it?
- Would all training need to be one on one or would group training work?

If proceeding to a trial

- Develop a trial tool
  - Manufacturer may provide an evaluation tool
    - Pros
    - Cons
  - In the evaluation, measure the thing that is making you think about using the product
  - Measure both:
    - Patient benefits
    - Employee benefits
  - Who will be involved in the trial
    - Complex changes vs. easy change
    - Outside your department if appropriate

- If the change is soley financial, does the cost of the training, the trial and elimination of old stock exceed the claimed savings?

- What looks like good economic sense can be very expensive (Example: buy my identical widget for $3 less per unit)
  - Exclusivity clauses in existing contracts
  - Trial may be needed if new product from current vendor
  - New product may need other products to support it
- Outcomes vs. income in the new CMS environment of Accountable Care
- Cost of product vs. cost avoidance

Remember there is always a cost of doing something

Vendor Partners vs. Sales Reps

When All Things Are Equal *(ie: Indication, Studies, Guidelines) …*

…Vendor Partnerships can make the difference

- Representative and Nurse Educator Program
- Availability and ongoing education
- Follow Up
- Webinars
- Speaker Programs
- Point Prevalence/ Surveillance
- Local Support and involvement with professional organizations (ie: INS, AVA, APIC, ONS, AACN, etc…)

Other Considerations

- Partnering with a company
  - Do their practice survey tool definitions meet yours?
  - Based on guidelines vs. hospital policy?
- Mixed Reviews- Love/ Hate
  - In-service Issues
  - Work Load Issues
  - All other things being equal rely on
    - Outcomes
    - Patient benefit
    - Employee benefit
    - Economic benefit
- Don’t Accept Forced Changes
  - Make your case if patient outcomes are at stake
  - Mixed systems do exist and can provide excellent care for the patient
- Gradual vs. Rapid Roll Out

In Summary

- When evaluating products, choose products that are solution oriented and evidence based to help support the needs of the changing healthcare landscape
- Patient outcomes equal hospital income, and evidence based products can improve patient outcomes
- Evaluation of products should be systematic and well thought out
- Not all data supporting products are equal
- In-servicing and roll out plans for products are important to the success of the outcomes