How to Inaugurate Change to Advance Surgical Site Infection (SSI) Reduction

SSI Symposium VI

Medical College of Wisconsin

September 21, 2018

Russ Nassof, JD

RiskNomics, LLC

Objectives

- Delineate the differences between clinical practice guidelines (CPGs) and evidence-based medicine (EBM) and recognize the importance of using CURRENT best evidence in clinical practice
- Recognize the similarities in off-label usage and EBM and how the two concepts can promote advancement in medical practice, products, and technology
- Initiating improvement in surgical site infection reduction requires an assessment of current practices which can lead to audits to see if/where improvements can be made which meet evidence based criteria even if in conflict with current guidelines
- Understand how using potential monetary penalties/incentives can assist in effectuating improved surgical site infection prevention practice
- Cite specific examples of surgical site infection interventions where evidence based practice may not align with industry guidelines

SSI Reduction- A Worthy Goal

- SSIs
  - Most common and most costly healthcare-associated infection (HAI)*
  - Occur in up to 5% of surgical patients**
  - Patients with SSIs
    - Longer hospital stays
    - 2-5 times more likely to be readmitted***
    - Greater risk of mortality
    - Account for up to $10 billion annually in healthcare costs****

*Anderson D, Podgorny K, et al. Strategies to prevent surgical site infections in acute care hospitals: 2014 update. Infect Control Hosp. Epidemiol. 2014 Jun; 35(6):605-627.

**Cheadle WG, Risk factors for surgical site infection. Surg Infect. 2006;7 Suppl 1:S7-11.

*** Kirkland KB, Briggs JP, Trivette SI, et al. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. Infect Control Hosp Epediol. 1999;20:725-730.

****Scott RD. The Direct Medical Costs of Healthcare-associated Infections in US Hospitals and the Benefits of Prevention. CDC. Atlanta 2009. http://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf.

Clinical Practice Guidelines (CPGs)

- Clinical Practice Guidelines (CPGs)
  - Contemporary Professional Belief
  - **Customary Practice** (i.e. what other similarly situated practitioners are doing)
    - "If its not in the guidelines it shouldn't be done"
    - Failure to perform in accordance with "customary practice" would raise an inference of failure to meet the standard of care
    - Clinician would at least have to explain "why"

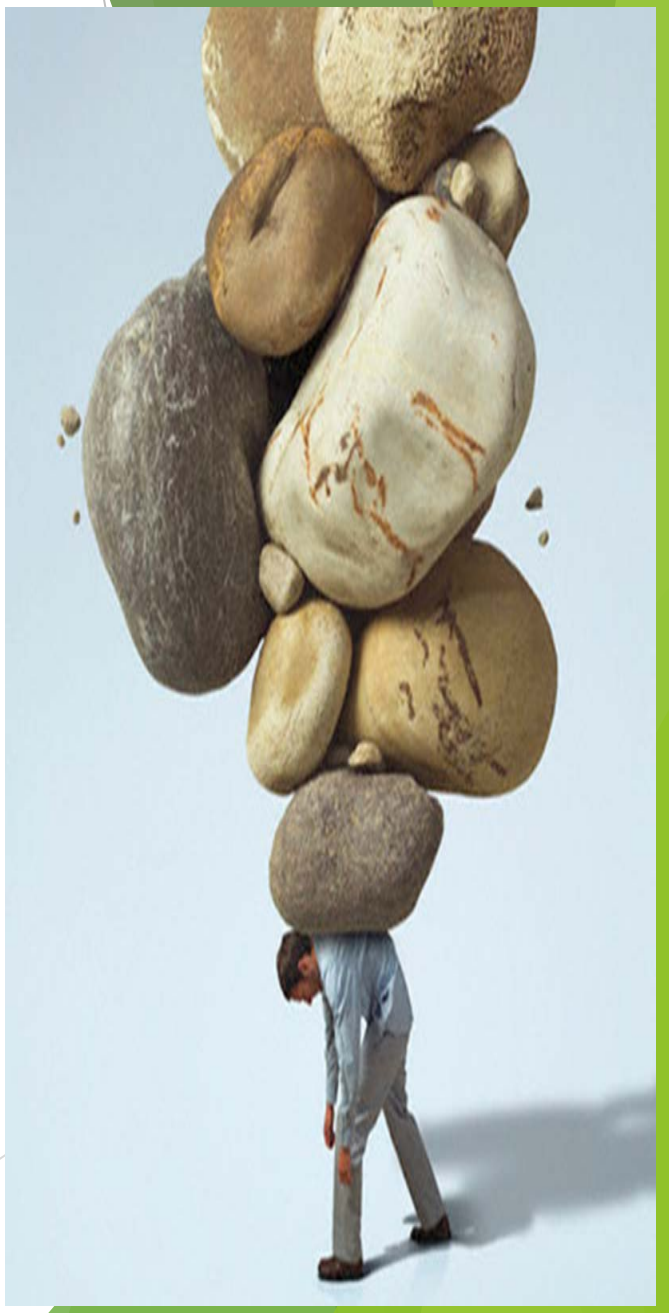
Clinical Practice Guidelines (CPGs)

- The Problem with CPGs
  - Because every patient is like a snowflake…

Customary Practice Does NOT Always Equate To Good Patient Care !

Clinical Practice Guidelines (CPGs)

- The Problem with CPGs
  - May limit innovation, improvements, change… at least until new CPGs gain adherents and form a new standard of care
  - May not necessarily be current
  - May be influenced by the organization drafting the CPGs
  - May NOT always reflect CURRENT BEST EVIDENCE and therefore may not meet the standard of care

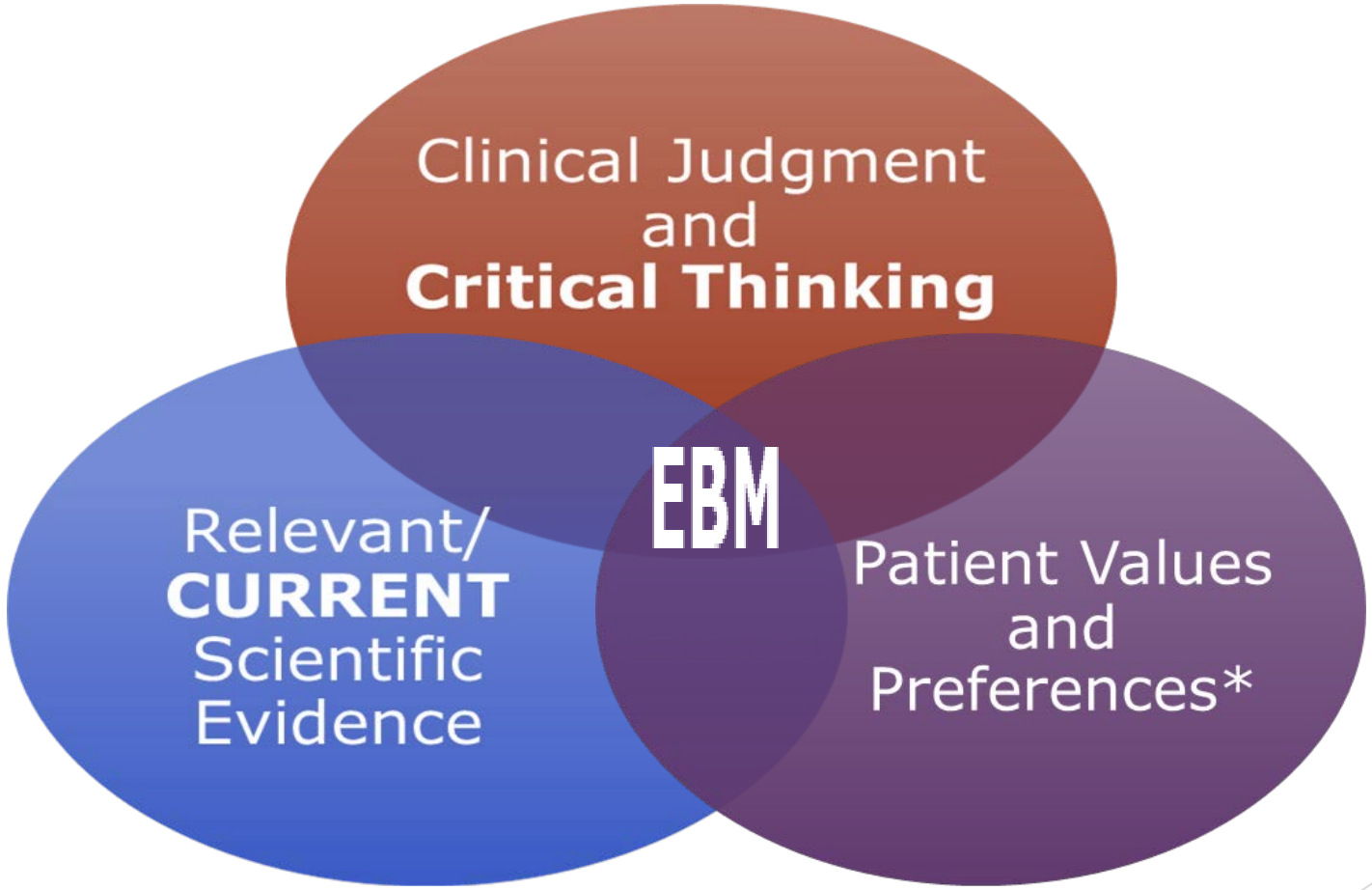


Standard of Care (SOC)

- Standard of Care
  - The caution that a reasonable person in similar circumstances would exercise in providing care
    - You are allowed to be wrong
    - You are allowed to make mistakes
    - You are NOT allowed to be negligent
  - There is also an obligation to stay abreast of new developments
  - **The TJ Hooper (1932)***

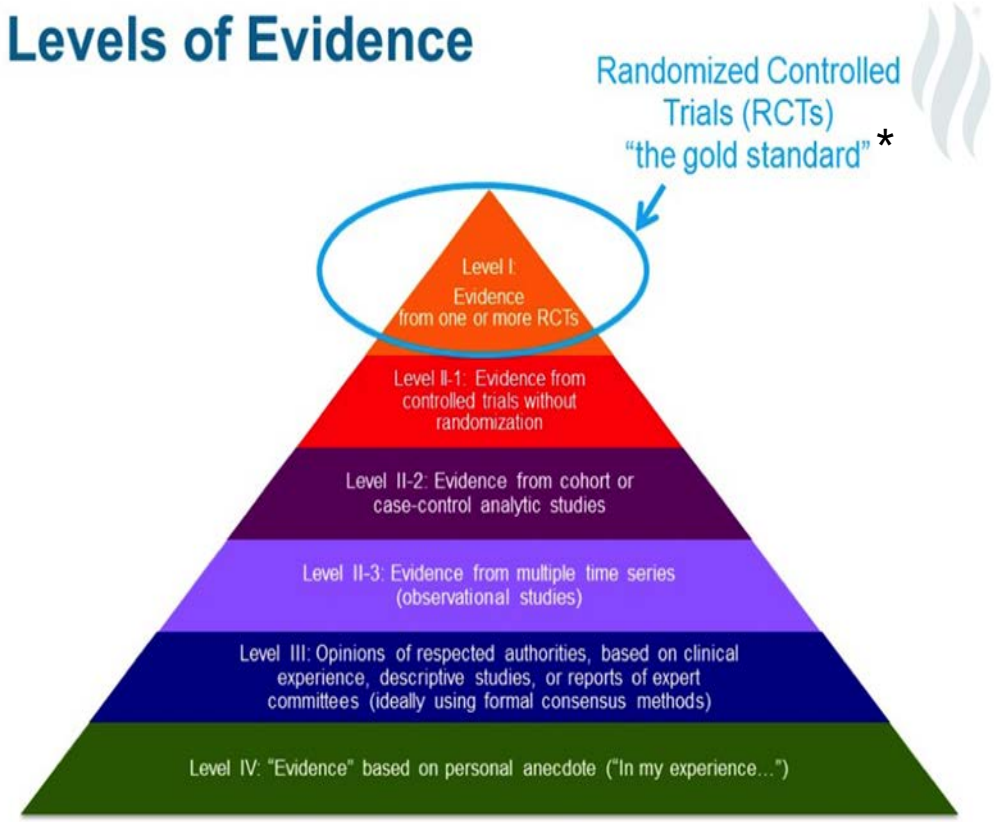
*The TJ Hooper, 60F 2d 737-38, (2d Cir. 1932).

Evidence-based Medicine (EBM)



Sackett DL, Rosenberg W, Gray JA, et al. Evidence Based Medicine: What It Is and What It Isn't. BMJ.1996;312:71-2.

Evidence-based Medicine-EBM



*http://www.bushcenter.org/publications/articles/2013/03/the-randomized-controlled-trial-in-program-evaluations-a-gold-Rush-too-rushed.html.

Evidence-based Medicine (EBM)

- Why Randomized Control Trials (RCTs)?
  - Randomization ensures balance and removes bias*
  - Only expected difference between the control and the experimental group is the outcome variable being studied**
  - Approved for wider use only if the product on trial shows a level of efficacy which is greater than an acceptable level of adverse effects**
  - Look to the number of RCTs, percentage of adverse events, product delivery/composition when evaluating the evidence
  - **Can Reduce Fear of Early Adoption**

*https//www.ncbi.nlm.gov/pmc/articles"PMC3124652

**https://Himmelfarb.gwu.edu/tutorials/studydesign101/rcts.html.

Evidence-based Medicine (EBM)

- Can you inaugurate change without an RCT?
  - **Evidence-based medicine instructs clinicians to rely on current scientific evidence EVEN BEFORE that evidence is regarded as the prevailing custom***
  - **Washington v. Washington Hospital Center (1990)**
    - **If the relevant practice or product was found acceptable by a REPUTABLE SUBSET of the profession it would NOT be regarded as improper EVEN if few clinicians had adopted it at the time****
    - Validates the importance of **small evidence-based studies**

*David L. Sackett et al., Evidence-based Medicine and Clinical Practice Guidelines, 46 Health Policy 1, 1-19 (1998)

**http//archive.ahrq.gov/research/findings/evidence-based-reports/jhppl/rosoff2.html.

**E Monico et al., The Impact of EBM and Evolving Technology on the SOC in Emergency Medicine: The Internet Journal of Law, Healthcare, and Ethics, 2004, vol 3 no. 2. Washington v. Wash Hosp. Ctr., 579 A. 2d 177, 180 (D.C. Cir. 1990)

Evidence-based Medicine-(EBM)

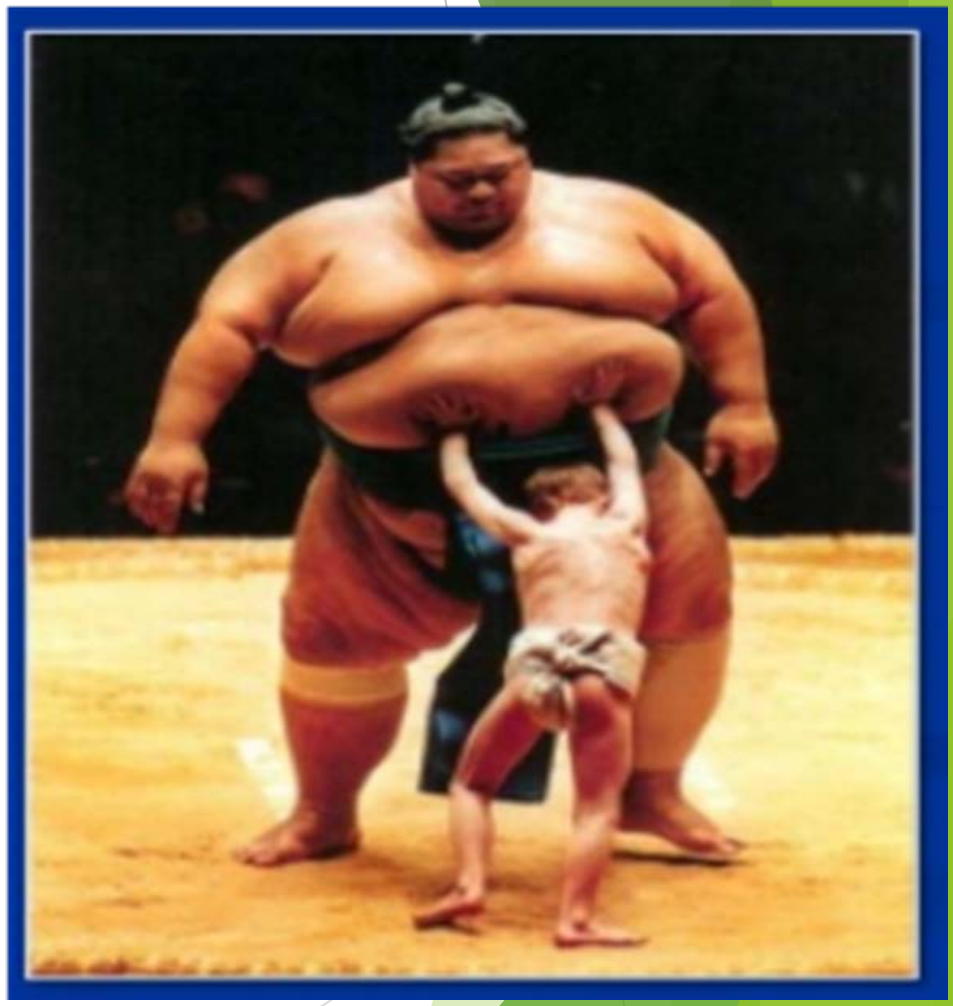
- Early Adoption without an RCT
  - Standards of care are evolutionary and not static and providers have an obligation to stay abreast of new techniques and developments **even before RCTs can be conducted***
    - **Helling v. Carey (1974)****
      - **What is customary may NOT be reasonable**

*Carter L. Williams, Evidence-based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the SOC? 61 Wash & Lee L. Rev., 479, 508-512 (2004)

**Helling v. Carey, 519 P.2d 981, 985 (Wash 1974).

Evidence-based Medicine (EBM)

- What's Stopping Us?
  - Cost
  - Lack of Resources
  - Fear of Being the Canary
  - If it's not in the guidelines… it shouldn't be done
  - **LIABILITY????**



Evidence-based Medicine (EBM)

- Medical Malpractice
  - The failure to adhere to the standard of care (SOC) and negligence results in harm to the patient
  - Malpractice standards change because of changes in technology and NOT changes in law
    - Results in legal ambiguities during times of technology change since it is rarely a smooth process

SSIs and Medical Malpractice

- Medical Malpractice Claims (HACs)
  - Failure to prevent
    - **Up to 60% of SSIs have been estimated to be preventable through adherence to evidence-based guidelines***
  - Failure to promptly and/or properly treat
  - Burden of proof (BOP) on hospital to prove patient protected from harm**

*Meeks DW, Lally KP, Carrick MM, et al., Compliance with guidelines to prevent surgical site infections: as simple as 1-2-3? Am J Surg. 2011;201 (1):76-83

*Umscheid CA, Mitchell MD, Doshi JA, Agarwal R, Williams K, Brennan PJ, Estimating the proportion of healthcare-associated infections that are reasonably preventable and the related mortality and costs. Infect Control Hosp Epidemiol. 2011;32 (2):101-114.

**Cope v. Bro Morgannwg NHS Trust, Klotz v. Shapiro and Metro Heart Group

Off-label Usage

- Off-label Usage
  - FDA makes it clear they **regulate the marketing** of drugs/medical devices **NOT** the prescribing*
  - Gives freedom to MDs and (other learned intermediaries) to apply new therapeutic options based on the latest evidence**
  - Manufacturer of a product/drug has fulfilled their duty of care when they provide all the necessary information to a "learned intermediary" who then interacts with the consumer and makes decision
  - Corollary of the FDA's mission NOT to interfere with the practice of medicine which could stifle improvements/advancements/change

*https://news.uchicago.edu/article/2009/08/21/label-use-oft-not-evidence-based

**Gupta S, Nayak R, Off-Label use of medicine: Perspective of physicians, patients, pharmaceutical companies and regulatory authorities, J. Pharmacol Pharmacother. 2014 Apr-Jun; 5(2):88-92.

Off-label Usage

- Off-label Usage Rationale
  - **Regulations cannot keep up with up-to-date medical practice-allows physicians to anticipate growing level of efficacy prior to formal evaluation***
  - **Patients demand new approaches/treatment particularly for orphan disease/condition, pediatrics, oncology, psychiatry**
  - **Manufacturers cannot include all possible indications due to time and cost constraints**
  - **Physicians may lawfully prescribe approved drugs/devices for any use consistent with available scientific data and proper medical practice****

*https://news.uchicago/edu/article/2009/08/21/label-use-oft-not-evidence-based.

**Gupta S, Nayak R., Off-label use of medicine: Perspective of physicians, patients, pharmaceutical companies and regulatory authorities, J. Pharmacol Pharmacother, 2014 Apr-Jun; 5(2):88-92.

Off-label Usage

- Informed Consent (varies by state law)
  - Disclosure of Off-label use to patient generally NOT required by MD but strongly recommended:
    - Reasonable Patient Standard
    - Reasonable Physician Standard
    - Actual Patient Standard

EBM and Off-label Usage

- Is Off-label Usage Evidence-based?
  - Potential for harm greatest when there is a lack of a solid evidentiary basis
  - Off-label usage may be recognized as the **Standard of Care**
  - Criteria
    - Used in the best interest of the patient without fraudulent intent
    - Urgency of patient's condition
    - Benefit outweighs the risk
    - Nonexperimental use
    - Used successfully by other reputable practitioners in the field (i.e. small evidence based studies sufficient)
    - The greater the peer review… the better

Initiating Change

Assessment

- Defines current reality- the good, bad, and ugly- should paint a picture and review new insights and point in the direction of doing an audit*
- *https://leanlearningcenter.com/blog/tag/assessment/
- **https://en.Wikipedia.org/wiki/Clinical.audit

Audit

- Quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change**

Initiating Change

- The Audit Process
  - Plan
  - Do
  - Study
  - Act
  - Implement

Initiating Change

- Audits can **provide the justification to make changes** which result in improvements
- Less than ideal audit results can **provide direction where you need to refocus** your efforts*

*Ray-Barruel G. (2017a) Using Audits as Evidence, Br J Nurse 26 (8) S3.

Initiating Change

- Performing **audits** based upon evidence-based medicine will identify gaps in practice, process, (i.e. failure to meet the standard of care), products, and people and will highlight variability across the continuum of care.
- Audit results should lead to improvements that may change policy **even if in conflict with CPGs.**

Initiating Change

- **Plan**
  - Step 1- **Setting a goal/purpose**
  - Step 2- **Asking the good question**
  - Step 3- **Building your case (use of small evidence-based studies ok)**
- **Do**
  - Step 4- **Surveillance/assessment**
  - Step 5- **Audit-focus on products, people, practice, and policy**
- **Study**
  - Step 6-**Analysis**
- **Act**
  - Step 7-**What are you going to do with your data?**
- **Implementation (post audit)**

Effectuating Change

- Who?- The Tall Poppy
  - Early adoption of any new medical device, product, practice, technology, etc. carries with it some form of liability (malpractice, negligence) risk but there is still an obligation to stay abreast of new techniques and developments to meet the evidence-based standard of care.

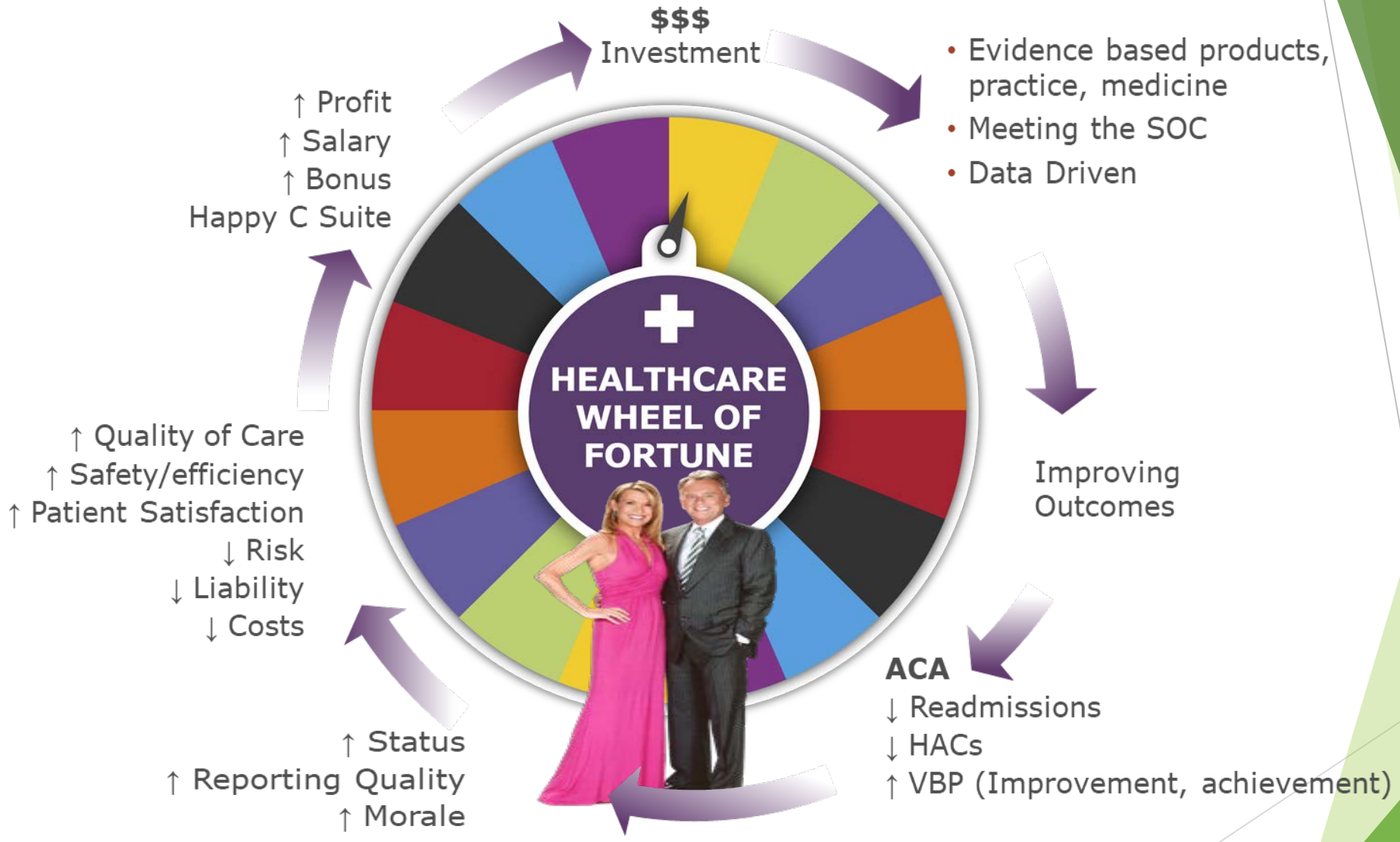
Effectuating Change-Tall Poppy

- Effectuating Change-Becoming an Early Adopter

Alignment?

- Promote evidence-based medicine and raise awareness when standards, policies, and/or practice do not meet evidence-based criteria.
- Just because it is customary **does not mean it is reasonable !**
- **Don't be afraid to use the $$ argument**

Effectuating Change- $$$



Effectuating Change-Follow the $$$

- Fee for Service vs. Pay for Performance
  - 2008- Center for Medicare/Medicaid Services (CMS)- "To encourage hospitals to prevent certain HACs not POA"*
  - Deficit Reduction Act (DRA)- Hospitals will no longer be paid the differential (enhanced payment) when the sole reason for the differential was reasonably preventable through adherence to **evidence-based guidelines****
  - POA conditions become critical

*https//www.fojp.com/sites/default/files/infocusFall10.pdf.

**https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitalacqcond/hospital-acquired_conditions.html.

Effectuating Change-Follow the $$$

- The Affordable Care Act (2010)
  - Fee for Service vs. Pay for Performance
    - Hospital Readmissions Reduction Act
    - Hospital Acquired Conditions (HACs)
    - Hospital Value Based Purchasing
    - Hospital Inpatient Quality Reporting
  - Improving Outcomes/Reducing Costs

Effectuating Change-Follow the $$$

- Hospital Readmission Reduction Program
  - Penalties (up to 3%) on hospitals that have excess readmissions (above the national average) for
    - Cardiac – AMI- heart failure
    - Pulmonary-Pneumonia/COPD
    - **Orthopedic- Total Hip/Knee Arthroplasty**
  - **But you can come back for anything and that is considered a readmission**

Effectuating Change-Follow the $$$

- Hospital Acquired Conditions (HACs)
  - Penalties (1%) on hospitals in the top 25% for the following HACs (among others)
    - **Central venous catheter bloodstream infections**
    - **Postop hip fracture**
    - **Postop sepsis**
    - **Postop pulmonary embolism or DVT**
    - **CAUTI**
    - **SSIs of colon/abdomen/MRSA/*C.difficile***

Effectuating Change-Follow the $$$

HAC Program

Domain 1
(AHRQ Measure)

Weighted 15%

AHRQ Patient Safety Indicators PSI-90 Composite

This measure consists of:

PSI-3: pressure ulcer
PSI-6: iatrogenic pneumothorax
PSI-7: central venous catheter-related blood stream infection rate
PSI-8: hip fracture rate
PSI-12: postoperative PE/DVT rate
PSI-13: sepsis rate
PSI-14: wound dehiscence rate
PSI-15: accidental puncture

Domain 2
(CDC Measure)

Weighted 85%

2015 *(measures):*
CLABSI
CAUTI

2016
Surgical Site Infection (Colon Surgery and Abdominal Hysterectomy)

2017 *(2 additional measures):*
MRSA
C Diff

Association of American Medical Colleges presentation. https://s3.amazonnaws.com/public-inspection, federalregister.gov/2013-18956. Accessed 2/20/16.
www.stratishealth.org/documents/HAC_fact_sheet.pdf. Accessed 2/20/16

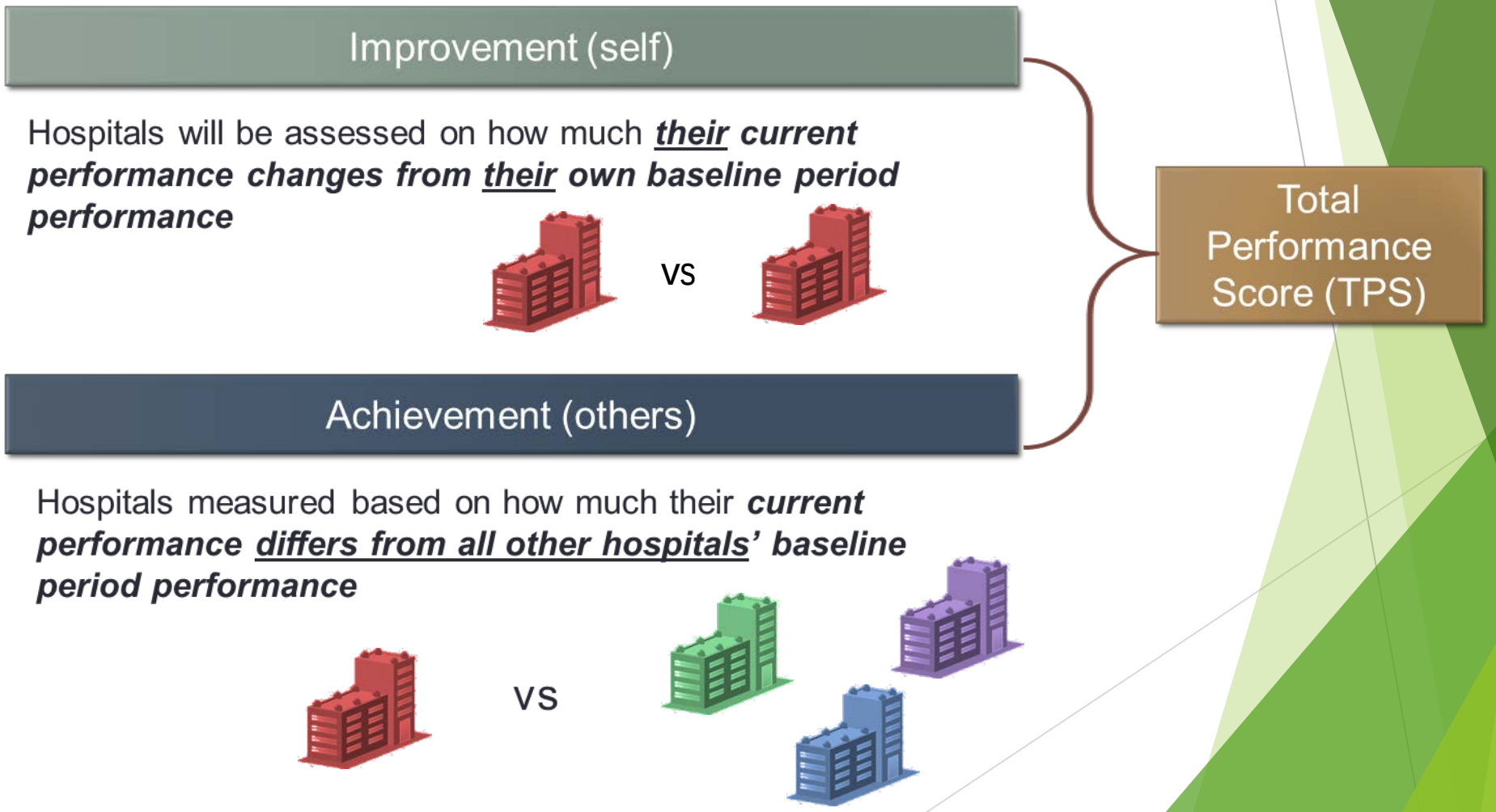
Effectuating Change-Follow the $$$

- Value Based Purchasing (VBP)
  - Penalties/Incentives up to 2%
  - Budget neutral for CMS
  - Hospitals ranked based upon Total Performance Score (TPS) and either win, lose or break even*

*http://www.cms.gov/Medicare/Quality-Incentives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing//

Effectuating Change-Follow the $$$

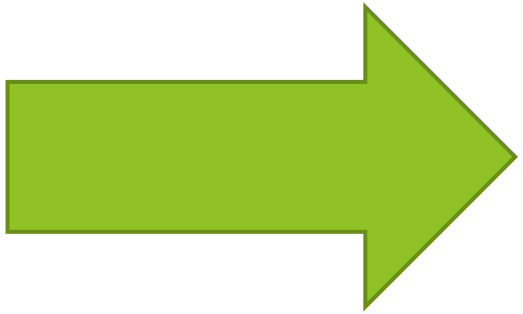
- Value Based Purchasing



Effectuating Change-Follow the $$$

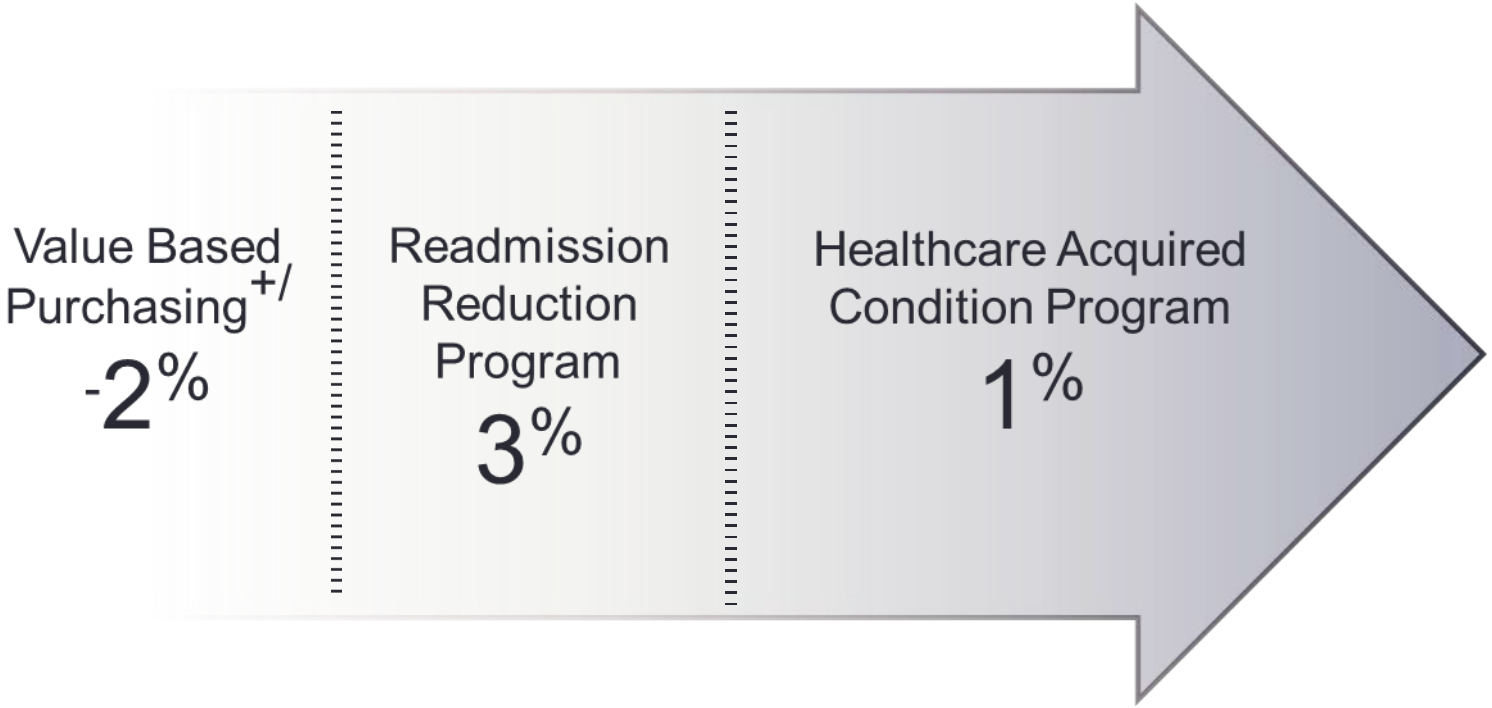
Value Based Purchasing

Domains/Scoring- 2013	Scoring- 2017
Clinical Process- 70%	5%
Patient Satisfaction- 30%	25%
Outcomes- 0%	25%
Safety- 0%	20%
Efficiency- 0%	25%



Effectuating Change-Follow the $$$

- 2017- Percent of $$$ at Risk



6% plus any deductions under the deficit reduction act and other regulations*

*The Advisory Board Company, Healthcare Industry Committee, Hospital Value-Based Purchasing. C-Suite Cheat Sheet Series. August 2013.-accessed 2/20/16
**The Advisory Board Company, Healthcare Industry Committee, Hospital Readmissions Reduction Program. C- Suite Cheat Sheet Series. August 2013.- accessed 2/20/16
***The Advisory Board Company, Healthcare Industry Committee, Hospital-Acquired Condition Reduction Program. C-Suite Cheat Sheet Series. August 2013. Accessed 2/20/16

Effectuating Change-Follow the $$$

- What does 6% Amount To?
  - Readmissions- $161,240
  - VBP- $91,873
  - HACs- $541,896
  - **Total = $795,009 (average)**
  - **Poor performers paid as much as $8,570,333***
  - **All 2015 amounts**

*https://www.ahd.com/state.html. Accessed 2/21/16
The Advisory Board Pay for Performance File-https://www.advisory.com/research/health-care-industry-committee/members/resources/2014/p4p-impact-file. Accessed 2/21/16

Effectuating Change-Follow the $$$

- Hospital Inpatient Quality Reporting
  - Incentive up to 2% for reporting quality of services so as to provide consumers with data to make more informed decisions re care (Hospital Compare)*
  - Includes HAIs including CLABSI, **SSIs,** MRSA, *C. difficile,* CAUTI and other adverse events
  - While there are problems with scoring validity- the numbers impact patient volume, staff morale, prestige, and type of services offered

*https://www/cms/gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalrhqdapu.html. Accessed 2/18/16

** http://www.qualityreportingcenter.com/wp-content/uploads/2015/01/IQR_FY-2016-Reference-Checklist.pdf. Accessed 2/18/16

Becoming a Tall Poppy

- Listen to patients, staff, and educators
  - What are the needs?
  - Where are the gaps?
  - What are the risks?
  - Competency?
- Responding to Adverse Events- sometimes an outbreak can make your case for needed change and/or raise awareness
- Understand and Promote the risks in **FAILING** to **keep current**

Becoming a Tall Poppy Or… What's In Your SSI Bundle?

- Evidence-based Interventions?
  - **Antimicrobial prophylaxis**
  - Weight-based dosing
  - Glycemic control
  - Normothermia
  - Appropriate hair removal
  - Oxygenation (colorectal procedures)
  - **Preoperative skin preparation and shower/skin cleansing with CHG**
  - Smoking cessation
  - **Intraoperative skin antisepsis-CHG cleansing of surgical wound**
  - **Wound closure antimicrobial sutures**
  - Blood and intraarticular corticosteroid injections
  - O.R. Air quality and traffic limitation
  - Keep sterile dressing intact for 48 hours

Becoming a Tall Poppy-Guidelines vs EBM

- Triclosan Coated Sutures (Cat.2)- A Weak Recommendation???? (HICPAC)- **Is there something better???**
  - Clinically shown to be safe in adults and peds.*
  - Effective against Gram-positive/negative bacteria**
  - Studies show Cat.1 clinical evidence in SSI prevention***
  - Recommended by WHO****
  - Use of staples shown to increase risk of wound complication/infections*****
  - Antimicrobial coatings may help us to get to zero SSIs******

*Leaper D, et al. Antimicrobial sutures and prevention of SSI: Assessment of the safety of the antiseptic triclosan. IWJ 2011;8:556-566

*Renko M, et al. Triclosan-containing sutures versus ordinary sutures for reducing SSIs in children: A double-blind, randomized control trial. Lancet Infect Dis. 2016 Sep 19 pii:S1473-3099(16)30373-5.

**Edmiston CE, et al. Clinical and microbiological aspects of biofilm-associated SSIs. Advances in Experimental and Medical Biology 2015;830:47-67.

***Wang ZX et al. Systematic review and meta-analysis of triclosan-coated sutures for the prevention of SSI. Br J Surg 2013;100:465-473

****WHO Global guidelines on the prevention of SSI. http://apps.who.int/iris/bitstream/10665/250680/1/9789241549882-eng.pdf?us=1 (accessed 6/18)

*****Smith TO, et al. Sutures versus staples for skin closure in orthopaedic surgery. BMJ 2010;340:c1199.

******Darouiche R, et al. In vivo efficacy of antimicrobial-coated devices. J Bone Joint Surg 2007;89:792-797.

Becoming a Tall Poppy-Guidelines vs EBM

- Intraoperative irrigation of deep or subcutaneous tissues with aqueous iodophor solution to prevent SSIs (Cat 2)- A Weak Recommendation???? (HICPAC). **Is there something better?**
  - Current studies suggest aqueous .05% CHG is an effective wound irrigation solution to prevent SSIs*
  - RCTs currently underway to assess clinical efficacy of .05% CHG intraoperative irrigation for open laparotomies**
  - CHG exhibits excellent activity against gram-positive and good activity against gram-negative organisms and fungi and has excellent persistent activity***

*Edmiston C, et al. Intraoperative surgical irrigation of the surgical wound: What does the future hold-Saline, antibiotic agents or antiseptic agents? Surg Infect 2016;17:656-664.

**http://www.hret.hiin.org/Resources/ssi/17/20170629_ssi_slides.pdf. (Accessed 6/18).

***Doufas AG. Consequences of inadvertent perioperative hypothermia. Best Pract Res Clin Anaesthesiol 2003;17(4):535-54.

Becoming a Tall Poppy-Guidelines vs. EBM

- Perform intraoperative skin preparation with an alcohol-based antiseptic agent, unless contraindicated (Cat.1A)- A Strong Recommendation **BUT is there something better?**
  - 2% CHG with 70% alcohol- also safe for OBGYN procedures*
  - Some studies have shown CHG with alcohol superior to iodoform-based compounds**
  - Supported by NQF***

*Al-Niaimi A, et al. Safety and tolerability of CHG (2%) as a vaginal preparation in patients undergoing gynecologic surgery. Am J Infect Control 2016 May 24. pii:S0196-6553(16)30007-4. doi:10.1016/j.ajic.2016.02.036

**Darouiche RO, et al. Chlorhexidine-alcohol versus povidone-iodine for surgical-site antisepsis. N Engl J Med 2010;362:18-26.

***Guide to the Elimination of Orthopedic SSIs, APIC, 2010:43.

Becoming a Tall Poppy-Guidelines vs. EBM

- Unresolved issues (HICPAC) surrounding preoperative showers (timing, antiseptic agents used, number of applications, application method, etc.) **What do you do with an unresolved issue?**
  - Standardize procedures/recommendations based upon RCTs or even small evidence-based studies
  - Using 2% CHG coated polyester cloth or washing with 4% aqueous CHG found to result in high residual skin surface concentrations of CHG which could inhibit bacterial skin growth*
    - Need to educate/instruct patient/staff on required regimens ensuring proper procedure, concentration, application, timing

*Edmiston CE, et al. Evidence for a standardized preadmission showering regimen to achieve maximal antiseptic skin surface concentrations of CHG 4% in surgical patients. JAMA Surg 2015;150:1027-1033

*Edmiston CE et al. Preadmission application of 2% CHG: Enhancing patient compliance while maximizing skin surface concentrations. Infect Control Hosp Epidemiol 2016;37:254-259.

Impediments to Implementation

- **Implementation**
  - Things to watch out for:
    - Resource availability/needs
    - Implementation of change should be gradual if possible
    - Must be affordable/attainable
    - Must be consistent/uniform
      - Problem of the alternate site
      - Floating staff

Impediments

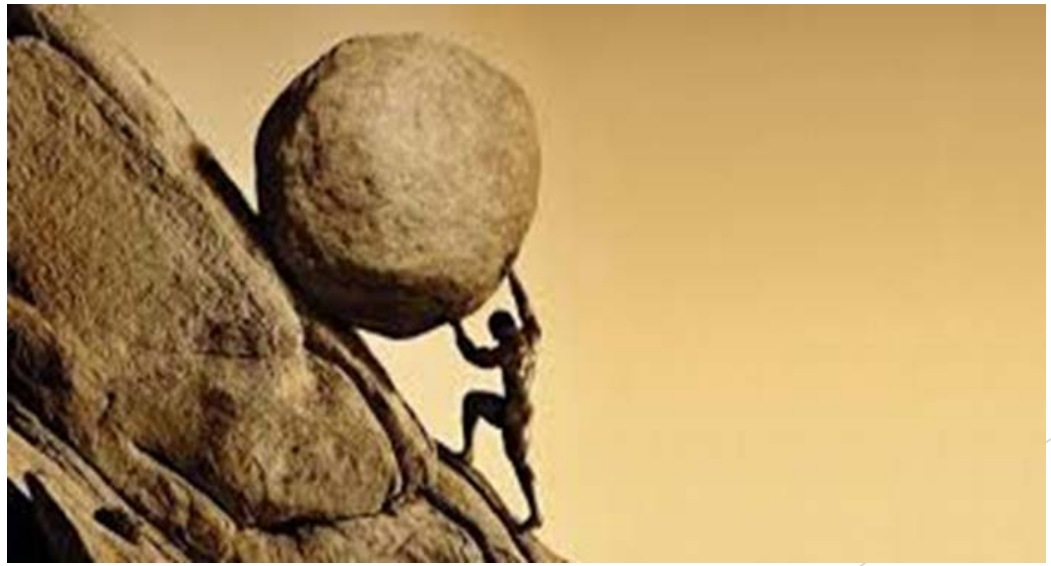
- **Implementation**
  - Things to watch out for:
    - Sustainability
      - Message MUST resonate
      - Message MUST be memorable
      - Message MUST be conveyed by leaders
      - Culture MUST support the message
      - Incentives/Sanctions/Visual Reminders may help

Impediments

- **Implementation**
- **Can You Really Do This???**
  - Resources unavailable to facilitate compliance
  - Lack of competency
  - Lack of administration support
  - Conflicts with current policies
  - Time or $$$
  - Brings new risks to patients
  - Technology requires maintenance that is unavailable
  - Informed consent required but cannot be obtained

Requirements

- **Implementation**
  - **Surveillance should never end**
  - **Must continuously assess to see if/when/where/audits are needed so that improvements can be implemented**



Summary

- To meet the evidence-based standard of care clinicians must stay abreast of new developments even before RCTs can be completed and even if in conflict with CPGs (i.e. should not fear being the “Tall Poppy”)
- Similar to off-label usage, a purpose of EBM is to encourage advancements, improvements and change to improve patient outcomes
- Financial incentives/penalties can be an important mechanism to promote change and meet the evidence-based standard
- Assessments which lead to audits must be performed to identify where/if change is needed and if/what improvements can be made
- Upon assessment completion, clinicians should review their SSI bundles to identify which interventions need to be updated to align with evidence-based practice to improve patient outcomes and reduce costs