Evidence Based Strategies for Effective Skin Antisepsis: An HAI Prevention Approach

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Disclosures

PDI Healthcare

Employee

Objectives

- Discuss the impact of contamination of the skin on the risk for HAI
- Review the FDA's Tentative Final Monograph for skin antiseptics
- Review the evidence-based methods to reducing CLABSI
- Discuss the standard evaluation questions to consider when evaluating skin antiseptics

What do these have in common?

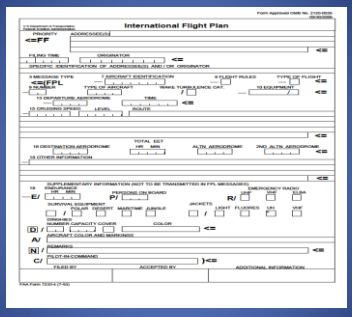
Transportation Security Administration

Self Check

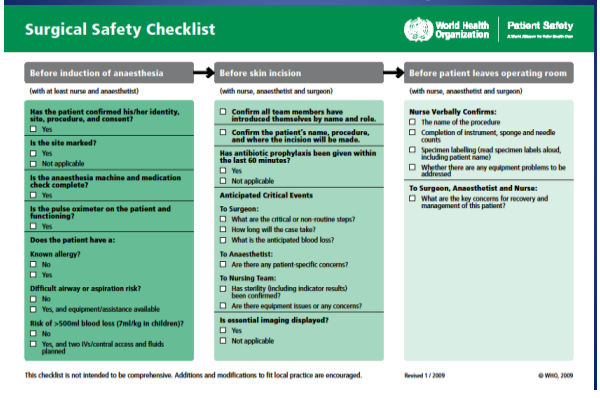
"So with all of the evidence based practices that exist for the prevention of HAIs, why do most healthcare facilities fail to utilize these recommendations approximately 60% of the time?"

Consumers Union

The Importance of a Checklist


International Flight Plan

WHO Checklist for Safer Surgical Care


Surgical Safety Checklist

World Health Organization | Patient Safety

Before induction of anaesthesia (with at least nurse and anaesthetist)

- **Has the patient confirmed his/her identity, site, procedure, and consent?** ☐ Yes
- **Is the site marked?** ☐ Yes ☐ Not applicable
- **Is the anaesthesia machine and medication check complete?** ☐ Yes
- **Is the pulse oximeter on the patient and functioning?** ☐ Yes
- **Does the patient have a:** **Known allergy?** ☐ No ☐ Yes
- **Difficult airway or aspiration risk?** ☐ No ☐ Yes, and equipment/assistance available
- **Risk of >500ml blood loss (7ml/kg in children)?** ☐ No ☐ Yes, and two IVs/central access and fluids planned

Before skin incision (with nurse, anaesthetist and surgeon)

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**
- **Has antibiotic prophylaxis been given within the last 60 minutes?** ☐ Yes ☐ Not applicable
- **Anticipated Critical Events**
  - **To Surgeon:** ☐ What are the critical or non-routine steps? ☐ How long will the case take? ☐ What is the anticipated blood loss?
  - **To Anaesthetist:** ☐ Are there any patient-specific concerns?
  - **To Nursing Team:** ☐ Has sterility (including indicator results) been confirmed? ☐ Are there equipment issues or any concerns?
- **Is essential imaging displayed?** ☐ Yes ☐ Not applicable

Before patient leaves operating room (with nurse, anaesthetist and surgeon)

- **Nurse Verbally Confirms:** ☐ The name of the procedure ☐ Completion of instrument, sponge and needle counts ☐ Specimen labelling (read specimen labels aloud, including patient name) ☐ Whether there are any equipment problems to be addressed
- **To Surgeon, Anaesthetist and Nurse:** ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009 © WHO, 2009

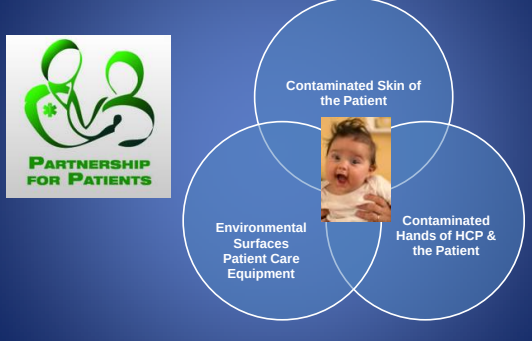
Healthcare-Associated Infections (HAIs)

- **1 out of 25 hospitalized patients affected**
- **Associated with increased mortality**
- **Attributed costs: $26-33 billion annually**
- **HAIs occur in all types of facilities, including:**
  - Long-term care facilities
  - Dialysis facilities
  - Ambulatory surgical centers
  - Hospitals

How do you view life?

How do you view mortality?

How Does Transmission Occur?



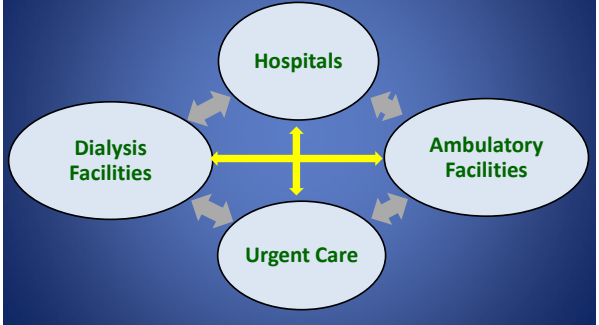
Sources of Evidence

Child Health Corporation of America

Outbreaks vs. Endemic Problems

- ***Endemic problems represent the majority of HAIs***
- **Device-associated infections**
  - Catheter-associated urinary tract infections (CAUTI)
  - Central line-associated Blood stream infections (CLABSI)
  - Ventilator-associated Pneumonia (VAP)
- **Procedure-associated infections**
  - Surgical site infections (SSI)
- **Adherence problems**
  - Antimicrobial stewardship
  - Hand hygiene
  - Isolation precautions

Healthcare has moved beyond hospitals

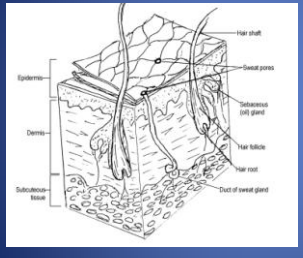


Challenges of Tomorrow

- Decreasing Reimbursement
- Evolving Technological Needs
- Resistant Microbes
- Antimicrobial Resistance
- Higher Acuity
- Staffing
- Transparency
- Public Reporting

Physiology of the Skin

Illustration of Cross-section of Human Skin



- Skin is composed of two layers –epidermis & dermis
- Bacterial flora are on and within the epidermis, hair follicles, sweat & sebaceous glands
- Dermis and subcutaneous tissue are free of microbial flora

Source: Snyder, O. Peter "A Safe Hands Hand Wash Program" Available at; http://www.h-tm.com/Documents/Safehands.html Accessed November 29, 2005.

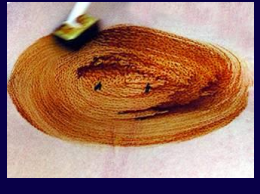
Patient Preoperative Skin Preparation

Label Indication:

- Helps reduce bacteria that potentially cause skin infection.
- For the preparation of the skin prior to surgery.
- For the preparation of the skin prior to injection.

Testing Process:

- Measures immediate and persistent reduction after single treatment.

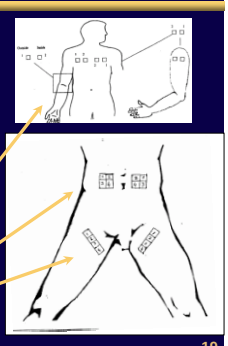


TFM Endpoints:

Bacterial Reduction (log_{10})
1-log CFU / pre-injection
2-log CFU / abdomen (dry site)
3-log CFU / groin (moist site)

Patient Preoperative Skin Preparation Methodology

- Inclusion / Exclusion
- Washout period for 14 days
- No bathing 24 hrs prior to baselines
- Baseline screening counts
  - Pre-injections $\geq 1.0 \times 10^3$
  - Large enough to show
    $\geq$ 2 log for Abdomen (dry site)
    $\geq$ 3 log for Groin (moist site)



Patient Preoperative Skin Preparation (Abdominal Site)

- Application of prep formulation
- Cover area with a sterile gauze pad

Courtesy of Hill Top Research Inc.

Patient Preoperative Skin Preparation

Surgical Scrub	Industry Coalition's Proposal Reduction (log_{10})	FDA TFM Proposal Reduction (log_{10})
Pre-injection	1	1
Abdomen	1 (No persistence criteria)	2 (persistence*)
Groin	2 (No persistence criteria)	3 (persistence*)

* Persistence: prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after product application.

Industry Coalition's Comments

TFM Criteria

- "overly stringent"
- inappropriate in antiseptic products with proven clinical benefit because they cannot meet the current criteria.
  - Monograph: alcohol & iodine
  - NDA: chlorhexidine gluconate
- all antiseptic products only need to be effective after a single use.

Current utilization

- Pre-Operative Skin Antiseptics:
  - Vascular Access
    - PICC Line Insertion
  - Traditional Operating Room
    - Hips, CABG, etc.
  - Cardiac Catheterization
    - Femoral Catheter Insertion
  - Special Procedures
  - Primary Care and Ambulatory Surgery
    - Minor Knee Repairs, Excisions and Biopsies, etc.
  - Site Maintenance
    - Orthopedic Pin Care
  - Dressing Changes

Back to the Basics

- Aseptic Technique is a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens
- Goals of skin antisepsis:
  - Designed to minimize exposure to pathogenic organisms (both intrinsic and extrinsic)
  - Reduce the likelihood of infection
  - Prevent spread of pathogen

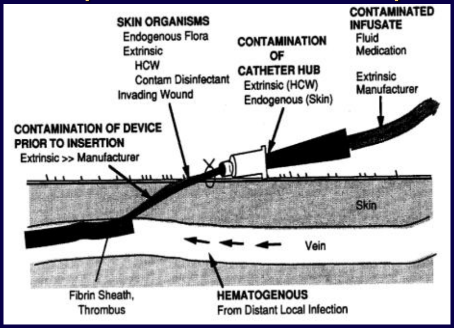
Properties of an *Ideal* Antiseptic

- Broad Spectrum
- Quick
- Ease of Use for Clinician
- Persistence
- Maintain activity in the presence of organic matter
- Non-irritating

2013 AORN Guideline

- Nonscrubbed personnel should apply the skin antiseptic. The risk of contamination to sterile gown and gloves is high, in most circumstances, when scrubbed personnel perform the prep.
- Sterile gloves should be worn unless the antiseptic prep applicator is of sufficient length to prevent the antiseptic and patient's skin from contact with the non-sterile glove

Purpose of Skin Antisepsis



Source: Medscape, www.medscape, electronically accessed 12/2/12.

Potential Risk Factors:

What are the concerns of IPs and Vascular Access Professionals?

Table 1-2.
Intrinsic and Extrinsic Risk Factors for CLABSI

Intrinsic Risk Factors (nonmodifiable characteristics of the patient)	Extrinsic Risk Factors (potentially modifiable factors associated with CVC insertion or maintenance)
Patient's age	Prolonged hospitalization before CVC insertion
Underlying diseases or conditions	Multiple CVCs
Patient's gender	Parenteral nutrition
	Femoral or internal jugular access site
	Heavy microbial colonization at insertion site
	Multilumen CVCs
	Lack of maximal sterile barriers for CVC insertion
	CVC insertion in an ICU or emergency department

Sample Core Questions to Ask

- Is your product FDA registered/approved? If so, what is the FDA registration number?
- Are there any independent studies available supporting the efficacy of your product?
- Is it broad spectrum?
- Is it non-irritating?
- Is it compliant with the CDC EBP?
- What value-adds are available to enhance compliance, improve outcomes, and decrease cost?
- Is it aligned with the healthcare reform outcome measures?

Transient vs. Resident Skin Flora

- Transient flora is found on and within the epidermal layer of the skin.
  -Almost all disease-producing microorganisms belong to this category
  -Is easily removed with proper skin prep and hand hygiene
- Resident flora is found in the dermis of the skin
  -Removal is more difficult

Antimicrobial Log Reduction Explained

- Log reduction in easy terms:
  - 1 $\log_{10}$ = reduced by 90%
    (90% of 100,000 organisms = 90,000 killed, leaves 10,000 on skin)
  - 2 $\log_{10}$ = reduced by 99%
  - 3 $\log_{10}$ = reduced by 99.9%
  - 4 $\log_{10}$ = reduced by 99.99%

Antimicrobial Log Reduction Explained

- Log reduction is the number of organisms reduced by the effect of an antiseptic
- 1 $\log_{10} = 10^1$
- 2 $\log_{10} = 10^2$
- 3 $\log_{10} = 10^3$
- Ex. 100,000 *S. epidermidis* on skin
  - After 1 $\log_{10}$ reduction = 10,000 bacteria left
  - After 2 $\log_{10}$ reduction = 1,000 bacteria left
  - After 3 $\log_{10}$ reduction = 100 bacteria left

FDA regulated antiseptics

- Isopropyl Alcohol
- PVP/Iodine
- PCMX
- Chlorhexidine gluconate

Antiseptic Agents for Skin Preps

Agent	Action	Gram Pos	Gram Neg	MTb	Fungi	Virus	Rapid Action	Resid. Action	Toxic
Alcohol	Denature Protein	Excellent	Excellent	Good	Good	Good	Most Rapid	None	Drying Volatile
CHG	Disrupt Cell Membran	Excellent	Good	Poor	Fair	Good	Intermed	Excellent	Ototoxic Keratitis
Iodine/ PVP	Oxid-ation Sub. Free prot.	Excellent	Good	Good	Good	Good	Intermed	Minimal	Absorb from skin with possible toxic skin reaction

Is it?

- Safe for the Patient
- Safe for the User
- Safe for the Skin
- Safe for the Environment

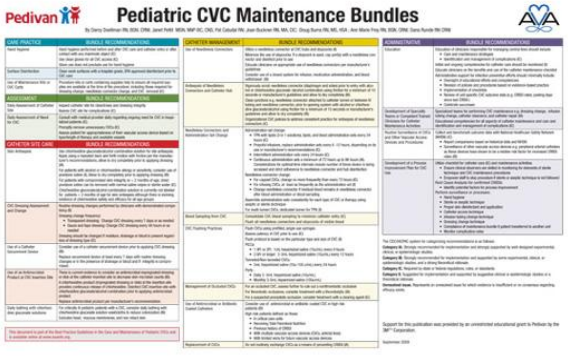
FDA Questions for Skin Antiseptics

- Is the product FDA approved as a skin antiseptic?
- What approvals does the product have? Preinjection or Preoperative?
- What is the wet prep time vs. dry prep time?
- What efficacy claims does the product have?
- Is the product compliant with the CDC Guidelines for Prevention of Intravascular Catheter Related Infections?

Impact of Neonatal CLABSI

- Inherent risk with CVCs
- Difficult to identify and treat
- Prolonged & often frequent exposure to antibiotics
- Major contributor of morbidity and mortality
- Increased length of stay and hospital costs
- Infants are especially vulnerable
- Standardization of Procedures

Holistic Bundled Approach



Pediatric CVC Maintenance Bundles

The Debate of CHG in Neonates

Summary of US Clinical Guidelines for Skin Antisepsis

Organization and Guideline	Skin Antisepsis Recommendations
Centers for Disease Control and Prevention: Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011 www.cdc.gov	Prepare clean skin with a >0.5% chlorhexidine preparation with alcohol before central venous catheter and peripheral arterial catheter insertion and during dressing changes. If there is a contraindication to chlorhexidine, tincture of iodine, an iodophor, or 70% alcohol can be used as alternatives. **Category 1A** Prepare clean skin with an antiseptic (70% alcohol, tincture of iodine, an iodophor or chlorhexidine gluconate) before peripheral venous catheter insertion. **Category IB**
Infusion Nurses Society (INS): Infusion Nursing Standards of Practice, 2011 www.ins1.org	Chlorhexidine solution is preferred for skin antisepsis. One percent to two percent tincture of iodine, iodophor, and 70% alcohol may also be used. Chlorhexidine is not recommended for infants under 2 months of age.
Society for Healthcare Epidemiology of America (SHEA): Strategies to Prevent Central-Line Associated Bloodstream Infections in Acute Care Hospitals www.shea-online.org	Use a chlorhexidine-based antiseptic for skin preparation in patients older than 2 months of age (A-I).43-46; Before catheter insertion, apply an alcoholic chlorhexidine solution containing a concentration of chlorhexidine gluconate greater than 0.5% to the insertion site.
The Joint Commission: 2011 National Patient Safety Goals for Hospitals www.jointcommission.org	Use an antiseptic for skin preparation during central venous catheter insertion that is cited in scientific literature or endorsed by professional organizations.
Infectious Diseases Society of America (IDSA): Clinical Practice Guidelines for the Diagnosis and Management of Intravascular Catheter-Related Infection: 2009 Update by the Infectious Diseases Society of America www.idsociety.org	Skin preparation for obtaining percutaneously drawn blood samples should be performed carefully, with use of either alcohol or tincture of iodine or alcoholic chlorhexidine greater than 0.5% CHG, rather than povidone-iodine;. Skin preparation with either alcohol, alcoholic chlorhexidine (>0.5%), or tincture of iodine (10%) leads to lower blood culture contamination rates than does the use of povidone-iodine.
APIC Guide to the Elimination of Catheter-Related Bloodstream Infections, 2009 www.apic.org	Although a preparation containing a concentration of alcoholic chlorhexidine gluconate greater than 0.5% is preferred, tincture of iodine, an iodophor, or 70% alcohol can be used.
APIC Guide to the Elimination of Infections in Hemodialysis, 2010 www.apic.org	For patients older than 2 months, a skin preparation solution containing greater than 0.5% chlorhexidine gluconate and 70% isopropyl alcohol should be applied to the insertion site and allowed to dry before the skin is punctured.

Summary of US Clinical Guidelines for Port/Hub Cleansing

Organization and Guideline	Port/Hub Cleansing Recommendations
Centers for Disease Control and Prevention: Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011 www.cdc.gov	Minimize contamination risk by scrubbing the access port with an appropriate antiseptic (chlorhexidine, povidone iodine, an iodophor, or 70% alcohol) and accessing the port only with sterile devices. Appropriate disinfectants must be used to prevent transmission of microbes through connectors. Some studies have shown that disinfection of the devices with chlorhexidine/alcohol solutions appears to be most effective in reducing colonization.
Infusion Nurses Society (INS): Infusion Nursing Standards of Practice, 2011 www.ins1.org	The needless connector should be consistently and thoroughly disinfected using alcohol, tincture of iodine, or chlorhexidine gluconate/alcohol combination prior to each access. The optimal technique or disinfection time frame has not been identified.
Society for Healthcare Epidemiology of America (SHEA): Strategies to Prevent Central-Line Associated Bloodstream Infections in Acute Care Hospitals www.shea-online.org	Disinfect catheter hubs, needleless connectors, and injection ports before accessing the catheter (B-II). Before accessing catheter hubs or injection ports, clean them with an alcoholic chlorhexidine preparation or 70% alcohol to reduce contamination
The Joint Commission: 2011 National Patient Safety Goals for Hospitals www.jointcommission.org	Use a standardized protocol to disinfect catheter hubs and injection ports before accessing the ports.
Infectious Diseases Society of America (IDSA): Clinical Practice Guidelines for the Diagnosis and Management of Intravascular Catheter-Related Infection: 2009 Update by the Infectious Diseases Society of America www.idsociety.org	If a blood sample is obtained through a catheter, clean the catheter hub with either alcohol or tincture of iodine or alcoholic chlorhexidine (>0.5%), allowing adequate drying to mitigate blood culture contamination (A-I).
APIC Guide to the Elimination of Infections in Hemodialysis, 2010 www.apic.org	Disinfect IV ports prior to accessing, using friction and 70% alcohol, iodophor, or chlorhexidine/alcohol agent. Allow to dry prior to accessing.

Survey of Neonatal CHG Use

- Survey of Neonatology Fellowship Directors in the United States
- 61% reported use of CHG for skin antisepsis for neonates
  - 51% limited use on basis of birth weight, gestational age or chronological age.
  - Skin reactions (erythema, erosions, burns) occurring primarily in those weighing <1500 grams were reported by 51%.
  - No difference in adverse events between the alcoholic or aqueous CHG preparations

Tamma, Aucott, & Milstone, 2010

FDA Releases New Labeling

"Directions" section of the *Drug Facts* label

Add the following direction (if there is no language currently on the label regarding use in infants) or replace current directions related to use in infants to read:

- Use with care in premature infants or infants under 2 months of age. These products may cause irritation or chemical burns.

What about me?

Can I be offered Hand Hygiene too?

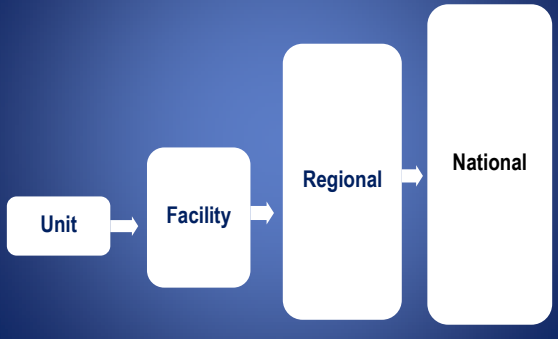
State of prevention knowledge and science

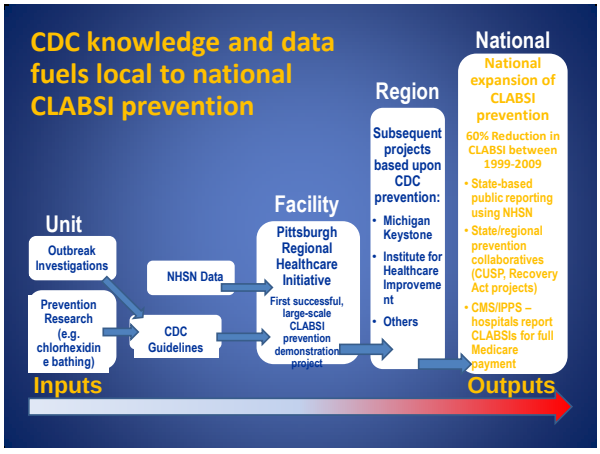
- **Guidelines developed for each type of infection and based on systematic reviews of medical literature**
  - Prevention of central line-associated blood stream infections
  - Prevention of catheter-associated urinary tract infections
  - Prevention of surgical site infections
  - Prevention of healthcare-associated pneumonia
  - Management of multidrug-resistant organisms
- **Recommendations graded according to evidence**
- **Guidelines contain many recommendations**
- **Current efforts to help prioritize interventions that are most effective**

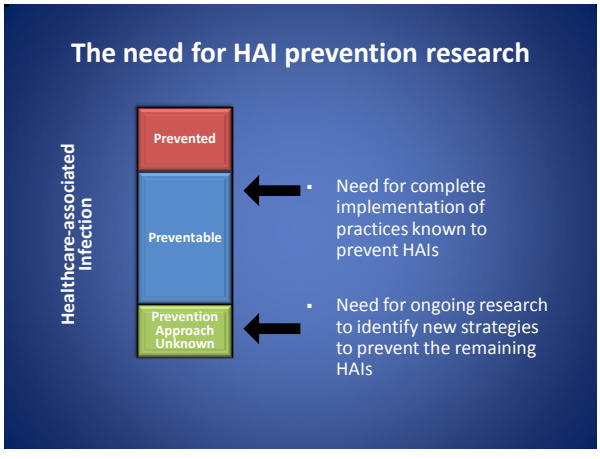
Adherence to infection control guidelines is incomplete

- **Many HAIs are preventable with current recommendations**
- **Failure to use proven interventions is unacceptable**
- **Only 30%-38% of U.S. hospitals are in full compliance**
- **Just 40% of healthcare personnel adhere to hand hygiene**
- **Insufficient infection control infrastructure in non-acute care settings has allowed major lapses in safe care**

Local success fuels national prevention




CDC knowledge and data fuels local to national CLABSI prevention
National
National expansion of CLABSI prevention
60% Reduction in CLABSI between 1999-2009
• State-based public reporting using NHSN
• State/regional prevention collaboratives (CUSP, Recovery Act projects)
• CMS/IPPS – hospitals report CLABSIs for full Medicare payment
Region
Subsequent projects based upon CDC prevention:
• Michigan Keystone
• Institute for Healthcare Improvement
• Others
Facility
Pittsburgh Regional Healthcare Initiative
First successful, large-scale CLABSI prevention demonstration project
Unit
Outbreak Investigations
Prevention Research (e.g. chlorhexidine bathing)
NHSN Data
CDC Guidelines
Inputs
Outputs


The need for HAI prevention research
Healthcare-associated Infection
Prevented
Preventable
Prevention Approach Unknown
Need for complete implementation of practices known to prevent HAIs
Need for ongoing research to identify new strategies to prevent the remaining HAIs


Formula for Success
GOAL: ZERO HEALTHCARE ASSOCIATED INFECTIONS
Healthcare Professionals
Evidence-Based Practices Implementation
Infection Prevention
INFECTION PREVENTION
IT'S IN YOUR HANDS

Prevention

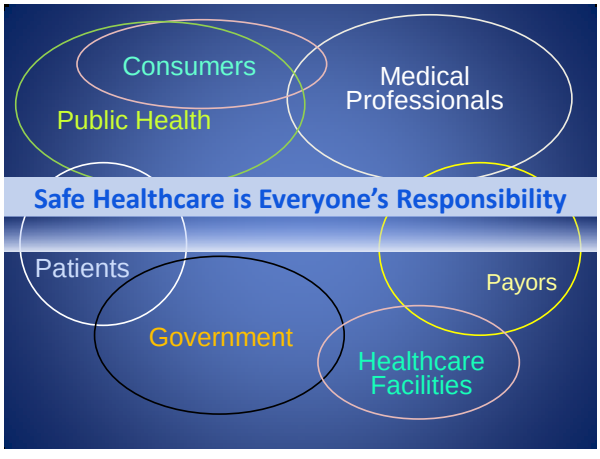
Hand hygiene

No touch technique

Skin antisepsis

Dressing

Injection cap/needleless connector



Hypothetical ?

- If you knew……
- That you could do something simple, easy, cost effective, and that was
- Evidence-Based, but took a little extra time…..
- Would you do it????? If it saved a life…..

Questions

- How will you approach Infection Prevention differently within your own practice setting?

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