



The Regulatory Aspects of Infection
Prevention and Control

J. Hudson Garrett Jr., PhD, MSN, MPH, FNP-BC, PLNC, CDONA, VA-BC, FACDONA

NADONA Infection Prevention and Control
Webinar Series





PRESENTS ...

The Regulatory Aspects of
Infection Prevention and Control

1 Contact Hour


*Participants must complete entire activity. No partial credit will be awarded
Participants must submit a post event evaluation form
There is no conflict of interest for any planner or presenter*

*This continuing nursing education activity was approved by the
Montana Nurses Association, an accredited approver by the
American Nurses Credentialing Center's Commission on Accreditation*

Objectives

- Discuss the role of the Food and Drug Administration and the Environmental Protection Agency in the usage of infection control products
- Review the current regulatory classification of healthcare disinfectants, skin antiseptics, and hand hygiene products
- Discuss the appropriate steps to evaluate infection prevention and control products


NADONA Infection Prevention and Control
Webinar Series



Just in the last 6 Months...

- Measles
- Ebola Virus Disease
- Enterovirus
- Influenza
- CRE
- Shigella
- Zika Virus

NADONA Infection Prevention and Control
Webinar Series



Safe Injection Practices



www.ONEandONLYcampaign.org



NADONA Infection Prevention and Control
Webinar Series





MENINGITIS OUTBREAK

284 Cases
23 Deaths



NADONA Infection Prevention and Control
Webinar Series



CDC Estimates of HAI's

722,000 estimates HAI's in the US healthcare system in the acute care population

75,000 deaths from HAI's in hospitalized patients

½ of HAI's are now occurring outside of the traditional ICU setting

1 in 25 hospitalized patients contract an HAI

NADONA Infection Prevention and Control Webinar Series

Table 2. Distribution of 504 Health Care–Associated Infections.*

Type of Infection	Rank	No. of Infections	Percentage of All Health Care–Associated Infections (95% CI)
Pneumonia†	1 (tie)	110	21.8 (18.4–25.6)
Surgical-site infection	1 (tie)	110	21.8 (18.4–25.6)
Gastrointestinal infection	3	86	17.1 (14.0–20.5)
Urinary tract infection‡	4	65	12.9 (10.2–16.0)
Primary bloodstream infection§	5	50	9.9 (7.5–12.8)
Eye, ear, nose, throat, or mouth infection	6	28	5.6 (3.8–7.8)
Lower respiratory tract infection	7	20	4.0 (2.5–6.0)
Skin and soft-tissue infection	8	16	3.2 (1.9–5.0)
Cardiovascular system infection	9	6	1.2 (0.5–2.5)
Bone and joint infection	10	5	1.0 (0.4–2.2)
Central nervous system infection	11	4	0.8 (0.3–1.9)
Reproductive tract infection	12	3	0.6 (0.2–1.6)
Systemic infection	13	1	0.2 (0.01–1.0)

* Infections were defined with the use of National Healthcare Safety Network criteria. CI denotes confidence interval.
 † A total of 43 pneumonia events (39.1%) were associated with a mechanical ventilator.
 ‡ A total of 44 urinary tract infections (67.7%) were associated with a catheter.
 § A total of 42 primary bloodstream infections (84.0%) were associated with a central catheter.

Table 3. Reported Causative Pathogens, According to Type of Infection.*

Pathogen	All Health Care–Associated Infections (N=504)†		Pneumonia (N=110)	Surgical-Site Infections (N=110)	GI Infections (N=86)	UTIs (N=65)	Bloodstream Infections (N=50)
	no. (%)	rank					
<i>Clostridium difficile</i>	61 (12.1)	1	0	0	61 (70.9)	0	0
<i>Staphylococcus aureus</i>	54 (10.7)	2	18 (16.4)	17 (15.5)	1 (1.2)	2 (3.1)	7 (14.0)
<i>Klebsiella pneumoniae</i> or <i>K. oxytoca</i>	50 (9.9)	3	13 (11.8)	15 (13.6)	1 (1.2)	15 (23.1)	4 (8.0)
<i>Escherichia coli</i>	47 (9.3)	4	3 (2.7)	14 (12.7)	1 (1.2)	18 (27.7)	5 (10.0)
Enterococcus species‡	44 (8.7)	5	2 (1.8)	16 (14.5)	5 (5.8)	11 (16.9)	6 (12.0)
<i>Pseudomonas aeruginosa</i>	36 (7.1)	6	14 (12.7)	7 (6.4)	1 (1.2)	7 (10.8)	2 (4.0)
Candida species§	32 (6.3)	7	4 (3.6)	3 (2.7)	3 (3.5)	3 (4.6)	11 (22.0)
Streptococcus species¶	25 (5.0)	8	7 (6.4)	8 (7.3)	2 (2.3)	2 (3.1)	2 (4.0)
Coagulase-negative staphylococcus species	24 (4.8)	9	0	7 (6.4)	0	1 (1.5)	9 (18.0)
Enterobacter species	16 (3.2)	10	3 (2.7)	5 (4.5)	0	2 (3.1)	2 (4.0)
<i>Acinetobacter baumannii</i>	8 (1.6)	11, tie	4 (3.6)	2 (1.8)	0	0	0
<i>Proteus mirabilis</i>	8 (1.6)	11, tie	1 (0.9)	5 (4.5)	0	1 (1.5)	0
Yeast, unspecified	8 (1.6)	11, tie	3 (2.7)	0	1 (1.2)	4 (6.2)	0
<i>Stenotrophomonas maltophilia</i>	8 (1.6)	11, tie	0 (0.0)	0	0	2 (3.1)	0
Citrobacter species	6 (1.2)	15, tie	2 (1.8)	1 (0.9)	0	1 (1.5)	0
Serratia species	6 (1.2)	15, tie	2 (1.8)	0	0	2 (3.1)	0
Bacteroides species	6 (1.2)	15, tie	0	5 (4.5)	1 (1.2)	0	0
<i>Haemophilus</i> species	6 (1.2)	15, tie	2 (1.8)	2 (1.8)	0	0	0
Viruses	3 (0.6)	19, tie	1 (0.9)	0	0	0	0
Peptostreptococcus species	3 (0.6)	19, tie	0	2 (1.8)	0	0	1 (2.0)
<i>Klebsiella</i> species other than <i>K. pneumoniae</i> and <i>K. oxytoca</i>	2 (0.4)	21, tie	1 (0.9)	0	0	0	1 (2.0)
<i>Clostridium</i> species other than <i>C. difficile</i>	2 (0.4)	21, tie	0	2 (1.8)	0	0	0
<i>Prevotella</i> species	2 (0.4)	21, tie	0	1 (0.9)	0	0	0
<i>Morganella morganii</i>	2 (0.4)	21, tie	0	1 (0.9)	0	1 (1.5)	0
<i>Lactobacillus</i> species	2 (0.4)	21, tie	0	0	1 (1.2)	0	1 (2.0)
Other organisms**	13 (2.6)	—	1 (0.9)	6 (5.5)	0	1 (1.5)	3 (6.0)

The Future of Healthcare Delivery

Image Courtesy: Institute for Healthcare Improvement

NADONA Infection Prevention and Control
Webinar Series

How Does Transmission Occur?

NADONA Infection Prevention and Control
Webinar Series

The Science of Safety

Image Courtesy: National Patient Safety Foundation

NADONA Infection Prevention and Control
Webinar Series

Applied to CLABSI

The diagram illustrates the path of infection for CLABSI. It shows a sequence of events: 1. Extrinsic Sources (e.g., healthcare workers, contaminated equipment) leading to 2. Contaminated Infusate (fluid in the infusion set), 3. An Invading Wound, 4. Extrinsic Contamination (e.g., a catheter with a breach), and 5. Endogenous Flora (e.g., skin flora) entering the bloodstream. A red arrow indicates the path of infection leading to a Bloodstream Infection.

Image Courtesy: PDI, Inc.

NADONA Infection Prevention and Control
Webinar Series

What do these have in common?

The slide features four images: the TSA logo, an airplane in flight, a nurse in blue scrubs, and a patient lying in a hospital bed with medical equipment.

NADONA Infection Prevention and Control
Webinar Series

The Importance of a Checklist

The image shows a standard 'International Flight Plan' form, which is a checklist used by pilots to ensure all necessary information is recorded before a flight. It includes sections for flight details, crew, aircraft, and other operational information.

NADONA Infection Prevention and Control
Webinar Series

Checklists for Safer Care

Surgical Safety Checklist

Patient Safety

Before induction of anaesthesia <small>(with at least nurse and anaesthetist)</small>	Before skin incision <small>(with nurse, anaesthetist and surgeon)</small>	Before patient leaves operating room <small>(with nurse, anaesthetist and surgeon)</small>
<p>Has the patient confirmed his/her identity, site, procedure, and consent?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<p>Confirm all team members have introduced themselves by name and role.</p> <input type="checkbox"/> Confirmed <input type="checkbox"/> Not applicable	<p>Nurse Verbally Confirms:</p> <input type="checkbox"/> The name of the procedure <input type="checkbox"/> Completion of instrument, sponge and needle counts <input type="checkbox"/> Specimen labelling (and specimen labels placed, including patient name) <input type="checkbox"/> Whether there are any equipment problems to be addressed
<p>Is the site marked?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<p>Has antibiotic prophylaxis been given within the last 60 minutes?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	<p>To Surgeon, Anaesthetist and Nurse:</p> <input type="checkbox"/> What are the key concerns for recovery and management of this patient?
<p>Is the anaesthetic machine and medication check complete?</p> <input type="checkbox"/> Yes	<p>Anticipated Critical Events</p> <p>To Surgeon:</p> <input type="checkbox"/> What are the critical or non-routine steps? <input type="checkbox"/> How long will the case take? <input type="checkbox"/> What is the anticipated blood loss?	
<p>Is the pulse oximeter on the patient and functioning?</p> <input type="checkbox"/> Yes	<p>To Anaesthetist:</p> <input type="checkbox"/> Are there any patient-specific concerns?	
<p>Does the patient have a:</p> <p>Known allergy?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes	<p>To Nursing Team:</p> <input type="checkbox"/> Has sterility (including indicator results) been confirmed? <input type="checkbox"/> Are there equipment issues or any concerns?	
<p>Is there an airway or aspiration risk?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes, and equipment/assistance available	<p>Is essential imaging displayed?</p> <input type="checkbox"/> Yes <input type="checkbox"/> Not applicable	
<p>Risk of >500ml blood loss (Fasting in children)?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes, and two Multicentral access and fluids planned		

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. Revised 1/2009 © WHO, 2009

Emerging Outbreak: CRE


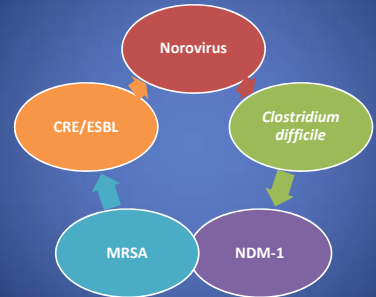


Image Courtesy: US Centers for Disease Control and Prevention

NADONA Infection Prevention and Control Webinar Series

Pathogens of Particular Concern



NADONA Infection Prevention and Control Webinar Series

Learn From The Past Prepare for the Future

Prevention of Transmission

Prevention of the Pathogen

NADONA Infection Prevention and Control
Webinar Series

What is the Ideal?

NO GERM ZONE

NADONA Infection Prevention and Control
Webinar Series

How do you view mortality?

NADONA Infection Prevention and Control
Webinar Series

FDA vs. EPA


FDA:

- OTC Drugs:
 - Skin Antiseptics
 - NDA or TFM
- Rx Drug
- High Level Disinfectants/Sterilants

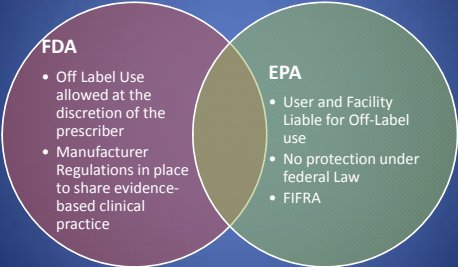
EPA

- Pesticides:
 - Healthcare Grade Disinfectants:
 - Low Level Disinfectants
 - Intermediate Level Disinfectants

NADONA Infection Prevention and Control
Webinar Series



Off Label Guidance by Federal Agencies




FDA

- Off Label Use allowed at the discretion of the prescriber
- Manufacturer Regulations in place to share evidence-based clinical practice


EPA

- User and Facility Liable for Off-Label use
- No protection under federal Law
- FIFRA

NADONA Infection Prevention and Control
Webinar Series




Pathogens of Significance



The Killers

- Yeasts
- ESBL
- Klebsiella
- MRSA
- E. Coli
- NDM-1
- CRE
- GNR


NADONA Infection Prevention and Control
Webinar Series



Sample Core Questions to Ask

- Is the disinfectant EPA or FDA registered/approved? If so, what is the EPA/FDA registration number?
- Does the team receive advanced training on the proper use of this product?
- Are there any independent studies available supporting the efficacy of the disinfectant?
- Is there a clinical support team if I have a medical question?
- What value-adds are available to enhance compliance, improve outcomes, and decrease cost?


NADONA Infection Prevention and Control
Webinar Series



Healthcare Grade Disinfectants

- All disinfectants used in the US MUST be EPA-registered
- In healthcare settings, use a healthcare grade disinfectant
- Do not use sanitizers in healthcare settings

NADONA Infection Prevention and Control
Webinar Series

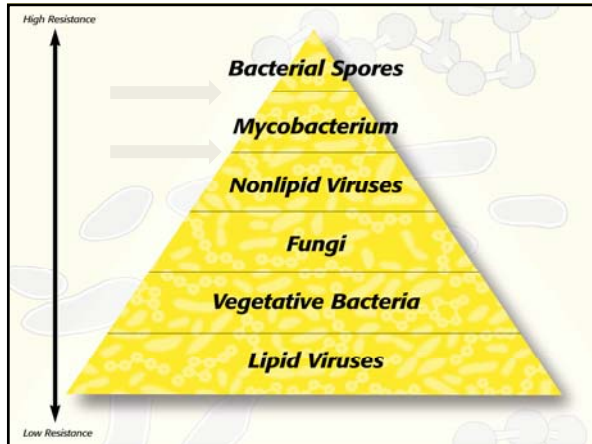


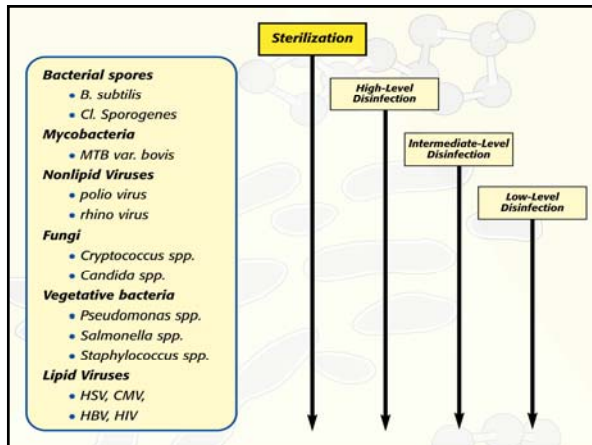
Levels of Sterilization/Disinfection Product Approval



NADONA Infection Prevention and Control
Webinar Series







All about Terminology

Critical Items (e.g., surgical instruments) are objects that enter sterile tissue or the vascular system and must be sterile prior to use.

Semi-critical items (e.g., endoscopes used for upper endoscopy and colonoscopy) contact mucous membranes or non-intact skin and require, at a minimum, high-level disinfection prior to reuse.

Noncritical items (e.g., blood pressure cuffs) are those that may come in contact with intact skin but not mucous membranes and should undergo low- or intermediate-level disinfection depending on the nature and degree of contamination.

Environmental surfaces (e.g., floors, walls) are those that generally do not contact the patient during delivery of care. Cleaning may be all that is needed for the management of these surfaces but if disinfection is indicated, low-level disinfection is appropriate.

NADONA Infection Prevention and Control
Webinar Series

Key Disinfection Recommendations for Environmental Surfaces

- Establish policies and procedures for routine cleaning and disinfection of environmental surfaces
 - Focus on those surfaces in proximity to the patient and those that are frequently touched
- Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare
- Follow manufacturer’s recommendations for use of cleaners and EPA-registered disinfectants (e.g., amount, dilution, contact time, safe use, and disposal)
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

NADONA Infection Prevention and Control
Webinar Series



Key Components for Evaluation of Environment of Care Disinfectants



NADONA Infection Prevention and Control
Webinar Series



Key Recommendations for Disinfection and Sterilization of Medical Equipment

Facilities should ensure that reusable medical equipment (e.g., blood glucose meters and other point-of-care devices, surgical instruments, endoscopes) is cleaned and reprocessed appropriately prior to use on another patient

Reusable medical equipment must be cleaned and reprocessed (disinfection or sterilization) and maintained according to the manufacturer’s instructions. If the manufacturer does not provide such instructions, the device may not be suitable for multi-patient use

Assign responsibilities for reprocessing of medical equipment to HCP with appropriate training

- Maintain copies of the manufacturer’s instructions for reprocessing of equipment in use at the facility, post instructions at locations where reprocessing is performed
- Observe procedures to document competencies of HCP responsible for equipment reprocessing upon assignment of those duties, whenever new equipment is introduced, and on an ongoing periodic basis (e.g., quarterly)

Assure HCP have access to and wear appropriate PPE when handling and reprocessing contaminated patient equipment

NADONA Infection Prevention and Control
Webinar Series



Total Contact Time


Contact Times:

- Bacteria
- Viruses
- TB
- Fungi
- Spores

Clinicians should follow the US EPA FIFRA standards, and all applicable user instructions

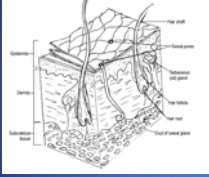
Total Contact Time is the longest contact time required

NADONA Infection Prevention and Control
Webinar Series



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.cdc.gov/hand/handwash/](#) Accessed November 29, 2005.

NADONA Infection Prevention and Control
Webinar Series



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

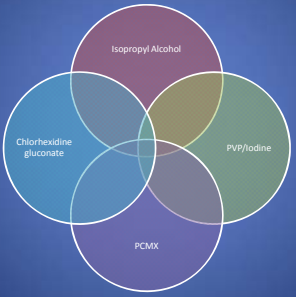
Resident flora is found in the dermis of the skin

- -Removal is more difficult


NADONA Infection Prevention and Control
Webinar Series



FDA regulated antiseptics



NADONA Infection Prevention and Control
Webinar Series



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.

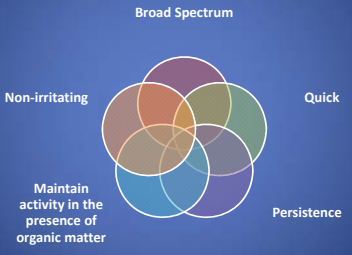
TFM Endpoints:

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


NADONA Infection Prevention and Control
Webinar Series

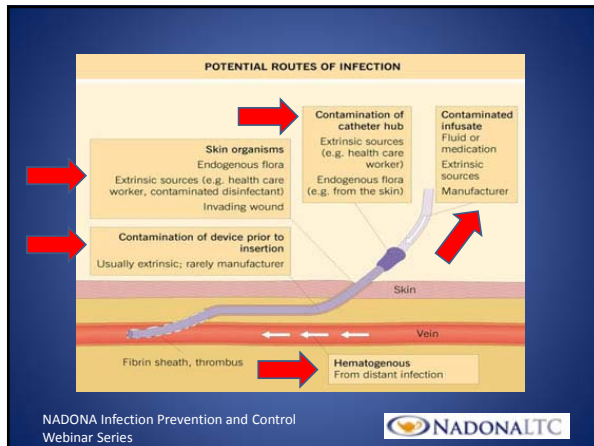


Properties of an *Ideal* Antiseptic



NADONA Infection Prevention and Control
Webinar Series

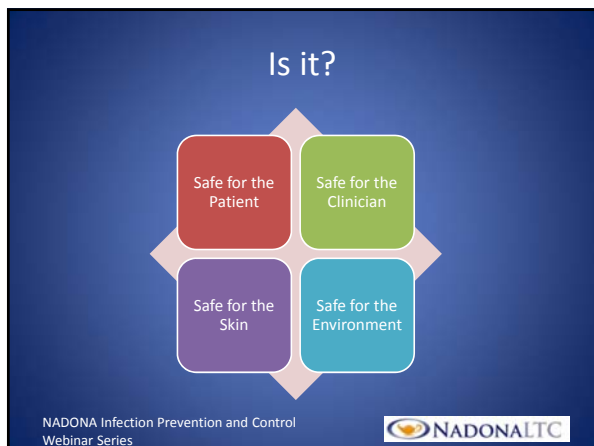




FDA Questions for Skin Antiseptics

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

NADONA Infection Prevention and Control
Webinar Series



Where do you even begin?

NADONA Infection Prevention and Control
Webinar Series

Evidence-Based Medicine

- 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

NADONA Infection Prevention and Control
Webinar Series

Opportunities for Improvement and Reform


- 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

NADONA Infection Prevention and Control
Webinar Series

Resolve the Process, Not Bring in Another Product

- Most lapses in Infection Prevention and Control Practices are not related to products, but rather related to systems and practice violations
- These practice lapses are opportunities for improvement and the system must be designed to be high reliability and sustainable
- It is important to address underlying practice related issues prior to implementation of any products
- Most infection prevention and control challenges do not require a “new product” but rather integration of the infection prevention and control practices to address the problems of today, tomorrow, and the future

NADONA Infection Prevention and Control
Webinar Series



Moving From the Past to the Future



NADONA Infection Prevention and Control
Webinar Series



Questions and Answers

- Whose Infection will you prevent when you return to your institution?
- How will you approach HAI prevention differently in LTCF's?
- Contact Information:
 - Email: Hudson.garrett@nadona.org
 - Visit www.nadona.org for more information

NADONA Infection Prevention and Control
Webinar Series

